

# **The effects of psychological factors on efficacy of Spinal Cord Stimulation**

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## **Abstract**

Spinal cord stimulation (SCS) appears to be an effective treatment for neuropathic pains, but long-term benefit of more than one year is only found in a proportion of patients treated. This thesis hypothesised that psychological factors may be important as determinants of outcome.

A literature review in this field, whilst demonstrating lack of reliable psychological predictors of SCS treatment, suggested that those thought to be predictive such as depression were more complex. Whilst depression was associated with lower efficacy of treatment by SCS, the treatment itself improved depression. Therefore, depression should not necessarily be seen as a contra indicator, especially when pain and depression interact.

A prospective study with one year follow up of patients implanted with spinal cord stimulator was conducted. Forty patients were included in the final analysis. Functional pain and psychological measures were recorded at six and 12 months, psychological predictors were not significant at six months but significant predictors were found at 12 months. Greater catastrophising, paired with greater anxiety and less perceived control were associated with a < 30 % reduction in pain.

A qualitative study of the experience of SCS using semi-structured interviews one year following SCS implantation revealed similar findings. Thirteen patients reported coping, lack of control and helplessness as impacting upon pain experience. A demand for clearer information systems was discussed in relation to SCS preparation. Information is needed to reduce unexpected experiences including potentially painful trial and body image concerns related to the implantable SCS device. Implications for practice included preparation with expert patients and a tailored preparatory CBT course.

The findings from the two studies demonstrate the necessity to improve the preparation process for patients prior to SCS. Results from both studies conclude that perception of control over pain is important for SCS efficacy and support with anxiety and catastrophic thoughts and behaviours may be advantageous. The predictive equation generated from this study needs to be tested prospectively on further cohorts of SCS patients in order to test reliability. In addition, evaluation of the impact of a tailored CBT course upon outcome needs investigation.

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## Abbreviations

ACC	Anterior cingulate cortical
ASIC	Acid sensing ion channels
ATP	Adenosine triphosphate
BDI	Beck depression inventory
CBT	Cognitive behavioural therapy
CNS	Central nervous system
DABS	Degoratis affects balance scale
DH	Dorsal horn
fMRI	Functional magnetic resonance imaging
GABA	Gamma-aminobutyric acid
GCT	Gate control theory
HAD	Hospital anxiety and depression scale
HPS	Hamilton psychiatric rating scale
IPG	Internal pulse generator
LREC	Local regional ethics committee
MHLC	Multidimensional health locus of control scale
MMPI	Minnesota multiphasic personality inventory
MMPI-2	Minnesota multiphasic personality inventory 2
MRI	Magnetic resonance imaging
ODQ	Oswestry Disability Questionnaire
PAG	Periaqueductal grey
PCSQ	Pain coping strategies questionnaire
PET	Positron emission tomography
RVM	Rostal ventromedial medulla
SCS	Spinal cord stimulation
SG	Substantia gelatinosa
SRM	Self regulatory model
TENS	Transcutaneous electrical nerve stimulation
VAS	Visual analogue scale
VR1	Vallinoid neurokinins

## **Publications, presentations and grants related to research presented within this thesis**

### *Journal publications:*

Sparkes, E., Duarte, R.V., Raphael, J.H., Denny, E. and Ashford, R.L. (2012). Qualitative exploration of the experience of Spinal Cord Stimulation. *Chronic Illness*. 8(4), pp. 239-251.

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Qualitative exploration of the experience of spinal cord stimulation. Oral presentation at Birmingham City University Students Presentation Day. Birmingham, June 2011.

Reviewing the literature on psychological factors and SCS. Oral presentation at Birmingham City University Students Presentation Day. Birmingham, June 2010.

Controlled comparison of SCS on surface hyperalgesia in neuropathic pain conditions. Oral presentation at Birmingham City University 5<sup>th</sup> Annual Faculty of Health Research Conference. Birmingham, November 2009.

Preliminary results of a literature review of psychological factors impacting upon the efficacy of Spinal Cord Stimulation. Poster presentation at British Pain Society 2009 Annual Scientific Meeting. Surrey, UK, 31 March to 3 April 2009.

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Medtronic Ltd. sponsored attendance of the 5<sup>th</sup> World Congress of the World Institute of Pain. New York, USA, 13-16 March 2009, £900.



# **Chapter 1**

## **Introduction**

## **1.1 Introduction to the study**

Pain is a pervasive symptom, which drives a patient to seek medical attention and impacts largely upon quality of life. Virtually everyone experiences pain at some point in their lives. Pain remains the universal form of distress from birth to old age (Hadjistavropoulos and Craig 2004). Pain is therefore the most common medical complaint. Being subjective and unique, pain is challenging to treat and control.

The physiological basis of pain is based upon the nociceptive pathways in the nervous system culminating in neuronal activity in parts of the cerebral cortex producing conscious appreciation of the unpleasant sensation. Tissue damage activates peripheral nociceptors that send electrical signals along peripheral nerves into the central nervous system to be passed via neuronal synapses to higher centres of the brain that activate centres of sensation, cognition and emotion. Pain is the result of a complex interaction of neurophysiologic events (both facilitatory and inhibitory events occur), which are processed by the brain (Costigan and Woolf 2002).

The pain experience is recognised as involving conscious awareness and these processes are acknowledged by the central nervous system, which go on to interact with higher psychological components (Derbyshire 2000; Melzack and Katz 2004). Therefore, the individual evaluation of the pain experience will contribute to the degree and incidence of pain. The neuromatrix (discussed in more detail in chapter 2, segment 2.3) maintains that individual differences in pain experience are dependent upon patterns recorded in the brain (Melzack and Katz 2004). Genetics, experience and knowledge are understood to underpin the evaluation of the sensory, visual and affective components of pain (Melzack and Katz 2004). The neuromatrix model reflects the complex analysis of pain sensations and individuality in the perception of pain.

Pain is defined by the International Association for the Study of Pain (IASP 1979) as ‘an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage’. This definition illustrates that the understanding of pain is not purely a sensory phenomenon but is also psychological. Pain is primarily a physiological phenomenon, however physiological explanations are limited, particularly in areas of the brain. Psychological and socio-biological models allow further

insight into the experience of pain (Melzack and Wall 1965, Melzack and Katz 2004, Turk and Monach 2002). The recognition that pain is not completely understood by neurophysiologic events results in a demand for psychological approaches to manage chronic pain. This research hypothesises that when treating individuals with chronic pain, psychological components may interact with interpretation and therefore response, with an impact on the efficacy of treatments.

There are several treatments for chronic pain, including pharmacological (e.g. medication), psychological (e.g. cognitive behavioural therapy), physical (e.g. physiotherapy) and interventional (e.g. surgery). Stimulation treatments are suggested for patients with neuropathic pain, when all other available treatments have ceased to be successful. Spinal cord stimulation (SCS), a treatment for chronic pain has been in use since 1967 (Shealy, Mortimer and Reswick 1967). SCS is expensive and invasive; therefore, careful selection for suitability is imperative. Although it has demonstrated efficacy, long-term results show a decrease in pain reduction at around 12 months (Cameron 2004; Kupers et al. 1994). Reduced efficacy of SCS has previously been considered to represent technical factors, for example scar tissue forming around the electrodes and leads (Mutagi, Southall and Raphael 2006). Placebo, tolerance of the nervous system and equipment failure has also been hypothesised as contributors to reduced efficacy. Studies have also considered the impact of psychological factors (Doleys 2006, Deer and Masone 2008).

Psychological processing influences the experience of pain. An individual will ascribe meaning to the pain and through learning will appraise the situation and react; coping is modified as a result (Melzack, Casey and Kenshalo 1968). Similarly SCS treatment efficacy for management of chronic pain may be moderated by psychological factors. Psychological factors are understood to interact with the pain experience, impacting on the response to pain and subsequent response to treatment (Turk et al. 2010). Patients selected for this treatment at the centre where the research was carried out have more often than not had chronic pain for long periods of time, in many instances more than a decade in duration. Patients have also tried other types of treatment to manage their pain. It is therefore understandable that patients may be experiencing increased psychological distress alongside the persistent pain. Research has shown that up to 59% of patients with chronic

pain treated in pain management clinics experience at least one psychiatric problem (Atkinson et al. 1991).

## **1.2 Introduction to my involvement in the research area**

Upon presentation of the problem of decreased efficacy for SCS patients at around 12 months, I was appointed to further investigate psychological factors that may interact with the interpretation of pain and consequently impact upon unsuccessful long-term outcome for SCS. Having completed an MSc in Health Psychology, I have a keen interest in the psychology of illness, pain and treatment experience. Prior to enrolment as a PhD student, I completed reports and case studies on patients with long term debilitating illnesses. I had also worked in a mental health setting developing a service to support patients who wanted to change maladaptive unhealthy behaviours to attain healthier lifestyles. Employing behaviour change strategies and training in this setting was both challenging and rewarding. After these experiences I was keen to research the effect of psychology and behaviours upon health, illness, treatment and resilience.

The ability to identify psychological factors associated with the efficacy of SCS treatment may enhance the selection of suitable patients. Highlighting psychological factors interacting with efficacy of SCS may also enable psychological preparation procedures to be implemented pre-treatment targeting potentially problematic psychological factors. Improvements in selection and preparation prior to treatment may reduce the number of patients experiencing loss of previously successful pain reduction.

This research aimed to investigate psychological factors impacting upon decreased efficacy of SCS treatment. A review of the literature was initially conducted, to enable insight into current knowledge. Following the literature review, a longitudinal prospective study was carried out, evaluating patients' psychological characteristics over the first year of SCS treatment. Psychological characteristics associated with reduced efficacy (<30%) at six and 12 months may be identified by comparing baseline psychological characteristics with percentage pain reduction ( $\geq 30\%$  or  $< 30\%$ ) at six and 12 months. Thirty percent was considered as a cutoff point, since a recent consensus statement classified this change as a moderately important clinical reduction in pain (Dworkin et al. 2010). Patients who obtain

≥30% pain reduction will be compared to those with <30% improvement in pain. An objective of the research was to develop a predictive equation of psychological characteristics that may influence achievement of ≥30% reduction in pain.

Interviews with patients at one year following implantation of SCS were also conducted to add another perspective to the research and to enable additional factors not covered by the questionnaires to be highlighted. The qualitative aspect to the research was conducted to highlight common themes regarding the patient experience, to reduce the likelihood of missing important aspects about the SCS experience and to add an additional perspective to the understanding of the psychological factors affecting efficacy of the treatment. Aims and objectives are highlighted below for clarity.

### **1.3 Aim and objectives**

The aim of the research was to investigate the contribution of psychological factors to the efficacy of SCS treatment outcome 12 months following implantation.

The objectives of this study were:

1. To review the current literature investigating the impact of psychological factors upon the efficacy of SCS.
2. To undertake a prospective study of a cohort of patients undergoing SCS using psychological questionnaires with a view to evaluating the role of such factors in treatment outcome.
3. To investigate patients' psychological perspectives of SCS treatment by carrying out interviews at one year with SCS patients. This was to enable further investigation of psychological factors not assessed by the validated questionnaires.

### **1.4 Synopsis of the thesis**

The following synopsis will guide the reader through the structure of the thesis, detailing briefly each individual chapter.

### *Chapter 1*

The current chapter briefly outlines the main areas of focus for the thesis: in particular the concept of pain and SCS. This chapter also highlights the complexity of treating pain, not solely on a medical basis, and speculates on the importance of other non-medical factors, which undoubtedly impact on the efficacy of certain treatment regimes. Chapter 1 introduces the development of the study, particularly from a personal perspective. As such I have taken the liberty to write parts of this chapter in the first person. Chapter 1 also delineates the aim and objectives of the study and provides a synopsis of all the chapters contained within this thesis.

### *Chapter 2*

Chapter 2 introduces the psychology of pain. The chapter describes a brief account of the historical development of the psychological understanding of pain including the influence of religion, Descartes' stimulus response theory and Beecher's research of world war soldiers. This is followed by an overview of The Gate Control Theory of pain and its relation to contemporary theories and models are then discussed. The explanation of the Gate Control Theory allows for the introduction of the neuromatrix concept. To complement these overviews this chapter also addresses the bio-psychosocial models of health, alongside health beliefs and models of health beliefs. The chapter ends with a critique of cognitive behavioural therapy, a discussion regarding placebo effects and its importance to medical research.

### *Chapter 3*

This chapter provides an overview of the physiology of pain followed by an outline of treatments available for individuals suffering with chronic pain. SCS is then described in detail and patient selection for SCS is also discussed. This chapter concludes with an overview of psychological characteristics, behaviours and beliefs known to affect the efficacy of chronic pain treatments and those known to enhance the likelihood of disability in response to pain. Chapter 3 provides the necessary background to chapter 4.

#### *Chapter 4*

The fourth chapter of this thesis critiques the research in the area of interest. A systematic review of the literature investigating the psychological factors affecting the efficacy of SCS is presented. The systematic literature review facilitated an insight into previous methodologies used and findings in relation to the focus of this current study. In particular, it helped to inform the researcher of the gaps in the literature and allowed an evaluation of methods employed to research in this area. The review suggested that a more rigorous longitudinal prospective study of psychological factors affecting efficacy for patients receiving SCS treatment was required. Many psychological factors remained inconclusive for prediction of SCS efficacy and methodologies often lacked long term follow up. The review also highlighted the importance of including interviews alongside questionnaires when investigating this area. Interviews may highlight additional factors to those covered by questionnaires. These findings provide a rationale for the methodology employed within this research.

*This systematic literature review was accepted for publication in PAIN (appendix 1). The lead author (researcher of this thesis) was invited to be interviewed on the findings of this review on a highly specialised pain clinician website ([www.painclinician.com](http://www.painclinician.com)).*

#### *Chapter 5*

This chapter gives an overview of the mixed methodology employed within this research. The researcher followed up SCS patients from baseline to six months and 12 months, firstly to assess psychological factors and functioning via questionnaires, secondly, to explore the patient's experience of the treatment. Qualitative interviews were carried out at 12 months. Interviews were conducted with an opportunity sample of patients invited to take part at follow up clinic appointments. The study approach and ethical considerations are described. This chapter includes reasoning for methods and tools selected for assessment of characteristics. The recruitment process and description of the cohort invited to take part in the research are depicted.

#### *Chapter 6*

Chapter 6 details the main quantitative study findings of the thesis. The questionnaire data for psychological factors and functioning at the three time points (baseline, six months and

12 months) is presented within this chapter. This chapter details the process undertaken by the researcher, with a focus on methodology and materials used to conduct the research. The results of the quantitative findings are presented following a logical flow of analysis including evaluation of the statistical tests assumptions. A backwards-stepwise logistic regression analysis was performed. This resulted in the construction of an equation, which included three psychological factors for the prediction of  $\geq 30\%$  pain reduction probability after 12 months undertaking SCS treatment. The equation developed from the results of the analysis is presented in three worked examples. The chapter concludes with a discussion of the findings and the relation between the three psychological factors found to be predictive of SCS efficacy at one year.

### *Chapter 7*

Chapter 7 details the methodology and findings from a qualitative exploration of SCS patients experience during their first year of treatment. A rationale is provided for the methods used and the analysis is described. Thematic analysis was utilised as the researcher was interested in the themes that emerged as part of the patients' SCS experience. This chapter concludes with a discussion of the main findings of this qualitative study and the implications for clinical practice. Highly recommended by patients was the recruitment of expert patients to provide a better understanding of the experience ahead for patients considered for SCS treatment. Chapter 7 enabled an insight into the patient's story and experience of SCS, complementing the quantitative findings of the study.

### *Chapter 8*

The concluding chapter draws upon the findings of the quantitative and qualitative studies and discusses the findings of the thesis as a whole. Considerations for weaknesses and strengths of the thesis are also detailed in this chapter. This chapter outlines implications for practice prior to SCS implantation and acknowledges future research considerations. This final chapter ends with reflections of the thesis.



## **Chapter 2**

### **Psychological factors and pain**

Presently psychology is recognised as being vitally important in chronic pain management. However, this has not always been the case, and charting the history and development of pain theories illustrates this relatively new inclusion. This chapter summarises some of the historical changes in the understanding of pain, starting with the basis of religious teachings informing the understanding of pain which later developed into a stimulus response understanding due to Descartes' philosophical teachings. Melzack and Wall developed the Gate Control Theory (GCT), since Descartes' pain pathway description was limited in terms of separation of mind and body. The contribution of GCT is discussed and critiqued leading to the description of the neuromatrix model of pain. The neuromatrix provides an explanation for pain considering the more complex nature of pain, including pain without sensory input (not explained by the GCT) and the influence of genetics and behaviour upon pain experience. The beliefs that an individual holds regarding their illness and subsequent treatment impact upon the behaviours and therefore the coping mechanisms employed. This chapter describes models and theories of health behaviours, demonstrating the influence of beliefs upon illness and treatment response. This chapter review the psychological factors and theories that are deemed important when considering the experience of pain and selecting for pain treatment. Cognitive Behavioural Therapy (CBT) is the most common psychological therapy suggested for pain management to enable individuals to modify beliefs and improve behaviours; the therapy is described and discussed in relation to other therapies. Finally placebo and nocebo response are considered, demonstrating the power of certain beliefs and the context in which they are delivered. This is also important when considering psychological factors that impact upon treatment outcome, as with any treatment a placebo effect may occur in the beginning of a therapeutic intervention. This chapter highlights the importance of recognising the influence of psychology when treating individuals with chronic pain.

## **2.1 History of pain theory**

Historically, theories of pain were governed by religious teachings. Throughout much of history, the Christian church was at the heart of all significant experiences in an individual's life, including many ministers being physicians. The priest was called upon for all significant life events, namely baptism, marriage, illness and death (Caton 1985). Little was understood about the control of disease but people turned to the church for comfort and support

regarding ill health. Sacred interpretations of pain dominated, seeing pain as something to be remedied by forgiveness from God. Greek teaching influenced Christian understanding of disease and pain: pain was punishment for sin and those who regained good health had been cured by God (Caton 1985). These connotations led to people hiding their pain, viewing pain as a test of faith and reliance on God for recovery and cure. These religious beliefs resulted in little progress being made in the management of pain for centuries (Meldrum 2003). Religious beliefs about the origin and causation of pain have been prevalent among many cultures and similarly Judaism and Islamic teachings regarding pain centred on beliefs that pain was a result of sin or some sort of test of faith. Filipino, Saudi and Asian cultures beliefs were based on supernatural and religious explanations, viewing pain as a consequence of the evil eye and remedy resulting from turning to religion and spiritual healing (Lovering 2006). Still today religious and spiritual beliefs have great impact on an individual's adaptation and coping with pain. Research has demonstrated that up to 80% of Americans believe that prayer can improve the course an illness takes (Wallis, 1996).

In the 1600s a movement away from passivity governed by religious teachings saw a more reasoned approach to the understanding of pain. Descartes defined pain in the 17<sup>th</sup> century as a stimulus response mechanism, known namely as specificity theory (Descartes 1664). Although a huge step forward in the understanding of pain, specificity theory gives little explanation for the psychological processes we now understand to be involved in the pain experience. Pain was described as following a simplistic pathway. Injury was understood to activate receptors, which project pain impulses via the spinal cord to the pain area of the brain (Melzack, Casey and Kenshalo 1968). Dualism stated that cognitions had little impact on pain, and behaviour in response to pain resulted from physiology alone (Hatfield 2007). The mind and body were described as very separate entities. Specificity theory influenced the early understanding of pain and continued for three centuries into the first half of the 20<sup>th</sup> century. Melzack, Casey and Kenshalo (1968) criticised the theory for the lack of consideration of influential factors including attention, emotion, cognitions and learning. Biomedical models today acknowledge cognitive and emotional influences on the pain experience; however, primary sensation is often still the main focus.

Despite the simplistic nature of Descartes' theory, dualistic thinking continued for three centuries after its introduction and pain was viewed for centuries as either physical or psychological. Persistent pain without identifiable causes was viewed as psychological; this theory lacked the concept we recognise today of chronicity, mind and body interaction. The emergence of psychodynamic theory during the early 20<sup>th</sup> century brought forth a new perspective to enduring pain. Freud viewed pain as originating as a somatic complaint, with psychological instability and emotional distress acting as maintainers for pain (Von Knorring et al. 1983). Freudian theory proposed that pain was maintained by psychogenic factors, for example innate drives such as aggression, the result of aggression towards oneself from chronic guilt. However no causal relationships have been established to date for Freudian theories of pain (Hadjistavropoulos and Craig 2004). Although no direct causal link has been established for psychodynamic theories of pain, this stage in pain theory development started to highlight the importance of emotion in the pain experience.

Recognition for the emotional influence on the processing of the pain experience continued during World War II. Following his experience as a practising doctor in World War II, Beecher (1946) published findings of his hypotheses of the involvement of psychological factors in the experience of pain. He discussed at length how emotion interacted with pain experience after noticing that 75% of severely wounded soldiers reported not requiring pain relief medication (Beecher 1946). Beecher proposed that the absence of a need for pain relief medication was a result of the emotions associated with the pain. His observations led him to further investigate these hypotheses and test the influence of emotion upon the pain experience. When comparing a cohort of injured soldiers with a cohort of civilian patients with surgical wounds he found differences in pain relief consumption. As previously reported 75% of soldiers said no to narcotics for pain relief. When asking the same question to the civilians, 83% requested pain relief medication (Beecher 1956). Severely injured soldiers would be released from duty to return home, and therefore be removed from danger. Contrarily, a civilian with surgical wounds would see the pain as the beginning of an undesired event. Beecher's findings paved the way for further development in the understanding of pain.

Melzack and Wall (1965) developed the Gate Control Theory (GCT), the most widely recognised and accepted development in the understanding of psychological processes in

the pain experience. The GCT, in contrast to Descartes' specificity theory, described pain as a more complex phenomenon. GCT proposes that the transmission of nerve impulses can be modified by concurrent activity in the dorsal horn within the spinal cord. This theory has dominated the field of pain psychology, providing an understanding of the processing of pain, including the influence of cognitive, behavioural and emotional factors. Before the introduction of this theory, pain was often viewed as a product of illness alone. The GCT brought forth the concept that pain was a phenomenon to be targeted in its own right, in addition to any illness.

## **2.2 Gate Control Theory of pain**

The GCT follows a series of principles; transmission of nerve impulses from afferent fibres along the spinal cord are modulated by a spinal gating system proposed to be located in the substantia gelatinosa (SG) cells in the dorsal horn (Novy, Nelson, Francis and Turk 1995). The opening and closing of the 'gate' is proposed to be modulated by activity from the large (L) and small (S) diameter fibres (figure 2.1). The L fibres (responsible for touch and vibration sensations) upon stimulation are understood to inhibit nociceptive activity at the dorsal horn synapses. Activity from the L fibres inhibits synaptic transmission to projecting transmission cells (T cells) (closes the gate), whereas, activity from the S fibres facilitates T cells activity (opens the gate) (Melzack and Wall 1965; Novy, Nelson, Francis and Turk 1995). The action system is activated when the output of the spinal cord transmission (T) cells exceeds a critical level. The positive and negative effects of the large and small fibre inputs tend to counteract each other but if stimulation is prolonged the large fibres begin to adapt, causing an increase in small fibre activity. This results in the gate opening further and the output of the T cells to rise; however, if the large fibre activity is raised by vibration or scratching (which can overcome the tendency of the large fibres to adapt), the output of the cells decreases (Melzack and Wall 1965).

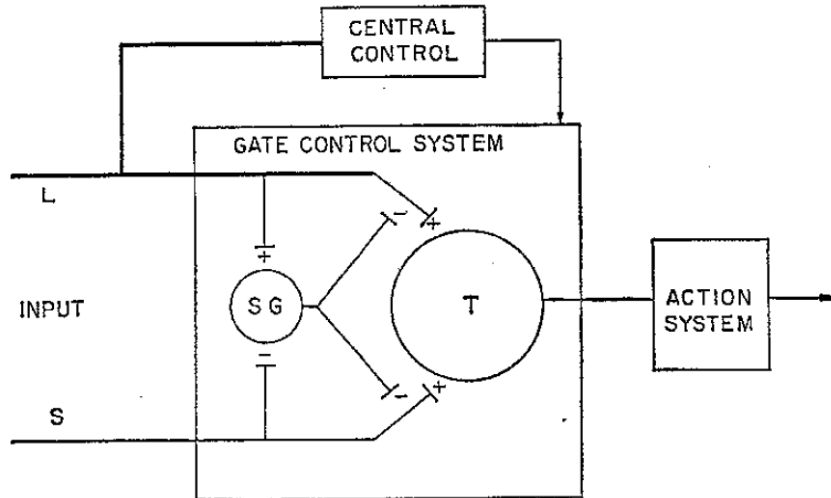


Figure 2.1 Gate Control Theory of pain (Adapted from Melzack and Wall 1965)

This theory proposes that complex neurophysiologic events in the spinal cord and brain modulate afferent pain signals including cognitions and affective states, influencing the transmission and perception of noxious stimuli (Melzack and Wall 1965). This is where the involvement of higher level processes within the brain can be considered to be part of the processing of pain. The combination of the messages travelling from the periphery via ascending fibres, alongside the descending information from the brain (including cognitions and affective states) determines the eventual perceptual experience of pain (Kugelman 1997). A specialised system of fast conducting fibres activates cognitive processes which influence the descending fibres carrying messages, which modulates the gating system (Melzack and Wall 1965). Cognitive (boredom), emotional (depression) or physical (inappropriate levels of activity) messages can be understood as cognitive and affective states that influence pain perception to be heightened. Opposing this, medication or massage (physical), positive emotion (emotional) and diverting attention to enjoyable activities (cognitive) can have the reverse effect, reducing the pain sensation experienced. According to the concept diffuse noxious inhibitory control, if the brain is receiving concurrent messages at the same time as pain stimuli, the pain can be reduced and the sensations lowered. The experience of pain according to the GCT therefore is one that is ongoing and the interactions within the 'gating system' impact on the experience of pain.

The GCT is different from early explanations of pain as it describes the role of the individual in the degree to which pain is experienced. The individual is understood to be active in the

experience rather than passive, responding to and appraising the painful sensations. The variation in the individual perceived pain is explained by the degree to which the 'gate' is opened or closed, which is moderated by a multitude of factors and not just physical in nature. However, the GCT has been subject to several criticisms. The theory aimed to explain pain in terms of the body and the mind, but the GCT was criticised for viewing mind and body as separate entities (Nathan 1976; Nathan and Rudge 1974). The GCT although attempting to integrate mind and body still views them as separate processes, explaining that physical processes are influenced by psychological processes, therefore describing two distinct separate processes. Nathan (1976) alludes to the continuing debate surrounding the locality and mechanism of the gate and the finer details surrounding the theory. Although there is evidence supporting the GCT mechanisms of increased and decreased pain perception there is no clear evidence for the location of the gating system (Novy, Nelson, Francis and Turk 1995). Another consideration for the GCT is that organic pain can also trigger pain in other areas of the body (Merskey and Evans 1975), which the GCT is unable to explain. Also for consideration is that phantom pain may occur without neural stimuli, demonstrating that stimuli may trigger patterns of response but not necessarily produce them (Melzack and Katz 2004). The GCT model assumes an organic basis for the pain and this may not always be the case. These challenges to the GCT model of pain led Melzack to further develop the model of pain transmission, proposing a neuromatrix of pain (Melzack 1999).

### **2.3. Neuromatrix of pain**

The neuromatrix proposes that pain is multidimensional and characterised by patterns of nerve impulses. The proposed patterns are understood to be the result of numerous factors including genetics, learning, emotion and behaviour. This neuromatrix model overcomes the criticisms of the GCT, which assumes a sensory basis for pain. The neuromatrix further developed the understanding of pain processing explaining how noxious stimuli are processed taking into consideration several factors at the same time. The neuromatrix proposed that the pain experience is additionally influenced by sensory inputs and cognitions. The model can be understood as describing a feedback loop influencing behavioural responses. The feedback loop of neural pathways is recognised as being influenced by multiple factors including; sensory stimuli, genetics, immune system, learnt

behaviour, cultural and emotional factors and autonomic and endocrine systems. Melzack (1999) stated that chronic pain may be determined by genetic influences on synaptic architecture. The concept of the neuromatrix adds an additional consideration to the experience of pain, the generation of perceptual experience by the brain without external input. Brain processes are inbuilt and although the processes are understood to be modifiable and changed via experience, there are genetic properties that will interact with pain experience. Derbyshire (2000) studied the existence of the neuromatrix and demonstrated that a range of areas of the brain are involved in the processing of noxious stimuli. Areas including those processing affective, sensory, cognitive, motor, inhibitory and autonomic messages were observed to be involved in the processing of pain. Beyond this, chemical changes are also understood to explain alterations in pain perception (further discussed in chapter 3 of this thesis).

In response to pain and chronic pain, behaviours can be developed and learned and may respond to pain automatically. An understanding of the pain experience can be generated by the consideration of behavioural response and learnt behaviour. From the awareness of a painful sensation, a range of response behaviours is developed. Pain has emotive and cognitive aspects and therefore we may know that someone is in pain by observing certain behaviours. Behavioural aspects of psychology have a clear role in understanding pain and individual response to pain. For example, Fordyce et al. (1968) found that the pain experienced by an individual was associated with changes in behaviours, such as limited activity in response to chronic pain. Behavioural responses occur in response to recognised stimuli, learnt through experience and meaning. The proposed neuromatrix model was developed from understanding that genetic and learnt patterns affect and modify the meaning regarding a stimulus (Melzack and Katz 2004). According to the neuromatrix concept, the response or behaviour is determined by the analysis of input within the neuromatrix. This potentially explains differences in behavioural response to pain. The individuality can be explained by the patterns held within the neuromatrix model, presumed to be related to genetics, experience and knowledge (Melzack 2001). Therefore, individuals respond independently and according to the analysis of the sensory, visual and affect of pain. It can be further understood that these behavioural reactions in response to the neuromatrix analysis are in turn producing a feedback loop into the neuromatrix experience.



Behavioural models have been developed to understand pain and response to pain. These models enhance the understanding of response behaviours and how they affect long-term pain.

#### **2.4 Biobehavioural model**

The biobehavioural model (Turk, Meichenbaum and Genest 1983) was one of the first models to describe pain with regards to inclusion of other influential factors, namely the influence of cognitive and behavioural factors. This brought a challenge to the traditional biomedical model viewing mind and body as separate. The biobehavioural model describes pain as being governed by cognitive, behavioural and physiological aspects. Conditioning is proposed by the biobehavioural model to influence the pain through mechanisms such as response and avoidance behaviours. Theorists discussed pain being influenced by patterns of operant and classical conditioning (Fordyce, Fowler and Delateur 1968). Fordyce and colleagues (1968) found that changes in environmental responses to pain behaviours were associated with changes in behaviours, such as limited activity in response to chronic pain. Reinforcement is recognised to influence pain behaviours (emotional reactions are likely to become associated with particular movement and situations). Hence, behavioural interventions have become essential to improve coping with pain. Cognitive Behavioural Therapy (CBT) is one such intervention that has proved successful (Fishbein 2000). CBT teaches individuals to change maladaptive thinking that influences certain negative behaviours, which are understood to aggravate the pain.

A diathesis-stress response was described as part of the biobehavioural model (Monroe and Simons 1991). The model leads to an understanding that the response an individual has towards their pain will interact with physiological processes leading to a reduced pain threshold due to conditioned bodily processes. This reduced threshold is understood to be an accumulation of genetics, learnt behaviours and external influences such as social norms, which combine, leading to an alteration in physiological response to the evaluation of negative sensory stimuli. Therefore, the model describes that a conditioned response occurs from the autonomic and central nervous system when an individual experiences nociception. Behavioural responses such as fear, avoidance and hypervigilance have a subsequent effect on continuation and development of chronic pain.

## **2.5 Biopsychosocial model**

The biopsychosocial model proposes that pain is shaped by dynamic and reciprocal interactions between biological, psychological and socio-cultural variables (Turk and Monach 2002). The biopsychosocial model focuses on illness experience as an interaction of factors rather than just the physiological aspects, which is recognised by biomedical approaches. Everyone will evaluate the symptoms they experience differently. This also reverts back to the concept of the GCT and neuromatrix, an evaluation of what the symptoms mean to individuals differs based on learning, experience and knowledge. Biopsychosocial models of illness suggest that any illness experienced is the result of the interaction of factors and this hypothesis explains why one person may experience pain so differently from another.

The experience of pain is determined by a person's genetic endowment, learning, individual characteristics, behaviours and affective state (Turk and Melzack 2001). The pain experience can be illustrated in the following way: biological factors shape pain sensations, psychological factors are responsible for appraisal of sensation and social factors interact and influence behavioural responses to pain. Behavioural responses to pain impact upon coping and adjustment. Someone who becomes withdrawn may experience less support and motivation to cope, encouraging focus upon pain and maintaining high attention to symptoms. Individuals can be understood to respond to pain in terms of what it means for them, from experience, learning and beliefs (Main, Foster and Buchbinder 2010). The reason why some people continue with daily life, whereas others adopt the 'sick role' is explained to some degree by the biopsychosocial model. The sick role can be characterised as withdrawing, leaving work, becoming emotionally distressed and absolving themselves of responsibility for improving their condition (Parsons 1996).

How people repeatedly respond to pain according to the biopsychosocial model has an influence upon subsequent experience and development of long-term pain. It must be considered that the responses and coping mechanisms that individuals have developed in response to pain are influenced by beliefs. These developed beliefs will also impact on treatment outcomes. The impact of health beliefs that an individual may hold are considered in the following section by discussing health beliefs models and theories to date, including a critique of relevant empirical research.

## **2.6 Health beliefs**

It is recognised that certain beliefs can influence behavioural changes in response to pain. The fear avoidance model has provided explanation as to why individuals may develop chronic pain (Vlaeyen and Linton 2000). The principle of the fear avoidance model is built upon cognitions, hypothesizing that individuals who become fearful of pain or possible pain/injury avoid activity in response to these fearful thoughts. In response to these avoidant behaviours individuals may experience levels of disability and disrupted mood. Once avoidant behaviours commence, a cycle may occur: fear, leading to reduced social interaction and mobility which in turn may lead to depression and an increased focus on pain. Figure 2.2 demonstrates the interaction of cognitions upon the experience of pain.

The fear-avoidance model illustrates the cycle that individuals may experience, giving some explanation as to why some individuals develop varying degrees of chronic pain and others do not. The development of the psychological understanding of pain has involved a transition from stimulus response to the concept that pain involves higher cognitive components that influence the overall experience.

It is important to consider how individuals perceive their health. The thoughts and beliefs that someone holds about their health lead to certain behaviours. The health behaviours that individuals carry out are a reflection of their cognitions. It is important that individuals hold the correct knowledge regarding health and conditions of ill health. The way in which an individual may try to solve a health problem will be a result of their cognitions. Therefore, the beliefs held about a treatment may affect outcome.

Numerous models of health behaviour have predicted the likelihood an individual will engage in certain behaviours. The health belief model (Rosenstock, Strecher and Becker 1988) proposes that behaviours are the result of a weighing up of the pros and cons of that particular behaviour, the cues to action for the behaviour and the severity and the susceptibility of the threat should they choose not to carry out the behaviour. This model can be used to explain for example adherence to pain medication; an individual may weigh up the side effects in comparison to the pain, the cues to action may be friends and family reminding them and finally the severity and susceptibility of the pain will influence the adherence. Research shows a significant relationship between knowledge and behaviour

(Glanz, Marcus, Lewis and Rimer 1997). However, Hill, Gardner and Rassaby (1985) found that routine was more predictive of behaviour than seriousness. Behaviour may not always be as rational as the model describes. There is also a lack of acknowledgement for emotional factors influencing behaviours when considering the usefulness of this model.

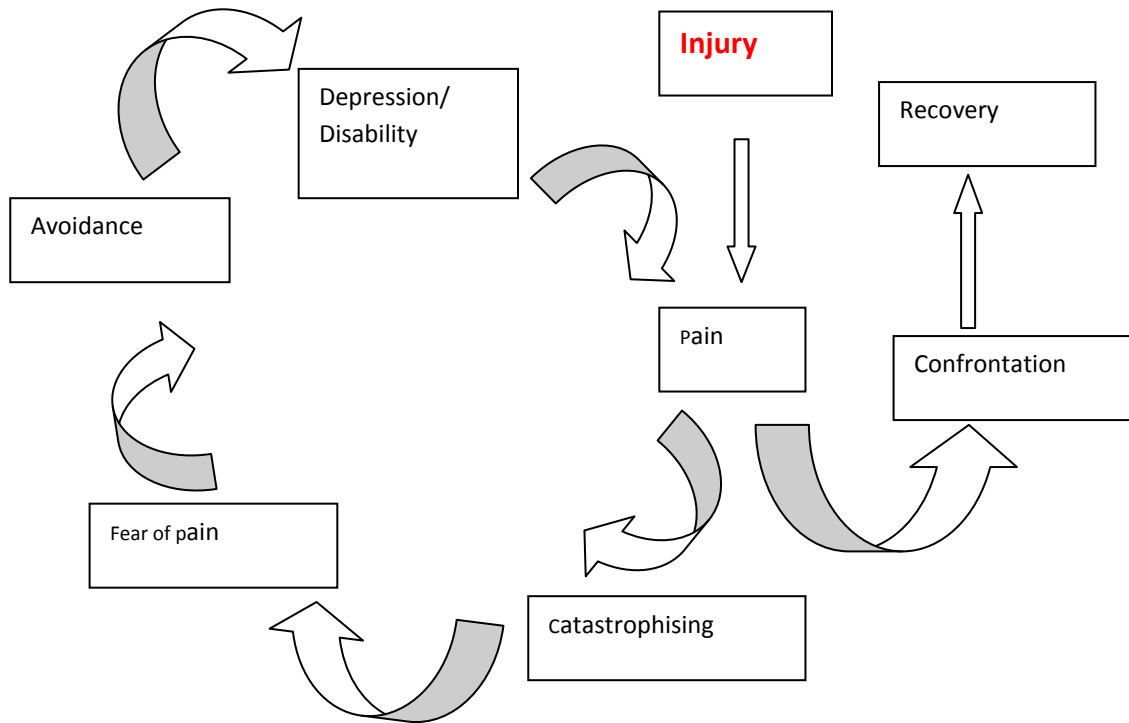


Figure 2.2 Fear-avoidance model (Adapted from Vlaeyen and Linton 2000)

Rogers (1975) has described the protection motivation theory. This model posits a range of predictors forming intention. The protection motivation theory proposes that carrying out behaviour is the result of intention, formed by self-efficacy, severity, effectiveness of behaviour and vulnerability. The model describes that people protect themselves by carrying out certain behaviours in response to the appraisal of the threat and their coping mechanisms. Again, under critical review the model fails to include the impact of previous experiences and how these may impact upon future behavioural intentions.

The theory of planned behaviour (Ajzen and Madden 1986) furthered the understanding of cognitions leading to behaviours by inclusion of perceived behavioural control in the prediction of behaviour. Perceived behavioural control is the extent to which an individual

perceives that they are able to behave in a certain way. Influences upon perceived behavioural control may include past experience, finance and on a more personal level, ability and personality traits. The model also includes the concept of the individual's own attitude toward a behaviour, built up by experience and knowledge. Subjective norms are also included as influential upon intention to carry out health behaviours. These norms are the extent to which an individual believes that other individuals and wider society perceive the behaviour as important. This model considers irrationality, emotion and the influence of past experience; however, intention particularly, does not always lead to action.

These models demonstrate the influence of cognitions, beliefs and thoughts upon behaviours. Recognition of cognitions is essential to understand how individuals react to illness and treatment, which may further influence efficacy of treatment.

#### *2.6.1 Self-regulatory model*

While health beliefs are sets of cognitions individuals hold regarding health behaviours, the self-regulatory model (SRM) posits illness beliefs that people hold about their illness (Leventhal, Meyer and Nerenz 1980). These authors proposed the model to describe and explain the changes and modifications an individual makes in response to the illness they face. The SRM has three specific stages: interpretation of the illness, coping and appraisal (figure 2.3). The beliefs an individual holds regarding their illness will influence their reaction and coping mechanisms chosen to deal with their change in health.

The model suggests that there are sets of cognitions (identity, perceived cause, time line, consequences and, control and cure) involved in interpretation (the first stage of SRM).

*Identity* - This is the diagnosis that an individual holds, the name for the symptoms experienced. This may be diagnosis from the consultant or self-diagnosis. Essentially, the individual gives meaning to the symptoms by labelling the state being experienced. Occasionally, individuals with chronic pain seek diagnoses which sometimes can be difficult to obtain. Patients can feel disbelieved without a label for their symptoms and often find a diagnosis is of great importance to them.

*Perceived cause* - This is another cognition proposed to take place when experiencing illness. The set of beliefs an individual holds regarding the underlying reasons for their illness may be based on individual research, experience, interactions with health care persons or myth. Certain beliefs may have negative impact upon behaviour when considering perceived cause. Latino/Vietnamese/Chinese Americans reported poor hygiene as a cause of breast/cervical cancer (Martinez, Chavez and Hubbell 1997). Individuals may hide symptoms if they understand the illness to be a punishment or a reflection on themselves as a person.

*Time line* - An individual will seek an estimated time scale for the illness. Similarly to perceived cause, this could be based on medical fact or experience or personal suppositions. Again, for many chronic pain patients the timeline may be estimated to be ongoing with no end in sight. Consequently, this may have great impact upon behaviours and coping styles.

*Consequences* - Individuals will consider the implications when experiencing illness and more importantly chronic illness. There may be many implications depending on individual circumstances. Specifically chronic pain patients may need to consider the financial implications if unable to work, the emotional toll of being subject to chronic illness and the physical and social consequences.

*Control and cure* - This belief is understood in two ways, the cognition that the illness can be cured and/or controlled. These thoughts will be governed by the individual alongside family and friends and most importantly medical health professionals. Often chronic pain patients are searching for a cure and have been through many treatment experiences with little or no success. This may then lead to an acceptance that control rather than cure is a more obtainable goal when enduring chronic pain. Individuals with chronic pain will differ in their cognitions regarding control and cure depending on information and experiences with those around them (friends/family/consultants).

The interpretation of an illness (consideration of the above mentioned cognitions) will then lead to emotions in response to the analysis of these interpretations. It should be recognised that emotions may result from the cognitions. For example, someone who is experiencing

chronic pain and has done so for a lengthy period of time, may have constructed a clear set of cognitions regarding their illness through their experiences. Understandably these cognitions will have resulted in emotional reactions such as fear, anxiety or anger. As described earlier, the fear avoidance model (Vlaeyen and Linton 2000) gives reason for withdrawal type behaviours. The cognitions regarding the pain may lead to fear, resulting in avoidance and withdrawal behaviours, which are understood to further affect disability and psychosocial functioning. Those who pay more attention to illness states tend to overestimate illness (Skelton and Pennebaker 1982).

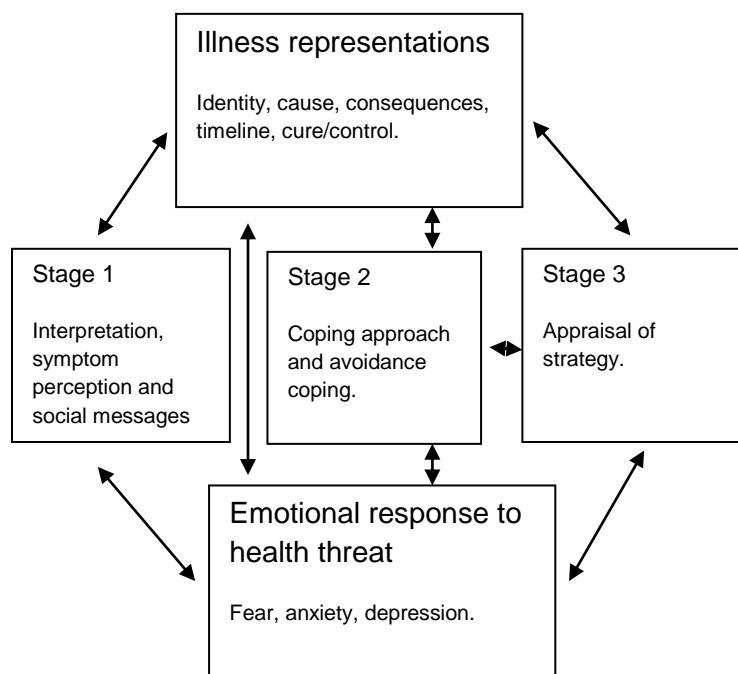


Figure 2.3 Self regulatory model (Adapted from Leventhal, Mayer and Nerenz 1980)

Coping is the second stage described in the SRM, it follows the interpretation stage and describes the actions an individual takes in response to the first stage. The SRM describes two coping styles an individual may adopt: approach coping where an individual will deal with the illness and take steps to improve the situation (adhering to regimes or medication, seeking support mechanisms/groups, modifying lifestyle to ease the effects of the illness) and: avoidance coping which describes how individuals avoid dealing with the illness and may even enter into denial (ignoring the symptoms, remaining optimistic, refusing appointments or medication). For chronic pain patients avoidance coping may involve non-

acceptance of the pain being long term and chronic, resulting in a continuous search for cure as a coping strategy.

The final stage of the SRM is the appraisal stage. During this phase, the model describes a process in which individuals will evaluate their coping mechanisms/behaviours they have adopted and how they have affected their lives in a positive or negative manner. An individual may not always reach the appraisal stage.

There has been consistent evidence for the SRM. Chronically ill patients when interviewed showed underlying beliefs from the five cognitions understood to inform the first stage of the SRM (Leventhal and Nerenz 1985). The three processes interrelate when interpreting symptoms resulting in emotional reactions, which may encourage further symptom perception due to focusing on illness. Identification and awareness of new symptoms may alter the chosen coping strategy and in turn modify the appraisal. The SRM demonstrates the relationship between psychological factors, perceived illness and emotional and physical changes. Rankin and Holtum (2003) explored the relationship between acceptance of pain and the five cognitive dimensions described by the SRM. Negative correlations were demonstrated for acceptance of pain with perceived severity, consequences and identity. No statistical relationship between acceptance of pain and beliefs surrounding duration or control and cure were found.

Empirical studies have shown that acceptance and modified beliefs correlate with treatment improvements for chronic pain patients (McCracken and Vowles 2008). Illness beliefs were studied in a longitudinal prospective cohort study of 152 patients with orofacial pain (Galli et al. 2010). It was found that believing that the pain would impact negatively upon life, that the pain was indefinite and that there was a lack of control over the pain were predictors for treatment outcome. The beliefs and views an individual holds about their pain will interact with coping and evaluation of subsequent pain. This is demonstrated not only theoretically in the models above described but also by the interactive process demonstrated by the neuromatrix research (Derbyshire 2000). This demonstrates the usefulness of CBT approaches to pain management. CBT may prove to be invaluable to aid an individual to acquire the coping skills required to adapt and respond to pain without using negative coping strategies.



## **2.7 Cognitive Behavioural Therapy**

Psychological therapy is now part of the multidisciplinary approach to support patients with chronic pain. Where previously it was used as a final attempt to help those not responding to physical and pharmacological treatments, it is now considered important as part of the overall treatment plan. This segment will provide an overview of a number of therapies utilised to support patients with chronic pain.

Cognitive therapy, first introduced by Beck (1976) involves identifying dysfunctional thinking, which induces negative emotional responses. By identifying certain beliefs and generating different ways of thinking and enabling attitudes to be changed, cognitive therapy was found to help individuals suffering with psychological morbidities. Behavioural therapy concepts introduced associative learning to enable behavioural change, changing behaviour via reward systems or pairing of stimuli (Pavlov 1932; Skinner 1987). The concept being that overt 'pain' behaviours including limping, grimacing or medication consumption were initially due to injury but may continue due to the reinforcement received. This could be through positive reinforcement, such as the attention received from others or via some avoidance of negative state (e.g. not having to work). Operant conditioning was proposed by Fordyce, Fowler and DeLateur (1968) to enable individuals to reduce pain behaviours and increase positive coping mechanisms including activity and continuation of daily routine. For operant conditioning to be effective, the patient needs to fully engage in the therapy process. Operant conditioning may involve a treatment programme which includes the patients maintaining a diary of their behaviours which the therapist can then draw upon with suggestions for altering or reducing any negative response behaviours (Sanders 2002). The use of positive reinforcement for changes maintained is also used. This form of shaping behaviours aims to gradually reduce the negative behaviours and increase positive coping style behaviours. Studies have shown effective reduction in negative pain behaviours (e.g. medication over usage) and increased positive behaviours (e.g. activity) when operant conditioning principles were applied (Fordyce, Fowler and Delateur 1968). Although studies using operant approaches alone are not frequent, reviews of this approach for chronic pain patients have been positive (Keefe and Bradley 1984; van Tulder et al 2000). There is also the consideration that for operant methods to be effective the patients' family need to be encouraged to engage in the therapy process considering the impact of social reinforcement, which is not always attainable.

Types of family therapy can be employed to support individuals with chronic pain and their families. The impact of chronic pain does not lie only with the individual suffering but it also impacts on those around them. This impact can be considered in terms of quality of life or psychological factors such as depression or anxiety (Turk et al. 1983). Family therapy can be employed to enable the family to re-establish the best possible living environment despite the experience of chronic pain, or to implement an operant conditioning approach where behaviours are acknowledged and patterns changed. There is limited empirical work reviewing the effectiveness of engaging the family in the therapy process. In a comparison study using CBT therapy approaches two groups were compared (couples versus individual patients) and there were no notable differences in terms of improvements (Moore and Chaney 1985).

Pain management clinics are advised to include CBT in the patients' treatment plan on a routine basis (Fishbain 2000). The perception individuals have of their pain is derived from their interpretation of the pain, which is developed from experience and beliefs (Main, Foster and Buchbinder 2010). CBT is designed to enable individuals to change their thoughts, beliefs and expectations to promote behavioural changes. The combination of both cognitive and behavioural therapy enables individuals to learn how different emotions are associated with certain thoughts, which may impact on behavioural responses. CBT uses a range of methods including worksheets identifying thoughts and behaviours, visualisation, problem solving, goal setting and behavioural practices such as rehearsal and shaping. Identifying problematic thinking allows breaking down of vicious cycles of thoughts (e.g. fear avoidance cycle) and changing negative feelings and behaviours to a more positive outlook. The combination of cognitive and behavioural therapy has proved successful for chronic pain patients (Morley et al. 1991). The role of attention is recognised as central to pain sensation and anticipation developed from a range of beliefs will also affect the processing of pain (Main, Foster and Buchbinder 2010). CBT works in the present and aims to enable individuals to change maladaptive thoughts and beliefs that are currently having a negative effect on their wellbeing. In some cases this treatment may not be appropriate for all individuals and consideration for early experiences, such as trauma in an individual's life, may also impact on the experience of chronic pain. It is hypothesised that earlier traumas may make individuals more vulnerable to chronic pain (Perlman 1996; Lakoff, 1983).

Gamsa's (1990) findings were contrary to this hypothesis when examining the relationship between psychological disturbance and pain. This author found that pain was not associated with personal history variables when comparing a cohort of chronic pain sufferers with a control group.

Psychodynamic psychotherapy involves a deeper understanding of the individual's world and the therapist rather than working in the present as is the case for CBT, which may explore earlier chapters of the individual's life. The therapy works by using the therapist-client relationship to facilitate change. Addressing emotional problems that are a result of earlier life experiences may be addressed in terms of the effect they have on the experience of the pain (Perlman 1996). This can result in long-term period therapy and is therefore costly. There has been limited amount of research on the effectiveness of psychotherapy for the chronic pain population; however some studies have demonstrated its effectiveness. Bassett and Pillowsky (1985) concluded that 12 sessions of psychotherapy may be useful for chronic pain patients, although a small cohort of 26 patients limited their findings; hence the authors concluded that larger studies were warranted. Guthrie (1991) also researched the effectiveness of this therapy on a group of 102 patients experiencing abdominal pain resulting from irritable bowel syndrome. Two thirds of the cohort studied experienced significant improvement in symptoms following brief therapy, however, long-term outcomes were not explored.

Client centred therapy developed by Carl Rogers (1951) focuses on the client reaching self-actualisation. Self-actualisation is a process by which an individual realises their full potential. Maladjustment in individuals is recognised as a discrepancy occurring between real self and ideal self and this therapy enables a decrease in this discrepancy. The therapist provides the client with a space to discuss their world and offers unconditional positive regard and empathy. Through this approach, the individual is supported through change, which is facilitated by them. Carl Rogers believed that the client knows best and that the therapist enables the client through a process of change, driven by the clients themselves. In comparison with CBT, client centred therapy is non-directive and the process is driven by the client. Critics of this therapy have discussed the risk of misunderstanding between self-actualisation and self image ideals (Perls 1969). When compared with physical therapy among a cohort of chronic low back pain patients in Brazil, client centred therapy

was significantly less effective upon improved disability (Machado et al. 2007). However, this study recruited low numbers, a total of 33 patients were included.

Research has demonstrated that psychological distress is more likely to be a consequence rather than a cause of chronic pain (Gamsa 1990; Simmonds, Kumar and Lechelt 1996). Empirical studies have demonstrated on many occasions that pain beliefs, avoidance and fear, are associated with certain behaviours leading to disability and withdrawal from social interaction and general goal attainment (McCracken and Turk 2002; Vlaeyen, Crombez and Goubert 2007). Negative appraisals are shown to be more predictive of poorer functioning, pain tolerance and psychological morbidities than measures of illness or physical impairment (Keefe 1989). Thought and behaviour patterns correlate positively with emotional, social and physical functioning in chronic pain (McCracken and Vowles 2008). CBT appears an essential add-on to any treatment proposed for chronic pain, as response to thoughts and beliefs surrounding both pain sensation and treatment will affect efficacy of treatment (Keefe 1989; Turk 1990). A systematic review of 25 randomised controlled trials investigating the effectiveness of CBT for chronic pain concluded that CBT is effective when compared with a control (Morley et al. 1991). The authors also concluded that CBT was as good as or possibly better than other psychological therapies for chronic pain. Nevertheless, caution should be taken when delivering brief CBT interventions. Williams et al. (1996) noticed that longer and intensive CBT was more effective in reducing pain and improving chronic pain patient's activity than brief interventions of CBT. Hadjistavropoulos and Craig (2004) highlighted considerations for the application of CBT. They considered that it is important for any instructors of CBT to remember that patients' goals may be very different from any personally perceived significant goals. It seems important that psychological treatment is personalised. Follow up sessions may also be important, as maintaining changes in behaviours may prove difficult, particularly when coping with chronic pain.

As discussed, beliefs and ways of thinking impact on the pain experience and response to treatment. It is therefore likely that some individuals will experience a placebo effect in the early stages of therapeutic interventions for chronic pain. Individuals have often been in pain for a number of years by the time that they seek treatment and are therefore keen to engage with the prospect of being cured of their pain. The strength of belief may inherit early

placebo effects, which once they are removed will affect the perceived efficacy of the treatment. The next section will consider the placebo and nocebo effects.

## **2.8 Placebo**

Beliefs about treatment and/or the health professionals and their team treating the individual can induce a placebo effect. Placebo offers a possible explanation for short-term positive outcomes for treatments. Placebo is Latin for 'I please' which can be described as a staged response to the health professional treating the individual. The patient receives benefit from an inert pill or treatment due to belief and expectation. Open administration of placebo is believed to be generally more effective, due to the effect of the presence of the therapist upon the patient. Psychological factors are imperative to the effect of a placebo. Changes in mood, environment, beliefs and expectations about the placebo will interact with effectiveness (Shapiro and Shapiro 1997).

A placebo is often used to test the effectiveness of new drugs (e.g. half of a cohort is given an inert pill and half the new drug). The concept of a placebo response can be understood in terms of the mind impacting upon the body, causing a reaction. Anxiety reduction as a result of a placebo can be observed since the belief in a reduction of symptoms will lead to a lowering of the anxiety. In this situation, we can imply that a reduction in anxiety may close the hypothetical gate suggested by the GCT. The lowering of the anxiety leads to less hypersensitivity to the symptoms allowing the participant to perceive an improvement in symptomatology. This effect, however, may be short-term as afterwards the perceived reduction in anxiety may no longer be sufficient to reduce the symptoms.

Psychobiological explanations of placebo include conditioning and expectation leading to physiological changes (Pavlov 1932). White coats/ physicians/ pills and surgery for example, are all associated with getting better. This belief can lead the participant to a level of conditioning. According to the general adaptation syndrome stimulus response explanation of stress, the sight of danger triggers the release of corticotrophin releasing hormone from the hypothalamus leading to cortisol being released from the adrenal glands, aiding escape mechanisms (Selye 1956). This stimulus response mechanism can be transferred to the understanding of placebo. Frontal cortical areas of the brain have been linked to patient

expectations of treatment effect (Lidstone and Stoessl 2007). The spinal cord is also understood to be involved in the placebo response. Spinal nociceptors were found to respond to placebo using a heat test where patients were administered a placebo or no treatment (Matre, Kenneth Casey and Knardahl 2006). The authors observed that the area of spinal sensory neurones that are responsible for hyperalgesia were reduced in the group receiving the placebo.

Patients can also experience nocebo effects, where undesirable events may be experienced in response to receiving a placebo treatment. Nocebo can induce both symptomatic and physiological changes. Barsky et al. (2002) performed a review of the literature on the nocebo effect in order to identify ways to reduce the unwanted nocebo effects patients may experience in response to medications. This review indicated the following factors as the main influences on a potential nocebo effect: the patients' beliefs and expectations of the prospective treatment, conditioning principles where a patient learns to associate symptoms with the intake of medication, certain psychological factors including anxiety and depression and, environmental factors associated with where the medication is administered. Barsky and colleagues concluded that these unwanted nocebo effects could be reduced by an improvement in the doctor-patient relationship, ensuring patients understand and hold the correct beliefs.

The placebo effect can be explained in individual differences in patients when responding to a treatment. Placebo conditions have been found to be as effective as commonly used painkillers. Evans (1974) estimated that placebo was up to 60% as effective as aspirin and codeine. This author considered this to be the case despite differences in the strength of the substance administered. Pascalis, Chiaradia and Carotenuto (2002) found that verbal expectancy and individual differences contributed to the magnitude of the placebo effect. Gracely et al. (1985) noticed that when doctors believed the patients would receive pain relief, the patients reported more pain relief. The impact of the doctor believing a positive effect would occur transferred on to the patient, illustrating the impact of the environment upon the patient's reaction to treatment. This should therefore be considered when critiquing methodologies exploring placebo effects. Is the effect a response to the treatment, or due to the impact of the doctor-patient relationship? The patients' expectations of a treatment may be modified by the doctor-patient relationship. Trials evaluating the effect of patients'

expectations can be problematic as merely partaking in a trial can alter these expectations. When taking part in a trial, the patients were aware that they are either going to receive an effective treatment or an ineffective/placebo alternative. The placebo effect is extremely important when evaluating the efficacy of a treatment.

In recent years, medicines have been found to be less likely to induce a placebo effect than surgical treatments, due to the clinical trials being controlled (Shapiro and Shapiro 1997). Surgical treatments are more likely to endorse a placebo effect since they cannot always be subject to controlled trials due to ethical considerations for invasive procedures (Shapiro and Shapiro 1997). Moreover, surgical treatments may cause far more emotions and psychological reactions since they can be invasive and the recovery can be lengthy with potential complications. These factors may influence certain beliefs and expectations inducing more placebo responses than administration of pills. This could be an important factor when considering SCS treatment. SCS is highly invasive and often a last resort treatment, which may increase the likelihood of initial placebo effects. This could be hypothesised as a reason for initial successful pain reduction, which is not successful in the long-term. Landsheere et al. (1992) when investigating the impact of SCS on reduction of painful symptoms among angina patients concluded that a placebo effect must be considered as neither the physician nor patient can be unaware of the effects of stimulation and, as previously mentioned, surgical interventions are more likely to produce placebo effects. Blinding is a problem when comparing SCS with a control group for placebo effects. Eddicks et al. (2007) tested placebo effects in SCS and concluded that in comparison to a low output phase of stimulation acting as a control group, those patients receiving conventional levels of stimulation experienced more improvement in functional status and symptoms of angina.

To complement the described pain models, the following chapter of this thesis provides a description of the physiology of pain and treatments for chronic pain.

## **Chapter 3**

### **Physiology of pain and chronic pain treatments**



### 3.1 Physiology of pain

When injury occurs, peripheral nociceptors are activated and the signal is conducted via afferent nerve fibres to the dorsal horn and the brain (figure 3.1). The brain also provides a feedback loop, fibres and connections loop back to provide feedback; the feedback provides signals on necessary adjustment. The nociceptive information is then interpreted by the brain, based on individual sensations or pain experienced (Brannon and Fiest 2010).

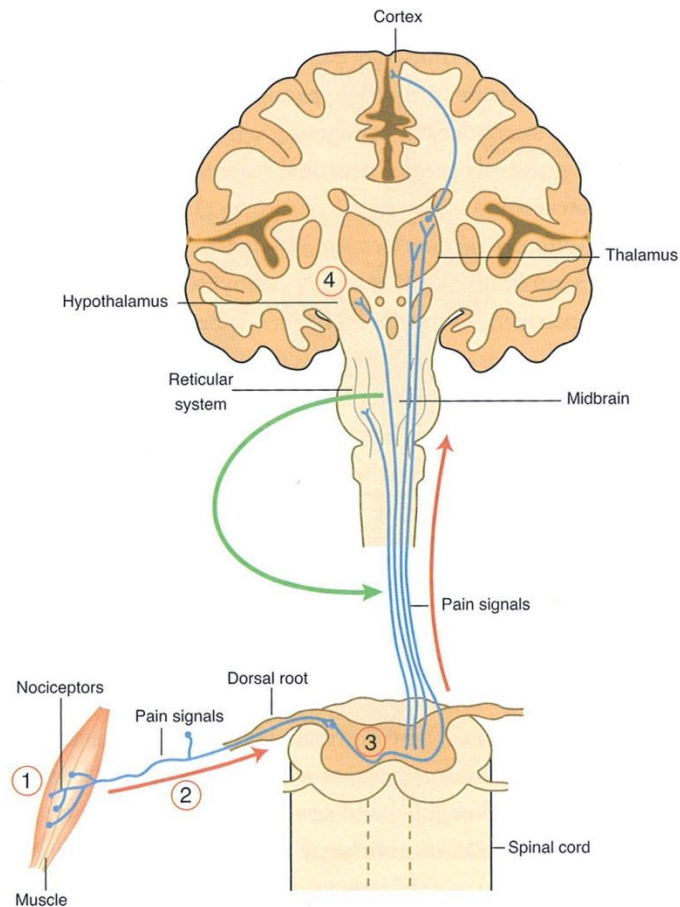


Figure 3.1 Pain pathways to and from the brain  
(1) Transduction; (2) Transmission; (3) Modulation; (4) Perception  
(Adapted Cepeda, Cousins and Carr 2007)

#### 3.1.1 Transduction

Transduction will enable positive ions to enter cells resulting in action potentials (figure 3.2). An action potential occurs when the membrane of a cell changes, allowing between cell communication. Once the membranes threshold is reached the channels open, allowing an

influx of sodium. A sequence of cell to cell action potentials convey signals. Nociceptors, distributed throughout the body tissues and viscera respond to tissue stimulation. The stimulus (mechanical, thermal or chemical) is detected by the nociceptive receptors. The nociceptors respond to substances released when tissue damage occurs and are further activated by prostaglandins, cytokines, vallinoid neurokinins and nerve growth factor. The different impulses are carried via the associated nerve fibre. Peripheral stimulation transmission involves three main types of nerve fibres, A $\beta$ , A $\delta$  and C fibres. Myelinated A $\beta$  fibres carry impulses at a faster rate than non-myelinated C fibres. While large A $\beta$  fibres conduct stimuli at the fastest rate, C fibres are more common, although they are the slowest (Melzack and Wall 1982). The A $\beta$  fibres are involved in non-nociceptive stimuli, responsible for vibration or touch, while the A $\delta$  and the C fibres are responsible for the transmission of the noxious signals to the central nervous system (CNS). The A $\delta$  fibres result in fast sharp sensations of pain and require a high threshold in order for transmission to occur while C fibres produce slower conducting and dull pain sensations (Urch 2007). C fibres respond to mechanical, thermal and chemical stimuli, while the A $\delta$  fibres respond to mechanical and thermal stimuli. If A $\beta$  fibres are stimulated at the same time as A $\delta$  and C fibres they can dominate, resulting in reduced or ceased pain transmission.

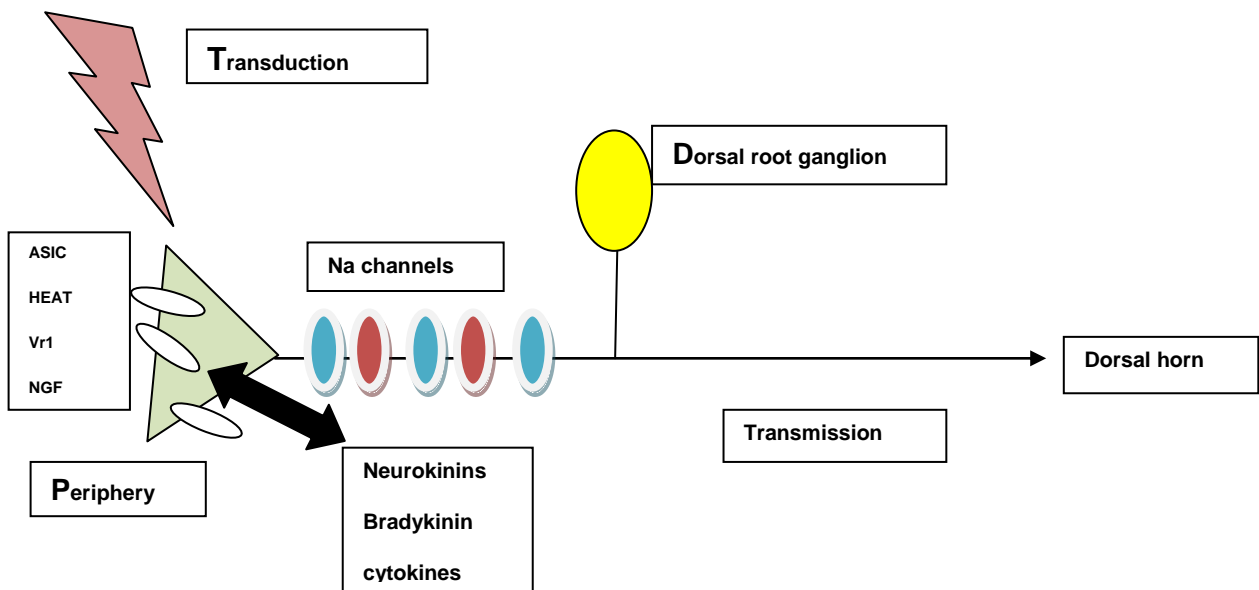


Figure 3.2 Schematic representation of transduction (Adapted from Urch 2007)

### *3.1.2 Transmission*

Transmission to the dorsal horn only occurs if stimulation reaches a certain threshold. Once transduction occurs at the receptors, sodium or calcium ions enter the cells. Calcium is the substance responsible for the changes in cellular expressions, which enables modification of receptors transmission. The primary transduction of the sodium or calcium ions enables depolarisation. If this influx continues, the threshold is reached enabling action potential within the cells. Therefore, the cell depolarises and an action potential travels along the axon to the main part of the cell. This action potential is transmitted along the neurone and to the dorsal horn. The cell passes messages to nearby cells through synapse.

Subsequently, the primary afferent nerve fibres enter the spinal cord at the dorsal root ganglion. The cell bodies of the primary afferent cells are responsible for transmitting pain signals, cell function regulation and activity level. Depolarisations alter the transmission of receptors which can be transmitted in either retro- or ante-grade ways. The alterations in transmission result in changes in the neurone expression and these changes are recognised as influential in peripheral sensitisation or attenuation. Changes in the neuronal expressions enable dynamic communications between receptors, causing release and activation of substances.

### *3.1.3 Modulation*

The nociceptive afferent fibres pass straight to the spinal cord and do not synapse outside of the dorsal root. The fibres have branching collaterals that enter the dorsal horn and substantia gelatinosa, where they synapse with transmission neurons. Upon entering the spinal cord, the fibres ascend one or two segments in the dorsolateral tract of Lissauer before entering the grey matter and terminating in laminae I, II or V (Cross 1994). The primary afferents transmit information to different laminae. The A $\beta$  fibres which carry the non-noxious information to lamina V, the A $\delta$  fibres to laminae I, and V and the C fibres to laminae I, II and V. Lamina V receives input from afferent fibres and interneurons in laminae I and II. A complex dynamic communication takes place at the substantia gelatinosa, which is formed from lamina I and II. The primary afferents synapse with projection neurones at the substantia gelatinosa and neural modulation by other ascending and descending fibres may occur. Neurotransmitters can occupy receptor sites of neurons at the synapse, each fitting a specific specialised receptor site. Neurotransmitters can be either

excitatory or inhibitory. When considering pain transmission, glutamate in particular is understood to be excitatory, transmitting pain signals to the brain, and GABA (gamma-aminobutyric acid) inhibits pain perception (Linderoth and Foreman 1999). Neurone receptor sites can be occupied with neurotransmitters including inhibitory neurotransmitters such as enkephalins or GABA, excitatory neurotransmitters such as glutamate, substance P, CGRP, noradrenalin and those with mixed excitatory and inhibitory effects such as 5-HT.

If a sufficient amount of glutamate is released, it will result in depolarisation and the opening of the NMDA receptor (glutamate receptor) causing a massive influx of calcium. Repeated stimulation results in a reduced threshold and an increase in electrical response build up within the CNS, known as 'wind up' reaction (Woolf 2011), which leads to intensified stimulation of nerve fibres (Helms and Barone 2008).

Inhibition involves the primary neurotransmitters GABA, endocannabinoids and enkephalins. These inhibitory neurotransmitters alter receptor activity in the CNS, specifically the dorsal horn area of the spinal cord. Inhibition can also be activated by the release of substances including glycine and GABA which can be modified by NMDA receptor activation. GABA can bind to GABA-A resulting in re-polarisation.

In chronic pain, non-neuronal cells within the CNS (glial cells and astrocytes) have recently been recognised as impacting upon continued neuronal activity (International Association for the Study of Pain 2008). None of these have axons and play no role in pain transmission until activated. However, they produce pro-inflammatory mediators (e.g. IL-1, IL-6, TNF, O, EAAs, PGs, ATP) that are neuroexcitatory. Spinal cord glia expresses receptors for substance P, glutamate, ATP and P2X4, which after injury are released in increasing amounts and form the primary afferent. Released neuromodulatory substances such as NO and Pgs activate neurons which also trigger protein production and release in the glia. Sensory afferent fibres in the dorsal horn may produce specific glial triggering chemokine such as fractalkine. Substances released in response to axonal injury (ATP, Pgs, heat shock proteins (HSPs)) bind to receptors such as the toll-like receptors (TLR) and activate the glia.

The understanding of some of the mechanisms involved in the supraspinal pathways, allow insight into the central neural networks. Although still not completely understood, research

using functional magnetic resonance imaging (fMRI) has enabled some development in the understanding of the supraspinal pathways (figure 3.3). The projection neurone conveys information from the lamina I to the thalamus and somatosensory cortical areas (S1 and S2) of the brain, but also to areas such as the hypothalamus, amygdala, insula and hippocampus. These latter areas are understood to be involved in the individual evaluation of the affective and emotional components of pain resulting in the subsequent behavioural responses to the noxious messages received.

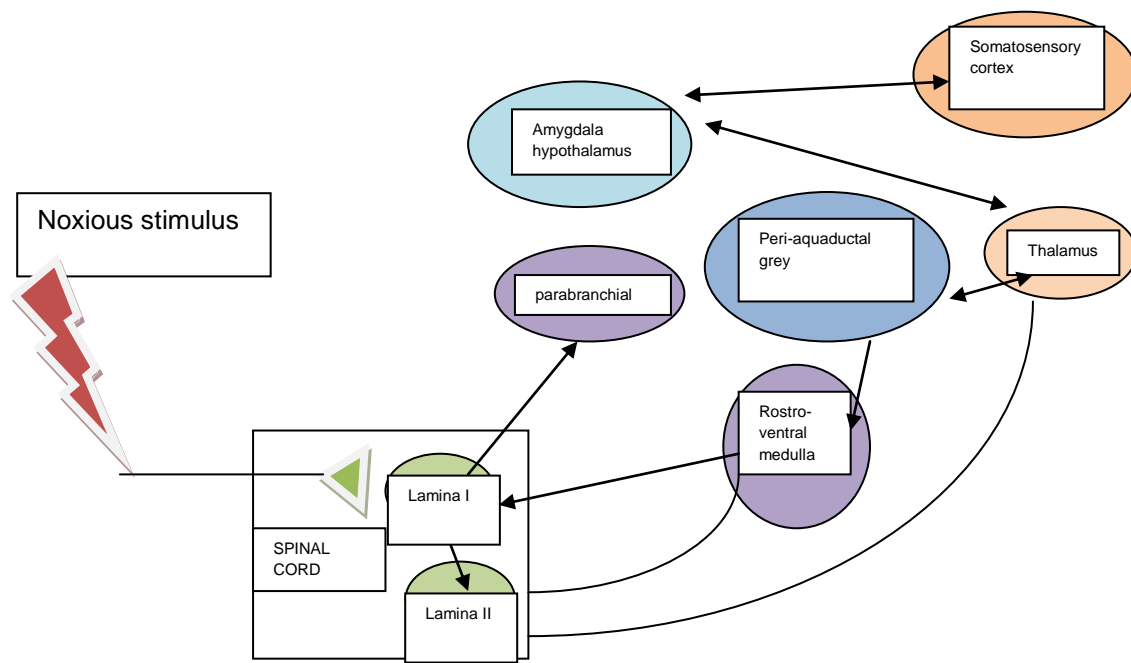


Figure 3.3 Diagram of supraspinal connections (Adapted from Urch 2007)

Descending information from the brain occurs via the periaqueductal grey (PAG) and rostro-ventral medulla (RVM). The descending pathway can convey transmission of both excitatory and inhibitory messages. Once the descending pathway is activated, PAG projects to RVM neurons, which sends inhibitory projections to the dorsal horn of the spinal cord. As a result, GABA is increased and glutamate inhibited, leading to antinociception (Palazzo et al. 2010).

### 3.1.4 Perception

We often judge events and situations as good or bad depending on how we feel. The greater the emotional distress displayed by an individual, the greater the perceived threat of

a situation for that individual. When experiencing pain, individuals will ascribe meaning to the pain in terms of what the pain means to them. The representation of the pain experience that an individual develops can result in negative emotion. The threat perceived by an individual regarding pain has been demonstrated to increase the affective dimension of pain (Chapman 2004). The frequency of signals to the nociceptive areas of the brain and the corticosubcortical structures increased in a study using functional magnetic resonance imaging (fMRI), where students were tested with noxious stimuli and a depressed mood was induced, (Berna et al. 2010). These areas are understood to be involved in the emotional processing. Negative emotion may result in an increased focus on the pain, possibly increasing awareness of sensations, leading to an increase in the perceived level of pain (Beauregard 2007).

The anterior cingulate cortex contains areas that recognise stimuli. Reduced pain reporting as a result of distraction is correlated with lower levels of activity in the ascending thalamocortical pain pathways (Villemure and Schweinhardt 2010). Whereas increased activity was noted in primary somatosensory cortical areas when individuals maintained a focus on pain (Villemure and Schweinhardt 2010). Research investigating the sensory and affective dimensions of pain using hypnotic suggestion has identified areas of the brain hypothesised to be responsible for the affective components of pain (Rainville et al. 1999). This research used positron emission tomography (PET) and magnetic resonance imaging (MRI) scans. The individuals were subject to hypnotic suggestion to alter the affective and sensory experience of pain induced by immersing a hand in water. This empirical research observed a possible relationship between pain affect and sensation with anterior cingulate cortical (ACC) activity. Findings suggested that pain related activity in the ACC was associated with changes in perceived unpleasantness of pain, hypothesising that the ACC area is involved in the emotional processing of pain. The insular cortex is understood to be involved in the emotional reaction to nociception. Studies using distracting tasks showed modulation of thalamus activity when processing pain, and studies inducing a depressed mood demonstrated increased pain processing in the frontal limbic areas (Beauregard 2007).

Specific moods and beliefs appear then to have a huge role within the experience of pain, and therefore treatment response. The following section will consider the classifications of

pain and the treatment available to patients with chronic pain. Often SCS patients have tried and tested many treatments before trialling for SCS. The following section will allow insight into the treatments available, with a focus on SCS and how the system is implanted. The following section will consider the progress to date in terms of patient selection for treatment. This section highlights the fact that no clear pathway has been established for selection for SCS and henceforth the need to further develop an understanding of the psychological factors that interact with treatment efficacy. The section ends with a focus on what the literature shows regarding the effect of psychological factors and coping strategies upon treatment outcome.

### **3.2 Classification of pain**

The classification of pain may take into consideration aspects such as duration, aetiology, intensity or type of injured tissue. Although pain is understood to be an indicator of medical problems, pain is not always proportional to the extent of the injury or diagnosis. Acute pain is characterized by a short duration, typically after an injury, surgery or disease and usually disappears during the healing process. Supraspinal mechanisms provide feedback between the area of pain and the sensations leading to learnt behaviour, enabling avoidance of painful stimuli. However, some acute pain develops into chronic pain, which is defined as lasting for more than three to six months (Verhaak et al. 1998). It is not the duration of pain that distinguishes acute from chronic, but the inability of the body to restore its physiological functions to normal homeostatic levels (Loeser and Melzack 1999). The injury may exceed the body's capacity to heal. This could be due to limb loss, extensiveness of the trauma and subsequent scarring, or damage to the nervous system (Loeser and Melzack 1999). Acute pain can be regarded as a transitional period between coping with the injury and preparing for recovery (Melzack and Wall 1988). A few types of acute pain, such as post-herpetic neuralgia (nerve damage caused by herpes zoster) can frequently give rise to chronic pain (Merskey 2007).

Chronic pain is understood to be the result of a combination of psychological and pathological events, which may have included tissue and/or nerve damage (Grady and Severn 1997). Chronic pain persists long after pain can serve any useful function and is no longer a simple symptom of injury or disease but a medical problem in its own right that

requires urgent attention (Melzack and Wall 1988). Pain remains one of the biggest challenges to the medical profession since many occurrences of pain cannot be accounted for by identified tissue damage (Auvray, Myin and Spence 2010). Pain without tissue damage can be understood to be due to sensitisation of the nervous system. For example, previously silent nociceptors are activated resulting in an alteration of sodium channels phenotype, receptor number and sensitivity (Woolf and Qiu 2007). Chronic pain can dominate the lives of individuals, impacting on daily life and affecting activities ranging from sleep to relationships and goal attainment. Chronic pain is a condition for which successful treatment outcomes are difficult to achieve and it has a huge impact on an individual's health, healthcare services and society (Smith, Macfarlane and Torrance 2007).

In Europe, one in five adults (19%) suffers from chronic pain and over one third of European households have at least one chronic or acute pain sufferer (Breivik et al. 2005). The prevalence of chronic pain in the United Kingdom is 13%, which accounts for approximately 3.8 million of the population and a third of those suffer with constant chronic pain (Breivik et al. 2005). As the lifespan increases, the debilitating effect of chronic pain upon quality of life will continue to increase and affect more individuals (International Association for the Study of Pain 1979).

Movement away from a biomedical approach towards a biopsychosocial one has enhanced the understanding of the role that psychology has in the pain experience (Kugelman 1997). Several difficulties in understanding and managing pain are recognised as psychological, for example beliefs about pain can impact on coping and acceptance which will be discussed in more detail in section 3.4.3 of this chapter.

Experiencing pain for long periods of time is different from short-term pain experiences. A patient experiencing acute pain, for less than a six month period, will experience elevated anxiety during the painful period, but this is decreased as their condition improves (Fordyce and Steger 1979). When pain becomes chronic, individuals maintain high levels of anxiety, and experience numerous additional psychological factors such as helplessness and depression. Psychological factors can influence the pain experience and therefore the behavioural reaction and response to treatment and, consequently, the management of chronic pain (Turk et al. 2010).



Pain can also be described in terms of type of injury. Nociceptive pain results from tissue damage, and activation of the nociceptors by noxious mechanical, thermal or chemical stimuli (Costigan, Scholz and Woolf 2009). Two types of nociceptive pain can be experienced, somatic and visceral. Visceral pain results from the activation of nociceptors (nerves in the skin and tissues) in the internal organs (viscera). Somatic pain results from nociceptors reacting to sensations including temperature, vibration and swelling in parts of the body such as skin, bones or muscle. Visceral pain can be difficult to pinpoint when compared to somatic pain. Visceral pain nociceptors are located within organs and sensations are often described as aching or squeezing and the pain can become referred. Referred pain is experienced in an area close to the original site of the pain (e.g. arm pain experienced after myocardial infarction, or women with irritable bowel syndrome experiencing exacerbation of symptoms during pre-menstrual phase). Sensations are described as sharp, dull or achy. Pathological pain can be understood as a result of the 'wind up' mechanism, which lowers the threshold enhancing nociception causing pathological changes. Therefore, an amplified response to acute pain may occur when neural functioning is altered or is dysfunctional. Pharmacological treatment for nociceptive pain is typically based around nonsteroidal anti-inflammatory drugs and opioids. Some pain can be a combination of both nociceptive and neuropathic (e.g. failed back surgery syndrome). The nociceptive pain may be in response to injury to the disc or bone, reaction to hardware or graft harvesting and the neuropathic component a result of nerve injury prior to or during surgery, chronic compression, scar tissue formation or arachnoiditis (Prager 2002).

Neuropathic pain causes a range of symptoms including numbness, pain and impaired movement. IASP (2012) has designated neuropathic pain as a clinical description rather than a diagnosis. Defining neuropathic pain has been controversial and previous classifications have been discussed as lacking boundaries. Neuropathic pain has been redefined as pain arising as a direct consequence of a lesion or disease to the somatosensory system (Treede et al. 2008). Peripheral neuropathic pain occurs when continuous action results in the neurons becoming sensitively heightened to stimuli. This can occur due to mechanical trauma, metabolic disease, neurotoxic chemicals, infection or tumour invasion involving numerous physiological changes within both the peripheral

nervous system and central nervous system (Dworkin et al. 2003; Woolf and Mannion 1999). Central neuropathic pain is understood to be the result of spinal cord injury or multiple sclerosis (Ducieux et al. 2006). Central sensitization occurs following ongoing activity in the periphery, with neurons becoming more receptive and developing heightened responses to stimuli, which would normally be perceived as non-noxious. A grading system is suggested for probable neuropathic pain (Treede et al. 2008). Confirmation must only be done via neurologic examinations.

A distinguishing feature of neuropathic pain is that the pain sensations can be continuous, i.e. independent of movement. However, for some individuals the pain is episodic, although still unrelated to movement. The pain sensation may resemble shooting pain, electric type pain or intense burning. Injury to the somatosensory system can result in pain being experienced without identifiable stimuli or in response to non-nociceptive stimuli. Neuropathic pain may cause allodynia, pain felt in response to non-nociceptive stimuli which occurs when the non-nociceptive A $\beta$  fibres synapse at the dorsal horn and the neurone responds as if they were nociceptive fibres, leading to pain being experienced even in response to light touch (Hawthorn and Redmond 1998). As previously mentioned a 'wind up' action can develop, where the second order wide dynamic range (WDR) neurons responses increase progressively leading to increased pain. If a painful stimulus is present for a long time, it may cause changes to the nociceptive pathway and potentially lead to hyperalgesia (heightened sensitivity), another hallmark of neuropathic pain (Hawthorn and Redmond 1998). Examples of neuropathic pain include diabetic neuropathy, trigeminal neuralgia, and post herpetic zoster pain. Possible treatments for neuropathic pain include anti-epileptic drugs, which inhibit nerve reactions, antidepressants which enhance dorsal horn inhibition and SCS which involves electrical stimulation of the large nerve fibres, reducing pain sensation.

### **3.3 Treatments for pain**

Pain is complex and therefore a range of treatments exist for its management. Often patients considered for SCS report having tried and tested many treatments without success. The following section outlines the range of treatments available. This section ends with a focus on SCS therapy.

### *3.3.1 Injections*

Injections of local anaesthetics and steroids around nerves subserving a painful area are commonly offered in pain clinics. In general they appear to provide short-term pain relief and are best used in chronic pain conditions within a broader rehabilitative framework. There is supportive evidence from controlled trials in selected conditions such as lumbar radiculitis (Buenaventura et al. 2009; Vad et al. 2002). Lesioning of nerves to provide longer-term relief can be offered in some cases. Controlled trial evidence is limited to certain conditions (e.g. facet joint pain) (Dreyfuss et al. 2000).

### *3.3.2 Physiotherapy and Chiropractic*

Physiotherapy is a common physical therapy used in pain clinics. It is widely offered, although there is limited evidence supporting its efficacy for chronic pain patients. Physiotherapy offers support for specific muscular problems and forms a holistic part of rehabilitation by improving self-efficacy via operant conditioning and therefore improving general well-being. Chiropractic involves manual manipulation of the spine, joints and soft tissues. Randomised trials provide evidence that chiropractic interventions support improved mobility for chronic low back pain patients (Meade et al. 1990).

### *3.3.3 Acupuncture*

Acupuncture involves the insertion of non-cutting ultra-fine needles into the skin surface and sometimes into the underlying muscles. In part it is thought to work via activation of opioid receptors. Results from controlled studies are sometimes controversial, since studies employing sham acupuncture as a control (needles placed anywhere) have obtained similar results to the correct acupuncture points group (Ezzo et al. 2000).

### *3.3.4 Pain management programme*

This is a commonly used form of psychological therapy for chronic pain. Pain management programmes are devised and run to enable patients to increase levels of self-efficacy and personal management of pain. Pain management programmes are highly recommended for patients in combination with other treatments since it addresses negative cognitions to improve coping and acceptance. Individuals can become helpless and lose confidence when experiencing pain on a daily basis. The pain management programme combines physical, psychological (cognitive behavioural therapy/operant conditioning principles) and practical

learning to improve coping, disability and general daily life. The programmes are run for a set number of weeks by a multidisciplinary team and include approximately six to 12 participants in each programme. Whilst limited empirical research presents support for modalities other than pharmacological interventions for pain relief, some have been demonstrated to improve physical and psychological function. Patients report improved mobility and psychological functioning after these interventions although pain reports are often similar (Flor, Fydyk and Turk 1992).

### *3.3.5 Antidepressants*

Antidepressants are thought to work for patients with chronic pain, by activating the descending pathways to the spinal cord limiting the pain signals travelling to the brain. Illustrating GCT suppositions, the noxious stimuli are inhibited by the antidepressants preventing the re-uptake of noradrenaline +/- 5HT. RCTs lend support to a beneficial effect, however with a modest effect size (Saarto and Wiffen 2005).

### *3.3.6 Anticonvulsants*

Anticonvulsants work mainly by the blocking of calcium or sodium channels on neurons. This is an effective treatment for some neuropathic pain conditions (e.g. diabetic neuropathy and trigeminal neuralgia). Although with a modest effect size, RCTs support benefit from anticonvulsants, particularly gabapentinoids (Backonja 2000).

### *3.3.7 Opioids*

Opioids bind and block receptors in the spinal cord and brain providing pain reduction mechanisms. Opioids increase potassium and reduce calcium conductance, and are thus inhibitory, reducing neuronal excitability (Kieffer and Evans 2009). Chronic pain often results in postsynaptic NMDA receptors being open leading to an increase in calcium, neurone activity and sensitisation. Some opioids work by blocking the NMDA channels, reducing sensitisation (Raphael et al. 2010). Clinical evidence of efficacy is uncertain, with few RCTs and none long-term. Concerns about the effect on quality of life and potential drug dependence have been raised.

### *3.3.8 Topical agents*

Lidocaine is used in medications for burning and skin irritations. This substance alters signal conduction by blocking sodium channels in the neurons cell membrane, resulting in a failure to depolarize and no action potential (Rowbotham et al. 1998). Capsaicin works by depleting or reducing the TRPV1 receptors and subsequent efficacy of neurotransmitters involved in sending pain signals to the brain (Backonja et al. 1998).

### *3.3.9 Transcutaneous electrical nerve stimulation*

The concept of applying electrical stimulation locally, within the dermatome of the pain, was developed based on the GCT. Transcutaneous electrical nerve stimulation (TENS) uses an electrical current which is applied via a device to the skin surface to stimulate the nerves. A TENS machine is usually in contact with the skin, is battery operated and used for both acute and chronic pain. The use of TENS reduces the activation of nociceptive signals with pre-synaptic inhibition occurring at the dorsal horn resulting in an increase of inhibitory neurotransmitters release (e.g. GABA). TENS is also understood to activate the release of serotonin (Sluka and Walsh 2003). Controlled trials are not entirely supportive of the efficacy of TENS (Robb et al. 2009).

## **3.4 Spinal cord stimulation**

Spinal cord stimulation introduced by Shealy, Mortimer and Reswick (1967) involves modulation of pain transmission by electrical stimulation of neuronal pathways in the spinal cord. This method of therapy has been in use for more than 30 years, developed initially as a clinical application of Melzack and Wall's GCT, which proposes that the levels of pain experienced are modified by other signals that the dorsal horn is receiving concurrently. Animal studies have shown inhibition of hyperexcitatory actions in the dorsal horn and increased levels of GABA released (Yakhnitsa, Linderoth and Meyerson 1999). Each year over 14,000 new individual patient cases undergo spinal cord stimulation treatment (Linderoth and Foreman 1999).

SCS involves electrodes being implanted into the dorsal epidural space. The electrodes also known as contacts, are connected to a pulse generator and are programmed to generate an electric field stimulating the dorsal horn and dorsal column axons (anode and cathode combinations) (Bradley 2006). Stimulation in this area results in supraspinal mechanisms,

reducing activity in the ascending pain pathway (spinothalamic tract) and increasing activity in the descending antinociceptive pathway (Linderoth and Foreman 1999). SCS produces paresthesia (tingling sensation) and the proportion of targeted nerves being stimulated in comparison to stimulated nerves not being targeted deems efficacy of the therapy. By activating pain inhibiting mechanisms (the vibration sensation caused by the electrical stimulation), the sensory experience of pain is altered, reducing intensity, frequency and duration.

Figure 3.4 illustrates the implantation of a spinal cord stimulator into the epidural space. The top of the figure depicts the leads that comprise the electrodes, which are connected to the lead anchors and tunnelled to connect to the implanted pulse generator (IPG).

The entire system is implanted, which allows the individual to carry out normal daily activities. The patient uses a remote control system to activate the SCS system. Some patients will use SCS during certain periods of the day while others will have the system switched on throughout the day and others throughout the night.

#### *3.4.1 Implantation*

SCS leads comprise between four and eight electrodes. The leads implanted are either surgical (paddle) or percutaneous (catheter). Paddle leads (one or more) are directional, focusing the electrical current towards the spinal cord, and their insertion usually requires a laminectomy (incisions to access the laminae). Percutaneous leads are inserted into the dorsal epidural space through a modified Tuohy needle (hypodermic needle, very slightly curved at the end). The leads (one or more) are implanted into the dorsal epidural space under fluoroscopy (x-ray guided procedure).

Only local anaesthesia is administered to the patient when the insertion of the leads takes place since the stimulation needs to be regularly investigated to ensure beneficial amounts of stimulation are targeting the desired area or in some cases multiple areas. Occasionally, the specialist may suggest the implantation of two SCS systems when individuals experience multiple areas of chronic pain.

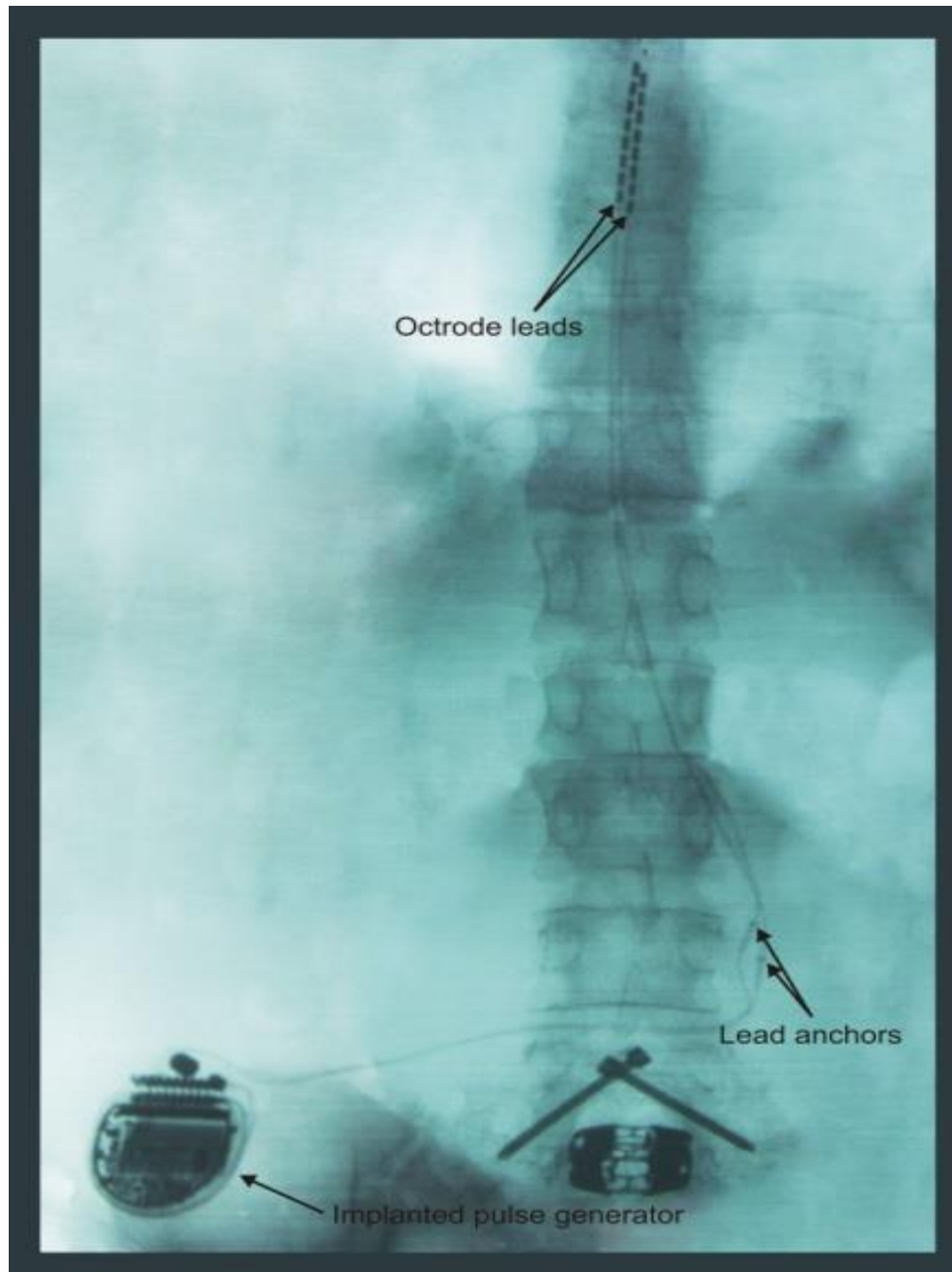


Figure 3.4 Implanted spinal cord stimulator

The leads are tunnelled internally and connected to a battery, also known as implanted pulse generator (IPG). The IPG generally has a battery life of nine years (Bradley 2006). The IPG is placed externally during the trial period and fully implanted upon successful reports of pain reduction (>30%). Trial periods range from four to seven days to assess the individual's response to treatment, usually measured with a visual analogue scale (Lee and

Pilitsis 2006). Patients are considered as suitable for full implantation of the stimulator if a targeted reduction in pain of at least 30-50% relief is achieved (Lee and Pilitsis 2006). The IPG is typically implanted either in the abdomen, chest wall, gluteal or infra-clavicular area (Raphael, Mutagi and Kapur 2009).

Once implanted, the SCS can be programmed to provide the greatest benefit to the patient. A technician will spend time with the patient generating up to three different stimulation programmes, which can be selected according to the patient's preference/pain/activity. The programmes may differ since different rates of stimulation may be required for lying down, sitting or walking. The programmes can be adjusted at any point and periodical follow up clinic appointments allow the patient and technician to find the most beneficial rates of stimulation. Occasionally the stimulation may decrease and the technician is able to change the parameters to find a suitable programme to provide the desired stimulation. When an optimum level of stimulation cannot be achieved, further investigations may take place in an attempt to detect possible complications such as lead migration (Sparkes et al. 2009).

#### *3.4.2 Selection criteria for SCS therapy*

The concept that pain is not purely a stimulus-response mechanism and involves a complex interaction of cognitive, affective and behavioural components (Melzack and Wall 1965) supports the need for a multidisciplinary approach to address an individual's chronic pain. NICE guidance stipulates the recommended treatment pathway for SCS to be within a multidisciplinary approach. A multidisciplinary approach is recommended to promote interdisciplinary decisions (De Andrés and Van Buyten 2006). In a standardised questionnaire based survey, 61% of pain management centres in the UK stated that patients were provided with a multidisciplinary approach to their treatment within the clinic, including psychological assessment prior to SCS (Ackroyd et al. 2005). However, there was no standard assessment protocol followed, and to date no gold standard has been established for the psychological assessment prior to SCS therapy.

A multidisciplinary approach involves collaborative teamwork from a variety of professions. In complex medical situations a solution is often best reached by drawing on the expertise of a diverse range of professionals. Within pain management the patient will frequently experience somewhat complex and individual symptoms. Through a multidisciplinary



approach, a line of treatment can be decided based on a variety of professional expertise. The multidisciplinary team at Russells Hall Hospital (where this research was carried out) include a pain consultant, a pain specialist nurse, a physiotherapist and a pain psychologist. During the year 2004, a change in the method of assessment for SCS suitability was made. Prior to this date, patients considered suitable for SCS by the physician would see a physiotherapist and a clinical psychologist for assessment. This team then met to discuss the patient's suitability, often including physiotherapists and psychologists not involved in the process alongside the physicians. If this team recommended SCS implantation the operation would take place. From 2004 onwards, all new patients referred to the pain centre met a physician, psychologist, physiotherapist and a pain specialist nurse during their first visit regardless of whether SCS was being considered at that stage. Selection for SCS after 2004 was based on a multidisciplinary approach in which psychological aspects of pain were considered from the first visit. This approach enables patients to understand the role of psychology in pain conditions independent of medical treatment. It also allows the psychologist to assess the patient prior to treatment expectations being raised. The psychologists felt that this assisted them in providing a more valuable opinion.

This change in assessment focussing on strengthening the psychological assessment was of interest to the researcher, to investigate if a difference in treatment efficacy was noticeable after changes to assessment were implemented. A preliminary study involving a review of case notes was carried out to compare the SCS treatment efficacy prior to and after 2004 (chapter 5, section 5.1).

### **3.5 Impact of psychological factors on treatment outcomes**

The mean duration of time in pain is seven years for patients seeking treatment for chronic pain (Flor, Fyding and Turk 1992). Therefore, it is not surprising that patients experience increasing levels of psychological and emotional distress, accompanying the persistent pain. Research has demonstrated that up to 59% of patients with chronic back pain treated within pain management clinics experience at least one psychiatric problem (Atkinson et al. 1991). Often physicians only start to consider the influence of psychological factors upon the pain experience once the pain cannot be explained by somatic aspects alone (Traue et al. 2010). This may lead patients to often feeling disbelieved, or patients with satisfactory somatic

evidence for their pain not receiving adequate psychological care for the psychological elements of their pain. Considering psychological factors such as pain anxiety, depression or negative coping behaviours such as catastrophising is important, since if not addressed, these may lead to exacerbated pain or worsening of situation. Pain is understood to consist of both somatic and psychological factors and dichotomization needs to be reduced (Traue et al. 2010).

As to whether psychological/psychiatric factors are causal or a result of the pain remains debatable. Regardless of the morbidity aspect, psychological factors interact with the pain experience and severity, impacting upon the response and adaptation to chronic pain (Turk et al. 2010). Consideration of specific cognitions (beliefs, attitudes, expectations), mood (anxiety, depression) and behaviours (response to symptoms), are suggested as imperative to the treatment outcome for an individual with chronic pain (Turk et al. 2010).

### *3.5.1 Cognitive processes*

The biopsychosocial model introduces cognitive-behavioural concepts to understand chronic pain, such as the concept that beliefs lead to subsequent behaviours. In response to a painful stimulus (when the nociceptive signal reaches the cortex) an unpleasant feeling is experienced, and negative responses occur (Melzack and Wall 1967). Individual interpretations of the painful experience interact with the affective component of pain. The attention and evaluation given to the pain experience appears to be central to the perception and subsequent experience (Verhoeven et al. 2010).

Weich, Ploner and Tracey (2008) observed that there are three influential cognitive factors when considering individual differences in pain experience: memories, as these underpin expectation and host a pattern of learned responses; hypervigilance because when the threat of pain is high, fear responses are activated resulting in escape and control behaviours; and catastrophisation since the tendency towards negative appraisal often leads to depression, low self-efficacy, less activity leading to disability and withdrawal.

Specific beliefs modulate the appraisal of pain influencing the behavioural and emotional reactions. The cognitive component of pain has been shown to have great impact upon functional disability. Beliefs about the extent of pain are understood to impact on an

individual's pain related disability and ability to carry on with daily life (Main, Foster and Buchbinder 2010). Fear-avoidance is the belief that activity will cause more pain, a commonly experienced belief among chronic pain patients that is associated with continuation of disability (Mercado et al. 2005). Increased fear of movement related to pain and negative outcome expectancies have been found to be related to uptake of passive pain coping strategies (Den-Boer et al. 2006). In a study with 277 patients, passive pain coping activities such as retreating and avoidance of environmental stimuli were predictive of disability at six months following lumbar disc surgery (Den-Boer et al. 2006).

Acceptance has increasingly become an important consideration for successful pain management (Lopez-Martinez, Esteve-Zarazaga and Ramirez-Maestre 2008). Acceptance can be understood as not employing avoidance or control behaviours, or fear of movement beliefs, continuing with daily routine and following personal goals (Lopez-Martinez, Esteve-Zarazaga and Ramirez-Maestre 2008). Esteve, Ramirez-Maestre and López-Marínez (2007) used structural equation modelling to investigate the impact of acceptance on chronic pain treatment outcomes. Lower levels of acceptance led to compromised functional ability and less improvement in adjustment but not pain intensity reporting. Catastrophising, measured using the Pain Coping Strategies Questionnaire, was the only pain coping variable associated with pain intensity, which indirectly increased depression. Catastrophising and passive coping were found to influence increased levels of anxiety. Active coping was found to result in lower levels of depression and pain intensity reporting. This research concluded that acceptance might lead to improved feelings of self-control and functional status but needs to be considered alongside catastrophising as a separate influencing entity.

### *3.5.2 Anxiety and Depression*

Individuals experiencing chronic pain may sometimes lack physical signs. The lack of physical explanation for many chronic pain cases can lead to feeling disbelieved which in conjunction with the debilitating effect of pain can increase distress, anxiety and depression (Clarke and Iphofen 2008). These authors found when interviewing patients that depression was one of the main themes deduced from the data, due to the unseen and isolating nature of chronic pain.

Depression has been described as being associated with and impacting upon the experience and perception of pain (Vlaeyen and Linton 2000; Turk and Okifuji 2002; Doleys 2006). Many of the symptoms of pain are similar to those associated with depression, which can lead to a lack of awareness that an individual may suffer with depression in addition to their pain (Turk et al. 2010). Signifiers of depression common to pain include sleep loss, fatigue, limited movement, changes in libido, weight and appetite, and memory and concentration difficulties. Depression can lead to increased pain reports among chronic pain patients (Salovey and Birnbaum 1989). When explored using fMRI scans it was noted that a sad cognitive mood altered the reported severity of pain, and also demonstrated changes in the emotional processing areas of the brain related to pain perception (Berna et al. 2010). Whether pain is a precursor or predecessor to depression remains debatable. Research indicates that depression is post morbid to chronic pain and impacts upon chronic pain treatment outcomes (Haythornthwaite, Sieber and Kerns 1991; Rudy, Kerns and Turk 1988).

Hamilton (1959) classified anxiety into three possible types: the result of a reaction to a potentially fearful situation, a pathological mood or a neurotic state. Anxiety is a feeling of apprehension accompanied by a state of readiness (McDowell and Newell 1996). It is often a response to events that are perceived as out of individual control, which could apply to episodes of chronic pain. Anxiety can incur some changes in cognitive processes as well, including confusion, changes in memory, poor decision-making and fearful thoughts.

Increased levels of anxiety are associated with a lower tolerance to pain (Carter et al. 2002) and a higher perception and reported experience of pain (Granot and Lavee 2005). Anxiety levels are likely to be influenced by environmental factors (e.g. the fear/avoidance model of pain). The model suggests that after repeated episodes of acute pain individuals respond to the threat of future pain with fear. Anxiety levels increase due to anticipation, which increases pain perception heightening the experience of pain. Experiencing anxiety for lengthy periods is notably recognised as impacting upon the individual's perception of pain (Merskey and Evans 1975).

### *3.5.3 Coping and behaviours*

Pain coping can either be active or passive. Active coping involves acceptance for responsibility in the management of pain and the continuation of physical activities. Negative

cognitions and emotions, including anxiety and depression can lead to maladaptive and passive coping strategies (Esteve, Ramírez-Maestre and López-Marínez 2007). Passive coping can include inactivity, reliance on medication and patients absolving themselves of personal responsibility for any reduction of pain. Passing responsibility to others, such as health care professionals, adversely affects an individual's life (Sullivan, Rodgers and Kirsch 2001). Maintaining individual responsibility for long-term conditions increases adaptation and motivation to improve the situation.

Mercado et al. (2005) researched the effect that active and passive coping strategies have on the development of disabling pain. They observed that passive coping, measured using the Vanderbilt pain management inventory, was significantly associated with disabling neck and back pain. This finding was independent of demographic, socio-economic and health factors. Lopez-Martinez, Esteve-Zarazaga and Ramírez-Maestre (2008) found that passive coping had a negative effect on function among chronic pain patients. Passive coping was also associated with increased levels of depression. This study noticed a negative relationship between active coping and functional impairment and depression. Research has shown that changes in an individual's cognitions and the degree of attention paid towards the pain can alter pain processing in the brain. Diverting attention, an active coping strategy, was shown to correlate with activity in the thalamocortical pain pathways of the brain where lower levels of activity correlated with less perceived pain (Villemure and Schweinhardt 2010).

#### *3.5.4 Catastrophising and helplessness*

Previous studies have found that methods of coping including catastrophising, praying/hoping, wishful thinking, helplessness, overt expression of emotion and reinterpretation of sensation, to be associated with a lack of adjustment in relation to chronic pain (Mercado et al. 2005; Den-Boer et al. 2006). Catastrophising alongside a lack of perceived internal control is associated with the onset and continuation of chronic pain (Jensen, Turner and Romano 2001; Spinhoven et al. 1989; Sullivan, Rodgers and Kirsch 2001; Turk and Okifuji 2002). Smeets et al. (2006) when studying 211 non-specific chronic low back pain patients using the Pain Coping Strategies Questionnaire, observed that pain intensity and disability increased, alongside increased levels of catastrophisation.

Catastrophic thinking can be explained in terms of exaggerated worry and distress in response to pain being reported regularly by patients with chronic pain (Sullivan, Rodgers and Kirsch 2001). Catastrophising is understood to consist of rumination (concentrating on the feeling of pain repetitively), magnification (increasing the affective component of pain by focusing on the pain) and helplessness (incapacity to take responsibility for the pain) (Sullivan, Rodgers and Kirsch 2001). Being one of the most recurring psychological factors involved in the pain experience, catastrophising needs consideration when selecting patients for treatment (Jensen, Turner and Romano 2001; Spinhoven et al. 1989).

Catastrophising and helplessness as coping mechanisms have been found to predict pain outcomes and response to treatment more effectively than numerous medical variables (Keefe et al. 1989). Catastrophic thinking is influenced and reinforced by social factors. The response to catastrophic behaviours is often of help and empathy from others (Vowles, McCracken and Eccleston 2008). If the behaviour is reinforced with empathy and support, the behaviour is likely to be repeated. Catastrophic thinking leads to exaggerated responses and avoidance behaviours, which in turn limits daily activities and goals (Vowles, McCracken and Eccleston 2008). Vowles and colleagues used three measures to explore catastrophic thinking. The pain catastrophising scale, chronic pain questionnaire and measures of patient functioning questionnaire were administered to 334 patients with an average duration of pain of 96 months. They observed that the impact of catastrophic thinking depended upon the context of occurrence, acceptance of pain, depression, fear of pain and disability. They concluded that noticing and accepting catastrophic thoughts reduced distress. This research was based on self-reports and the authors acknowledged the possible bias of self-report.

### *3.5.5 Beliefs and treatment*

Turk (1990) discusses the importance of customising pain treatments for certain populations with close consideration for psychological factors. Understanding patient beliefs about their pain and treatment may enable patients to change maladaptive beliefs known to lead to negative coping strategies before treatment commences which can be critical for a successful outcome. Pain management programmes often incorporate self-management techniques, however, these techniques may lack efficacy unless patients possess beliefs about their ability to self-manage (Hobro, Weinman and Hankins 2004). Hobro and colleagues (2004) suggest the importance of developing a cognitive behavioural theory

programme based on physical illness populations, taking into consideration illness perceptions, rather than an uptake of programmes based on mental health populations.

Maladaptive appraisal of condition thereby responding with passive and negative coping strategies are understood to exacerbate and maintain pain, reducing successful pain management and treatment (Turk and Melzack 2001). This study hypothesises that psychological factors may have an influence on the reductions in analgesia between 12 to 24 months following implantation of SCS. The following chapter reviews previous literature investigating the impact of psychological factors upon SCS treatment efficacy.

## **Chapter 4**

### **Systematic literature review**



This chapter presents a systematic review of studies investigating the effect of psychological variables upon the efficacy of SCS.

#### **4.1 Introduction**

All chronic pain is profoundly influenced by psychological processing and response (Turk and Melzack 2001). Pain research states that pain appears to be a catalyst for negative states; pain can lead to helplessness, isolation, sleep disturbance, frustration and depression (Tan et al. 2008). Pain also initiates a sense of loss for the individual where daily life can be impacted upon and activities that were once completed with ease can no longer be done (Tan et al. 2008). The psychological aspects of pain result in pain being subjective and unique to each individual, making it very difficult to measure. Pain from an operable disease may be experienced very differently from pain that has no visible or identifiable reason.

There is substantial literature indicating a strong association between chronic pain and high levels of anxiety, distress and depression (Rudy, Kerns and Turk 1988; Doleys 2003). Chronic pain is a highly prevalent condition, with a huge impact on an individual's health, healthcare services, and society. It is also a condition for which successful treatment outcomes are difficult to achieve (Smith, Macfarlane and Torrance 2007).

Shealy, Mortimer, and Reswick first described the use of SCS for pain control in 1967 after the introduction of the GCT in 1965 by Melzack and Wall. SCS is an invasive treatment involving electrodes implanted in the spinal canal to produce neurostimulation and paraesthesia in the area of pain. The mechanisms of SCS remain uncertain, but electrical activation of the large diameter afferents of the dorsal columns or dorsal roots appears to inhibit nociceptive small diameter afferent transmission providing pain relief (Meyerson and Linderorth 2006; Raphael et al. 2009). SCS has been demonstrated to relieve chronic neuropathic pain in randomised controlled trials (Kemler et al. 2000; Kumar et al. 2005; North et al. 2005) and systematic reviews (Mailis-Gagnon et al. 2004; Taylor et al. 2009).

Despite improvements in SCS therapy and increasing knowledge of the most appropriate medical diagnoses for treatment, 25-50% of patients report loss of analgesia within 12-24

months following implantation (Cameron 2004; Kupers et al. 1994). There has been speculation as to why loss of analgesia occurs with research focusing on operational factors (e.g. lead positioning, electrical parameters, and complications). However, as chronic pain is multidimensional, psychological characteristics may play a role in the efficacy of the treatment.

The European Federation of the International Association for the Study of Pain offers guidelines for the neuromodulation of pain practice (Gybels et al. 1998). The guidelines stipulate that a thorough psychological evaluation should take place during screening, however no details on specific tests are provided within this guidance. In a survey of pain management centres in the UK (response rate of 64%), 61% disclosed that a psychological assessment took place for the selection of patients for SCS, although the methods for assessment were not reported (Ackroyd et al. 2005). Psychological contra-indications to SCS implantation that were reported by these centres included drug or alcohol abuse, psychosis, insufficient understanding, lack of social support, poor compliance and severe depression (Ackroyd et al. 2005).

It is the role of the specialist to piece together the patient's 'story'; a multidisciplinary approach is being widely accepted nationwide as important for the selection of candidates for SCS. Doleys (2003) suggested that psychologic status should be a three legged stool comprising pain pattern, pain pathology and psychologic status. Patients are often selected for SCS when more conventional therapies have failed, or the side-effects become intolerable for the patient. This may have implications for the patient's psychological stability at the time of their assessment for SCS. The desperation for a "cure" and the patient's "willingness to try anything" could have implications for success with SCS, with optimistic patient expectations potentially providing a short-term positive outcome only.

There is to date no "gold standard" psychological test(s) or method of assessment to infer suitability for SCS therapy. A review of the literature investigating the influence of psychological factors on treatment outcome was undertaken to summarise current knowledge concerning the role of psychological factors upon the efficacy of SCS, identifying psychological characteristics that may help to predict outcome. By highlighting what is already known this research can expand current knowledge.

## **4.2 Methods**

### *4.2.1 Search strategy*

A search was carried out to review the current literature on SCS and psychological variables. A Boolean search was conducted in the Cochrane and EBSCOhost (CINAHL Plus with Full Text, MEDLINE, PsycINFO and PsycARTICLES) databases, with no restriction on language.

Psychological studies within SCS have been undertaken in recent years, subsequently rendering an electronic search as an appropriate approach. MESH/Thesaurus terms were employed according to the search engine. In addition the following keyword terms were used and combined for a more accurate search: patient recruitment; selection criteria; outcome; efficacy; psychological characteristics; spinal cord stimulation; SCS; and electric stimulation. All abstracts were screened and full papers of potentially relevant articles were obtained for further review. Additionally, grey literature and reference lists from all relevant articles were searched. Selection criteria (see below) were applied to all the abstracts and full papers were obtained for further review. The year of publication was restricted to between 1967 and July 2009. This period was covered for two reasons. Firstly 1967 was when SCS was first introduced. Secondly, the period up until the date of the search was selected to capture all empirical research to date. Following on from the literature search up until July 2009, a more recent search was run (December 2012) to check for any recent publications; the search did not result in any further articles.

### *4.2.2 Criteria check*

The resulting abstracts were screened by two independent reviewers (ES & RD) and coded red (unsuitable), amber (undecided, retrieve full copy) and green (suitable, retrieve full copy). Full copies of the identified articles were obtained for consideration and confirmation of inclusion. Disagreement was resolved through discussion, assisted by the use of the inclusion and exclusion criteria.

### *4.2.3 Inclusion criteria*

Papers were included in the review if the following conditions were met: (i) a method is used to ascertain the influence of psychological variables upon the efficacy of SCS, including one or more of the following: administration of psychological tests, interviews, algorithms,

questionnaires; (ii) patients are included in studies to gain insight into the psychological characteristics involved and to evaluate the efficacy of SCS; and (iii) the participant sample comprises chronic pain patients.

#### *4.2.4 Exclusion criteria*

Papers were excluded if: (i) they were reviews or guidance papers that did not present original work; (ii) they did not consist of chronic pain patients; (iii) they were single case studies; or (iv) they were studies that did not investigate psychological variables.

#### *4.2.5 Quality check*

Selected articles were checked for quality using the Public Health Critical Appraisal Skills Programme for Cohort Studies (Public Health Resource Unit 2009). The quality check covered four main issues: the validity of results; the results themselves; whether the results can be applied to local population; and whether the results fit with other similar research. Recruitment, bias, confounding factors and follow up periods are also subject to critique.

#### *4.2.6 Analysis*

Included papers were reviewed to enable reporting upon several factors: study design, population studied, participants (age, duration of pain, pain diagnosis/area), length of study, psychological variables studied, method of assessment, follow up time and outcome (pain score, questionnaire score, and functional improvement).

### **4.3 Results**

The search resulted in 95 articles, whose abstracts were reviewed. Grey literature did not reveal any additional suitable articles. Through screening of the abstracts, 17 were identified as possibly relevant and full articles were retrieved. After review, eight articles were considered unsuitable due to not assessing psychological characteristics (de Keift and La Porte 2008; Deer and Masone 2008; Kumar and Wilson 2007; Mailis-Gagnon et al. 2004; Olson et al. 1998; Van Buyten et al. 2001); not chronic pain (Levita, Sorkin and Waltz 1986; Sumner 2007) and nine articles were considered suitable for review (Table 3.1).

Date of publication of the studies ranged from 1982 to 2008. One of the studies was conducted in Belgium (Kupers et al. 1994) and the remainder were conducted in the USA. The age of participants ranged from 20 to 90; three studies did not report the ages of participants (Brandwin and Kewman 1982; Jamison et al. 2008; Kupers et al. 1994). There was a slight preponderance of women, except one study which had equal numbers of male and female participants (Burchiel et al. 1996). Two studies failed to report gender (Brandwin and Kewman 1982; Jamison et al. 2008). Numbers of participants ranged from 11-100.

Pain management clinics were the main source for patient recruitment except in one study where participants were recruited through a neurosurgical clinic (North et al. 1996). Pain areas were mainly low back and leg due to failed back surgery syndrome. The majority of patients had non-malignant pain conditions, although two studies included cancer pain patients (Brandwin and Kewman 1982; Kupers et al. 1994).

In the identified studies several methods were used in an attempt to predict outcome of SCS treatment via psychological factors. There was also considerable variability in the duration of study period for those using a longitudinal design. These findings resulted in the inability to conduct a meta-analysis.

Psychological factors and outcomes were assessed prior to trial in prospective studies attempting to predict SCS trial outcome in three studies (trial ranging from three to five days) (Olson et al. 1998; Ruchinskias and O'Grady 2000; Schocket et al. 2008). One of the studies was cross-sectional but did not specify when the assessment was carried out during treatment (Jamison et al. 2008). Five of the studies were longitudinal (Brandwin and Kewman 1982; Burchiel et al. 1995; Burchiel et al. 1996; Kupers et al. 1994; North et al. 1996) all of which examined SCS efficacy and psychological characteristics prior to trial and at follow up (three months (Burchiel et al. 1995), six months (Kupers et al. 1994), six to 20 months (Brandwin and Kewman 1982), one year (Burchiel et al. 1996), average of three and a half years (North et al. 1996)).

Different criteria were used across studies to try to determine the efficacy of SCS. In four studies the efficacy of SCS was determined by the patients' self report of at least 50% pain relief after trial (Burchiel et al. 1995; Burchiel et al. 1996; North et al. 1996; Olson et al.

1998). Successful trial was considered after > 30-40% pain relief reported by one study (Schocket et al. 2008). Success was judged as the patient reporting the SCS to be at least slightly helpful (in a verbal scale with the following items: unsuccessful, slightly helpful, moderately helpful, and successful) and a resumption of around 75% of activities previous to experiencing pain in one of the studies (Brandwin and Kewman 1982). Three studies did not specify how efficacy was determined (Jamison et al. 2008; Kupers et al. 1994; Schocket et al. 1967).

Diverse questionnaires were used to identify possible psychological characteristics influencing the outcome of SCS. The majority of studies used the MMPI (Brandwin and Kewman 1982; Olson et al. 1998) or MMPI-2 (Burchiel et al. 1995; Olson et al. 1998; Schocket et al. 2008; Ruchinskias and O'Grady 2000) to measure psychological characteristics alongside other psychological questionnaire measures (Table 3.2). One of the studies used the Hospital Anxiety and Depression Scale (Jamison et al. 2008). One study conducted a semi-structured psychological interview alongside questionnaires, reporting consistency between the two methods for all but one patient (Burchiel et al. 1995). Only one of the studies used screening interviews conducted by a psychiatrist instead of psychological questionnaires (Kupers et al. 1994).

The role of demographic variables was considered in relation to outcome. Regarding workers' compensation, four studies did not explicitly report on this (Brandwin and Kewman 1982; Burchiel et al. 1995; Olson et al. 1998; Schocket et al. 2008). One study reported that the sample comprised 41% of patients receiving workers' compensation (Burchiel et al. 1996). Similarly, another study reported 50% of the study group received workers' compensation, with no significant differences in outcome for SCS between the two groups (Prager and Jacobs 2001). Patients were excluded by one study if they were receiving compensation (Kupers et al. 1994); two studies reported that those receiving workers' compensation were at risk of an unsuccessful result for SCS treatment (Jamison et al. 2008; Shocket et al. 2008). Workers' compensation was determined as a risk to successful SCS therapy either through an algorithm (Schocket et al. 2008) or through less successful trials (Jamison et al. 2008).

Table 4.1 Articles selected for review

Author & Year	Design / Study Period	Assessment preceding implant	Number of assessments reported	Pain duration	Measure of efficacy of SCS
Brandwin and Kewman (1982)	Prospective 6-20 month follow up	Yes	1 (preceding trial) 1 (Follow up)	Not specified	Verbal scale, Resumption of > 75% activity
Burchiel et al. (1996)	Prospective 1 year follow up	Yes	1 (preceding trial) 1(Follow up)	73 ± 83 months (range 4-360)	≥ 50% pain relief
Burchiel et al. (1995)	Prospective 3 month follow up	Yes	1 (preceding trial) 1 (Follow up)	Not specified	≥ 50% pain relief
Jamison et al. (2008)	Cross-sectional	No	1 ( follow up)	>6 months	Not specified
Kupers et al. (1994)	Prospective 6 months follow up	Yes	1 (preceding trial) 1 (Follow up)	Not specified	Not specified
North et al. (1996)	Prospective Mean 3.5 years follow up	Yes	1 (preceding trial) 1 (Follow up)	Not specified	≥ 50% pain relief
Olson et al. (1998)	Cross-sectional	Yes	1 (preceding trial)	Not specified	≥ 50% pain relief
Ruchinskas and O'Grady (2000)	Cross-sectional	Yes	1 (preceding trial)	>3 years (median 6 years)	>30-40% pain relief
Schocket et al. (2008)	Cross-sectional	Yes	1 (preceding trial)	Not specified	Not specified

Table 4.1 (continued) Articles selected for review

Author & Year	Age / Gender	Sample size	Receiving workers compensation	Population
Brandwin and Kewman (1982)	Not specified	11	Not specified	USA Hospital
Burchiel et al. (1996)	33 Male Mean age=51 yrs, range 22-79	70	41% of sample	USA Pain Clinic
Burchiel et al. (1995)	20 Male Mean age=52 yrs	40	Not specified	USA Pain Clinic
Jamison et al. (2008)	Not specified	72	Concluded as a risk group, % not specified.	USA Pain Clinic
Kupers et al. (1994)	48 Male	100	Excluded from study	Belgium Pain Clinic
North et al. (1996)	26 Male Age range 20-65	58	Not specified	USA Recruited by neurosurgeon
Olson et al. (1998)	44% Male Mean age=49 yrs	43	50% of sample	USA Pain Clinic
Ruchinskas and O'Grady (2000)	20 Male Mean age=46 yrs	47	Not specified	USA Pain Clinic
Schocket et al. (2008)	25 Male Mean age= 56 yrs, range 30-90	60	Concluded as a risk group, % not specified	USA Pain Clinic



The main indications for SCS included neuropathic back and leg pain (Burchiel et al. 1995; Burchiel et al. 1996; Jamison et al. 2008; North et al. 1996; Olson et al. 1998; Ruchinskas and O'Grady 2000). Some studies included other pain areas and diagnoses such as spinal cord injury (Brandwin and Kewman 1982; Olson et al. 1998), reflex sympathetic dystrophy and chest pain (Schocket et al. 2008), failed back surgery syndrome, post herpetic neuralgia, brachial plexus and metastatic cancer (Brandwin and Kewman 1982). Duration of pain was reported by three studies as an average duration of  $73 \pm 83$  months (range 4-360) (Burchiel et al. 1996) and pain for more than three years (median six years) (Ruchinskas and O'Grady 2000). One study reported that duration of pain exceeded six months (Jamison et al. 2008). Pain duration was not reported by six studies (Brandwin and Kewman 1982; Burchiel et al. 1995; Kupers et al. 1994; North et al. 1996; Olson et al. 1998; Schocket et al. 2008).

In six studies (Brandwin and Kewman 1982; Burchiel et al. 1995; Kupers et al. 1994; Olson et al. 1998; Ruchinskas, 2000; Schocket et al. 2008), depression was considered as impacting negatively upon the efficacy of SCS. This was identified using the MMPI and MMPI-2. One study did not include patients with depression due to previous research findings of depression as a contraindication (Olson et al. 1998). Two studies noted significant improvement in depression with SCS therapy (Burchiel et al. 1996; Jamison et al. 2008).

Mania (two studies) measured by the MMPI (Burchiel et al. 1995) and MMPI-2 (Olson et al. 1998); hysteria (four studies) measured by the MMPI (Burchiel et al. 1995) and the MMPI-2 (Schocket et al. 2008; Olson et al. 1998; Ruchinskas et al. 2000) anxiety (two studies) measured by the DABS (North et al. 1996) and MMPI (Schocket et al. 2008); hypochondriasis (four studies) measured by the MMPI (Burchiel et al. 1995; Olson et al. 1998), MMPI-2 (Schocket et al. 2008) and psychiatrist interview (Kupers et al. 1994) were the other most common psychological characteristics identified as having an impact on the efficacy of SCS. Psychological factors were identified according to the criteria defined by the questionnaires. The study employing a psychiatrist interview (Kupers et al. 1994) did not specify the criteria for psychological factors other than the personal perception of psychological characteristics.

#### *4.3.1 Psychological factors highlighted in the review*

##### Depression

Depression was emphasised within the review as impacting upon the efficacy of SCS. Depression is characterised as a lack of hope for the future and poor morale coupled with an underlying general dissatisfaction with one's life (Zigmond and Snaith 1983).

##### Hysteria

This psychological factor highlighted by the MMPI suggests that individuals who score highly have hysterical reactions to stressful situations. Levels of hysteria are characterised by losing self control in difficult situations (Dahlstrom and Dahlstrom 1980).

##### Anxiety

This psychological factor can be understood as a mood state where an individual is prepared for negative forthcoming events which are perceived as out of control. Anxiety may be viewed characteristically as when an individual appears restless, apprehensive and nervous.

##### Hypochondriasis

This characterises patients who manifest symptoms and fixate on symptoms which they do not have. Hypochondriasis is demonstrated by a variety of complaints regarding their body.

##### Defensiveness

This factor is characteristic of denial and evasiveness. Individuals scoring high on defensiveness will be reluctant to accepted diagnoses.

##### Catastrophising

Catastrophising is characterised by negative self statements, ideation and continued worry about when pain will end (Rosentiel and Keefe 1983).

##### Paranoia

Paranoia is understood as a mood where individuals feel excessive sensitivity, show rigid thinking and opinions, experience feelings of persecution and suspiciousness.

### Mania

Mania or hypomania were psychological factors highlighted by the review. Measured by the MMPI, mania is characterised by an abnormally elevated often irritable mood. Persons experiencing hypomania will often have less need for sleep, appear energetic and have a drive to succeed (Dahlstrom and Dahlstrom 1980).

### Joy

The joy scale measured by the DABS questionnaire, measures contentment, affection and vigour. This is one of the positive psychological factors identified in the review.

### Belief pain is out of control

This psychological factor demonstrates a score highlighting the amount to which an individual feels that the pain they experience is beyond their capabilities of stopping or reducing it.

### Psychopathic deviate

On this scale a higher score represents rebellion, whereas lower scores demonstrate an acceptance of authority. High scores would demonstrate a level of social maladjustment.

Table 4.2 Psychological factors highlighted in the review

<b>Psychological Factor</b>	<b>Author(s)</b>	<b>Method</b>	<b>Result</b>
<b>Depression</b>	Brandwin and Kewman (1982)	MMPI	Depression was associated with a poorer outcome for SCS.
	Burchiel et al. (1996)	BDI	Depression improved after 1 year of SCS.
	Burchiel et al. (1995)	MMPI-2 / Interview	Increased depression was associated with reduced pain relief at 3months.
	Jamison et al. (2008)	HAD	Patients with implantable devices showed lower levels of depression.
	Kupers et al. (1994)	Interview	Major depression included in reservation group and those in the reservation group less successful.
	North et al. (1996)	MMPI	Elevated levels of Depression resulted in exclusion from SCS due to previous reported findings.
	Olson et al. (1998)	MMPI-2	Patients with >50% pain relief during trial period had lower scores for depression.
	Ruchinskas and O'Grady (2000)	MMPI-2	Lower levels of depression predict a better long term outcome.
	Schocket et al. (2008)	HPS / BDI	Lower levels of depression predicted to have a better outcome.
	<b>Hysteria</b>	Brandwin and Kewman 1982)	MMPI
Olson et al. (1998)		MMPI-2	Increased scores during trial were found to be related to improved pain relief.
<b>Anxiety</b>	Ruchinskas and O'Grady (2000)	MMPI-2	Successful pain relief during trial period associated with lower scores.
	Schocket et al. (2008)	MMPI-2	Lower levels predicted to have better outcome.
	North et al. (1996)	DABS	Lower anxiety scores associated with successful trials.
	Schocket et al. (2008)	MMPI-2	Lower levels predicted to have better outcome.

Table 4.2 (continued) Psychological factors highlighted in the review

<b>Psychological Factor</b>	<b>Author(s)</b>	<b>Method</b>	<b>Result</b>
<b>Hypochondriasis</b>	Brandwin and Kewman (1982) Kupers et al. (1994) North et al. (1996)	MMPI Interview MMPI	Lower score associated with failure. Considered as a contraindication and those in the reservation group were less successful. Elevation noted for those who went from trial to permanent implant.
<b>Defensiveness</b>	Schocket et al. (2008) Ruchinskas and O'Grady (2000) Schocket et al. (2008)	MMPI-2 MMPI-2 MMPI-2	Lower levels predicted to have better outcome. Those who were not implanted significantly higher scores. Those with higher scores predicted to have better outcome.
<b>Catastrophising</b>	Schocket et al. (2008)	CSQ	Lower levels predicted to have better outcome.
<b>Paranoia</b>	Schocket et al. (2008)	MMPI-2	Lower levels predicted to have better outcome.
<b>Mania</b>	Brandwin and Kewman (1982)	MMPI	High scores were significantly related to positive treatment experience
<b>Joy</b>	Olson et al. (1998) North et al. (1996)	MMPI-2 DABS	Higher scores were related to over 50% pain relief. Favourable long term outcome with an elevated score.
<b>Belief pain is out of control</b>	Ruchinskas and O'Grady (2000)	MHLC	Higher score was related to patients choosing full implantation.
<b>Psychopathic deviate</b>	Brandwin and Kewman (1982) Schocket et al. (2008)	MMPI MMPI-2	Higher in the Chronic Pain group compared with motor disorder group Lower levels predicted to have better outcome.

**Key:** BDI - Beck Depression Inventory; DABS - Degoratis Affects Balance Scale; HAD - Hospital and Anxiety Depression scale; HPS - Hamilton Psychiatric Rating Scale for depression; MHLC - Multidimensional Health Locus of Control Scale; MMPI - Minnesota Multiphasic Personality Inventory; PCSQ - Pain Coping Strategies questionnaire.

#### **4.4 Discussion**

One of the limitations of this review is the evident variation between studies. This can be seen in the multiple methodologies employed across studies, the different time points at which data was collected and also the inconsistent manner in which psychological aspects, particularly depression were classified. These factors precluded meta-analysis. Depression was measured using a variety of questionnaires (MMPI, BDI, HAD, HPS). Criteria for depression differed depending on the questionnaire used, however, these are validated questionnaires for the evaluation of depression (Castro et al. 2006; Moran and Mohr 2005; Van Buyten et al. 2001).

The MMPI and MMPI-2 were the most frequent questionnaires used. Depression is characterised within the MMPI by poor morale, lack of hope in the future, and a general dissatisfaction with one's own life situation (Dahlstrom and Dahlstrom 1980). Mania, hysteria and hypochondriasis were measured using the MMPI (Brandwin and Kewman 1982; Van Buyten et al. 2001) and MMPI-2 (Schocket et al. 2008; Olson et al. 1998; Ruchinskas et al. 2000). These questionnaires characterise mania by an elevated mood, accelerated speech and motor activity, irritability, flight of ideas, and brief periods of depression (Dahlstrom and Dahlstrom 1980). Hysteria is characterised by a particularly heightened distress to stressful situations (Dahlstrom and Dahlstrom 1980). Hypochondriasis is characterised by neurotic concern over body functions (Dahlstrom and Dahlstrom 1980). By recognising the characterisation for the psychological traits identified by the MMPI, these definitions can be considered during the selection of candidates for SCS.

The MMPI-2 includes virtually identical clinical scales as described for the MMPI whilst also featuring seven validity scales. Fishbain et al. (2006) reviewed the literature on the measurement of personality and chronic pain. One of the considerations was whether the MMPI and MMPI-2 evaluate state or trait personality. They concluded that caution should be taken when interpreting profiles as being indicative of pre-pain personality. Personality tests may not measure what they claim to measure; the results may indicate the current state of an individual's psychological state due to the onset of pain and not their personality traits, indicating that certain psychological characteristics may improve as a result of treatment and not hinder the efficacy of interventions (Fishbain et al. 2006). Research has demonstrated that changes in psychological functioning in relation to pain are post-morbid to the onset of

the pain (Rudy, Kerns and Turk 1988). This consideration would explain why in some of the studies mentioned in this review depression improved after successful SCS (Burchiel et al. 1996).

Findings obtained during the SCS trial period may contrast with those obtained at long-term follow up (Burchiel et al. 1996; Jamison et al. 2008; Olson et al. 1998). The consideration of the placebo effect should be acknowledged. Only after a substantial length of time with reduced pain relief resulting from SCS can the placebo effect be ruled out. Psychological profiles may produce false positives at initial assessment due to the effect pain is having upon mood. Characteristics may change or improve, possibly as a result of improvement in pain following SCS (Burchiel et al. 1996; Jamison et al. 2008). It may be that testing carried out over longer periods would give a better predictor for outcome in the long-term.

#### *4.4.1 Depression*

Depression was found to have a negative impact upon the efficacy of SCS, as identified by six studies. The literature indicated that patients with lower levels of depression were considered better candidates for SCS (Brandwin and Kewman 1982; Burchiel et al. 1995; Kupers et al. 1994; Schocket et al. 2008; Olson et al. 1998; Ruchinskas et al. 2000) Three of the studies had long-term follow up (Brandwin and Kewman 1982; Burchiel et al. 1995; Kupers et al. 1994) and the remaining three (Schocket et al. 2008; Olson et al. 1998; Ruchinskas et al. 2000) studied the trial period only. One study did not implant SCS for patients who had elevated MMPI depression scores, due to outcome data from a previous study which indicated a reduced efficacy of SCS among these patients (Olson et al. 1998).

None of the six studies clarified whether the depression was pre or post morbid to the onset of chronic pain. Morbidity in relation to depression may be an important factor to consider, given that in some cases, depression can improve with SCS or other suitable treatment and may not be a complete contra-indication (Burchiel et al. 1996; Jamison et al. 2008; Olson et al. 1998).

Hypotheses as to why improvement may occur include satisfaction that all other methods have been tried and tested or that SCS provides the attention and validation desired (Jamison et al. 2008). SCS patients are regularly monitored and invited to attend clinics for

follow up and regular care and this may provide the ongoing support and legitimisation they have longed for. These findings illustrate that depression, although functioning as a moderator of efficacy, may improve with situational changes (e.g. receiving SCS) or even additional psychosocial intervention (Olson et al. 1998). The improvement in depression with SCS may be due to the pain relief obtained. However, antidepressant treatments and SCS share a noradrenergic and serotonergic mechanism and a physiological effect can be hypothesised. Deep brain stimulation is used as a treatment for depression and it may be that the neurostimulatory effects of SCS have an overlapping effect.

#### *4.4.2 Mania*

Two studies indicated mania as impacting upon the efficacy of SCS (Brandwin and Kewman 1982; Olson et al. 1998). One study only investigated the trial period (Olson et al. 1998) and the other consisted of only 11 chronic pain patients (Brandwin and Kewman 1982). Although both studies reported mania as a positive indicator, further research is needed.

#### *4.4.3 Hysteria*

In all cases the MMPI was employed to measure hysteria, with outcome data yielding conflicting results across studies. Results identifying hysteria as a possible negative indicator for SCS (Schocket et al. 2008; Ruchinskas et al. 1998) were drawn from small samples during SCS trial period, based on questionnaire data only. No long-term follow up was available for comparison. Ruchinskas and O'Grady (2000) conducted *ad hoc* screening for psychopathology, potentially creating a bias in patient selection (Schocket et al. 2008).

Hysteria was found by two studies to be associated with increased pain relief following SCS treatment (Brandwin and Kewman 1982; Olson et al. 1998). However, these studies are limited by the small sample size used in one of the studies (11 chronic pain patients) (Brandwin and Kewman 1982) and the limited use of trial period data in the other (Olson et al. 1998). Further long-term research for hysteria is recommended.

#### *4.4.4 Hypochondriasis*

Disparity was also found for hypochondriasis. Two studies reported that higher scores were associated with positive outcome (Brandwin and Kewman 1982; Olson et al. 1998). Whilst Brandwin and Kewman (1982) studied a small number of chronic pain patients (n = 11) who



were followed up at between six and 20 months, North et al. (1996) recruited 58 patients with a long-term follow up of 3.5 years. Conversely, two other studies revealed hypochondriasis as a negative indicator (Kupers et al. 1994; Schocket et al. 2008). Schocket et al. (2008) also had a sizeable sample (n = 60) and considered hypochondriasis as a negative factor, however this was only studied during the trial period. Given the disparate outcomes across studies, no conclusion can be confidently drawn.

#### *4.4.5 Anxiety*

Elevated levels of anxiety were noticed in two studies to reduce the efficacy of SCS (North et al. 1996; Schocket et al. 2008). Measured with the DABS and MMPI-2 both studies concluded that anxiety had a negative effect upon treatment outcome. One study took place during the trial period and the other study at a mean of 3.5 years follow up. Although findings are consistent for the two studies, further studies are needed to determine the interaction between anxiety and SCS efficacy.

#### *4.4.6 Interviews*

Kupers et al. (1994) was the only reported study to use interview alone (n = 100), rather than psychometric administration. Their study had a 64% success rate for those pre-selected by an interviewing psychiatrist who judged SCS candidates as suitable. These patients were subsequently given a full SCS implantation. Interview techniques need to take into account the practice effect since the interviewer will become more competent at identifying characteristics after seeing a number of patients. Burchiel et al. (1995) demonstrated consistency between interview and questionnaires for all but one patient.

### **4.5 Conclusion**

Depression was identified as a characteristic that reduces the efficacy of SCS; however, depression may improve as a result of successful pain relief with SCS (Burchiel et al. 1996; Jamison et al. 2008) and may not be indicative of pre-pain personality (Fishbain et al. 2006). This indicates that depression may not be an exclusion criterion but alternatively a psychological characteristic that could be considered as a target of SCS treatment alongside pain relief. In-depth methods other than questionnaire assessment alone should be employed to investigate this area in order to limit false positives. Qualitative methods also

allow exploration of any other important factors and patient perspectives of the treatment and pain experience that the questionnaires do not highlight. Studies considering mania, hysteria and hypochondriasis have yielded discrepant results and are currently inconclusive as predictors for SCS outcome. This indicates that further studies are warranted, to investigate whether any psychological factors are significant in the likelihood of a positive outcome for SCS.

This review allowed investigation of the existence of evidence that psychological factors impact on the efficacy of SCS and that longitudinal prospective studies with more rigorous methods of assessment are warranted. This review provides reasoning for the methods used in this thesis, which are discussed in the following chapter.

## **Chapter 5**

### **Research design**

This chapter explains the rationale and provides justifications for the methods employed within this thesis, including ethical processes and recruitment. The research aimed to determine psychological factors affecting the efficacy of SCS. Two separate studies were carried out to explore potentially impacting psychological factors. Firstly, a longitudinal prospective study was conducted. Patients were recruited at baseline and followed for one year of treatment, assessing psychological factors and pain score at baseline, six and 12 months. Secondly, semi-structured interviews were conducted with patients upon reaching one year of SCS treatment. The qualitative study allows for consideration of any factors that the questionnaires may fail to explore.

This chapter begins with a small study conducted using patient case notes at the beginning of the research project. The notes were reviewed following a change in the screening process for suitability for SCS, to investigate if any alteration in pain relief reporting could be noted following these changes. This leads into the paradigm perspectives which are discussed and followed by the rationale for the selected quantitative and qualitative methods. The processes taken for both the qualitative and the quantitative study are explained, including rationalisations for questionnaires and methods selected. This chapter also discusses the ethical considerations and ends with a description of participants' recruitment.

### **5.1 Preliminary study**

Preliminary work was undertaken which consisted in reviewing the case notes with pain reports for SCS patients. The primary goal of this work was to examine the impact that the introduction of changes to the psychological assessment for SCS suitability had upon pain relief. This preliminary study was accepted and published as an abstract in the journal *Pain Practice*. Sparkes, L., Duarte, R.V., Raphael, J.H., LeMarchand, K., Ashford, R.L. (2009). Preliminary investigation of pain relief after introduction of psychological assessment in selecting for treatment with spinal cord stimulation. *Pain Practice*. 9 (Supplement 1), pp. 90.

The centre where the current research took place underwent a change in patients' psychological assessment in 2004. Prior to this date, patients considered suitable for SCS by the physician and having been seen by a physiotherapist were referred to a clinical

psychologist for assessment. This multidisciplinary team then met together to discuss the suitability of patients. The team often included physiotherapists and psychologists not involved in that particular case. Since 2004, all new patients referred to the pain centre would meet physicians, psychologists and physiotherapists during their first visit regardless of whether or not SCS was considered at this stage. Patients with neuropathic and/or ischaemic limb pain that had not responded to more conservative therapies including surgery, pharmacological, physical and/or psychological interventions are considered for SCS. The change in assessment of suitability led to patients being excluded on the grounds of unrealistic treatment expectations, lack of comprehension or unrealistic beliefs surrounding their pain. Those patients perceived as unsuitable or with an unsuccessful SCS trial continued to be treated by the pain clinic via other methods.

The psychologist has an important role within the multidisciplinary assessment for SCS treatment. In the short time allocated with the patient, a psychological evaluation of suitability for SCS must be conducted. Considering the emotions the patient may display due to the urgency to be treated the circumstances can be pressurising. Often patients with chronic pain are referred to a pain management programme to increase self-efficacy and adaptation to living with pain. Being supported psychologically and behaviourally is important for optimum treatment outcomes. As previously discussed the interpretations an individual has regarding their pain and treatment are understood to interact with treatment outcome (Turk et al. 2010).

This preliminary study aimed to explore whether the change in screening approach after 2004 resulted in improvements for the selection of patients.

#### *5.1.1 Method for preliminary study*

A longitudinal retrospective study was carried out including a total of 40 consecutive SCS patient case notes that included pain reports at frequent intervals. The aim was to provide an insight into the impact the changes to the introduction of psychological assessment for SCS suitability had upon pain relief. To investigate potential differences, patients implanted prior to 2004 were compared with patients implanted after 2004.

The time period between 24 and 48 months following SCS implantation was chosen, as this was the longest term outcome recorded for the majority of patients. Patients' pain relief was recorded in the case notes as good or bad by the consultant or nurse. The consultant indicated that good was recognised as more than 50% pain reduction and bad less than 50% pain reduction.

A mean age of  $50 \pm 12$  years (range 21-71) and a mean pain relief report taken at  $37 \pm 11$  months (range 24-48) was recorded for the group implanted prior to 2004. The group implanted after 2004 had an average age of  $49 \pm 11$  years (range 32-66) and a mean pain relief report taken at  $34 \pm 10$  months (range 24-48). Both groups presented a slight male preponderance.

### *5.1.2 Results*

Sixteen out of 21 (76%) patients implanted with SCS prior to 2004 reported  $\geq 50\%$  pain relief compared with eighteen of the nineteen patients (95%) implanted after 2004 (figure 5.1).

### *5.1.3 Discussion of preliminary findings*

The introduction of this change in screening of suitability for SCS centred on psychological assessment produced some improvements in selection. These results demonstrate the possibility of psychological aspects affecting efficacy and not only technical factors. This study was reliant on patients' case notes that had their pain scores recorded by the consultant and are therefore subject to potential bias. Currently, there is no recognised psychological assessment for SCS patients' selection. Further research is needed to be able to recognise typical psychological factors affecting SCS efficacy. A longitudinal, prospective investigation of psychological factors during screening and its relation to outcome was deemed necessary. Such a study would enable further insight into the range of psychological factors affecting SCS efficacy. Potentially, it may also identify specific factors, which may need close attention during the preparation and selection for SCS treatment.

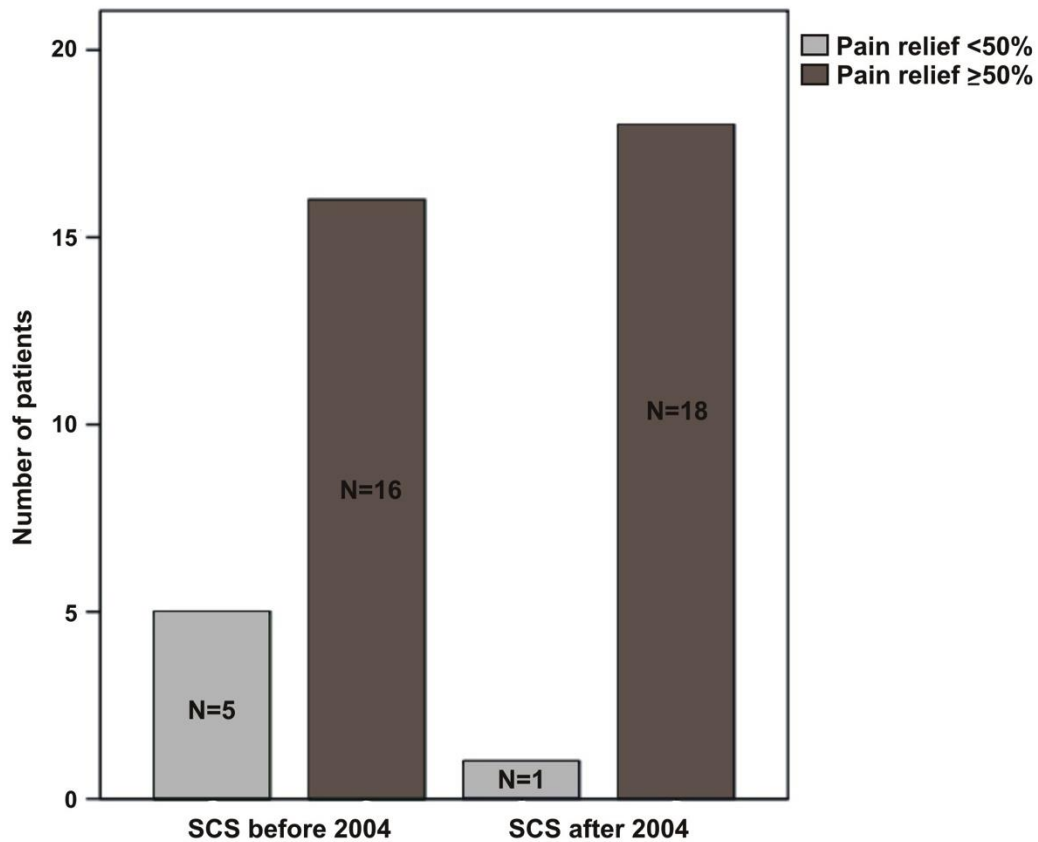


Figure 5.1 Changes in pain relief after psychological assessment

## 5.2 Methodology

### 5.2.1 Paradigm perspectives

When considering the methodology to use in any particular piece of research, the basic set of beliefs that govern and influence the research need attention. Traditionally, from a purist perception, quantitative and qualitative research can be seen as entirely separate methods from a positivist or constructivist perspective. Positivists keep their own values separate to the research and consequentially use deductive logic and quantitative methods to gain an objective view of reality. Constructivists understand meaning to be developed through multiple and subjective viewpoints, attempting to understand a phenomenon within its social context using qualitative methodologies (Rocco et al. 2003).

When researchers are more flexible about quantitative/qualitative ideologies they may employ mixed methodologies to investigate a particular phenomenon, seeing the integration

of qualitative and quantitative methods as advantageous. Mixed methods can be understood as using both numerical closed ended items and open ended items of a qualitative nature in the same investigation (Williams 2007). Two different perspectives are also recognised among those using a mixed methods approach, pragmatist and dialectical (Rocco et al. 2003). Dialectical researchers perceive mixed methodology as more ethical due to the integration of perspectives. The research is deemed as stronger and a more complete understanding is obtained through the different considerations of reality from the two approaches. Employing the combination of qualitative and quantitative methods allows for elements of intrinsic bias to be overcome (Denzin 1989). For example, when collecting data via questionnaire alone, the possibility of false positives, the influential nature of the questions asked and not asked, and the inability to follow up on respondent's answers needs consideration. The inability to explore participants' answers may lead to question the richness of the data (Bryman 2004). Using qualitative data collection such as semi-structured interviews, will allow in-depth analysis of the participants' experience. The use of semi-structured interview on its own may be considered limited for aspects such as small sample size and potential interviewer bias. A combination of methods reduces potential bias and criticisms of either method and allows for an improved understanding of a phenomenon (Patton 2002). A pragmatist employs a methodology on the basis of what is needed to successfully gain insight into an observable fact. Quantitative and qualitative methods should be valued as equally important, although a mixed methodology should be employed when the researcher feels that it could benefit a study (Rocco et al. 2003). Hammersley and Atkinson (1995, pp. 232) notably remarked, "one should not adopt a naively 'optimistic' view that the aggregation of data from different sources will unproblematically add up to a more complete picture". The current research employed a mixed methodology from a pragmatist perspective since the use of both quantitative and qualitative methods would benefit the study.

There are several features of a mixed methods approach that enhance the current study. Employing mixed methods in this research allowed for the consideration of multiple viewpoints, perspectives and positions (Johnson, Onwuegbuzie and Turner 2007). The quantitative data highlights specific characteristics associated with more or less than 30% reduction in pain while the qualitative element of this research aids to a conceptual understanding. The qualitative research enables some interpretation, clarification and



description of the SCS experience alongside the aspects derived from the quantitative data collection. Quantitative research, although rigorous and based on statistical analysis may be somewhat superficial, while qualitative research added a 'real life' perspective, generating a richer account of a phenomenon. Likewise, qualitative research alone may be critiqued for a lack of background understanding, while quantitative data collection may allow for the understanding of a group at a local/national level. The combination of methods seeks to expand the breadth and range of enquiry (Greene, Caracelli and Graham 1989). Qualitatively researching the phenomenon after quantitative data collection enables the researcher to probe the data set to determine its meaning.

For this particular research, collecting quantitative data initially also allowed for baseline information, ensuring that not all of the participants interviewed experienced the same outcome (level of pain reduction). This avoided only interviewing one particular group (e.g. participants experiencing successful pain reduction only).

#### *5.2.2 Rationale for mixed methods*

An open prospective cohort study was conducted in order to investigate the psychological factors that impact upon the efficacy of SCS. A mixed methods approach was employed through two separate studies. SCS patients were followed up from baseline to one year after SCS implantation using questionnaires at baseline, six months and one year. Additionally, a semi-structured interview was carried out at one year following SCS implantation.

Mingers (2001) reflected on the importance of doing what is necessary to research a particular phenomenon, and observed that the combination of qualitative and quantitative approaches can be compatible and complementary. Instead of a fight for the superiority of one method over another, matching the correct method to the purpose of the research seems imperative. A systematic review of the literature investigating the impact of psychological factors upon the efficacy of SCS confirmed the need for more in-depth methods alongside questionnaires to investigate the psychological factors affecting the efficacy of SCS (Sparkes et al. 2010). The complementary approach, using quantitative (questionnaire) and qualitative (semi-structured interview) allowed for increased validity and interpretability of the different facets of a phenomenon (Rocco et al. 2003). Where the quantitative measures will allow for an objective measure of reality, the qualitative element

will enable a better understanding of the complexity (Williams 2007). Using both quantitative and qualitative methods in a particular research problem to explore a phenomenon will provide richer data and generate new modes of thinking (Johnson et al. 2007).

This research uses a quantitative method to explore the variables impacting on the likelihood that an individual will experience a loss of previously successful pain relief, measured at six and 12 months. Thirty per cent pain reduction is the target of the treatment as it is considered a moderately meaningful reduction in pain (Dworkin et al. 2008). Therefore, this cut off point will be used to determine those patients who are successful at six and 12 months. This research additionally employs a qualitative approach by interviewing patients to capture their experience of treatment after the first year. The qualitative study aims to add a further perspective and highlight any interesting factors that the questionnaires may have failed to uncover. Due to SCS being a last resort treatment, the numbers available to recruit are relatively low and therefore the use of mixed methods allows enhancement of credibility. Increasing the breadth of enquiry to include both qualitative and quantitative exploration, will improve the range of knowledge about the phenomenon of why SCS patients experience a loss of previously successful pain reduction.

Greene, Caracelli and Graham (1989) distinguish between the types of mixed methodologies. Triangulation allows for the investigation of corroboration; complementarity allows for the elaboration of a research problem through the use of mixed methods; development where the researcher uses one set of results to inform the next part of the investigation; initiation sets out to discover any contradictions between the research findings; and finally expansion, the use of mixed methods expands the breadth and range of enquiry. The use of mixed methods in this research aims to allow an elaboration of the research problem and to expand the breadth and range of enquiry rather than test for corroboration as such.

### *5.2.3 Quantitative methods*

As previously mentioned quantitative research is independent of the researcher's views and theories (Rocco et al. 2003). The quantitative method objectively measures reality, building upon theory. The existence of a problem leads to a hypothesis, which is then explored using

numerical data and statistics. Quantitative data collection can be understood as descriptive, exploratory or causal comparative (Leedy and Ormrod 2001). Descriptive approaches examine situations as they stand, identifying attributes by observation or correlation between phenomena. Exploratory methods involve data collection via experimentation and investigation of the outcome of an intervention. A causal comparative approach, taken forth in this research, examines relationships and interactions between variables. Through quantitative analysis of data (collected via questionnaire), relationships between variables can be explored allowing further extrapolations between variables to be established (Leedy and Ormrod 2001). A prospective longitudinal design was carried out to explore how psychological characteristics may impact upon long-term efficacy of SCS treatment ( $\geq 30\%$ ).

#### 5.2.3.1 Questionnaires

Questionnaires involve a set list of questions, which generate quantitative data from participants. The questions can be closed or open ended. The latter allow qualitative explorations. The main purpose of the questionnaires used in this research was to assess specific psychological factors, behaviours and perceived health status. The questionnaires applied in this study have been previously validated, ensuring a corroborated assessment of the factors deemed important within this research. Questionnaires have limitations as any method of data collection. Although useful for measuring specific attitudes and behaviours, questionnaires may elicit reactive effects (e.g. social desirability). Although patients were assured of confidentiality, participants in a clinical setting may respond to the questionnaire in the way they perceive suitable. Demographic data was collected orally at assessment one week prior to surgery (pro forma in appendix 3). Patients were asked a series of demographic questions, including age, pain area, time in pain, diagnoses, current medication and previous pain treatments.

#### *Hospital Anxiety and Depression Scale (appendix 4)*

A review of the literature examining the psychological factors impacting upon SCS treatment outcome identified depression as a possible influential factor. Therefore, it was deemed important to assess depression in the current study. The Hospital Anxiety and Depression Scale (HAD) consists of eight items assessing anxiety and eight items evaluating depression. The patient selects one of four choices in response to each item related to anxiety or depression. The choices allow the patient to select how frequently they

experience that particular item (e.g. I feel tense and wound up: most of the time/ a lot of the time/ from time to time/ not at all). Based on the participant's response, each statement is scored from zero to three, and a score is generated for both anxiety and depression. The questionnaire takes approximately three to five minutes to complete. A systematic literature review revealed that depression had an impact upon the efficacy of SCS treatment, but effective treatment could also improve depression (Sparkes et al. 2010). The depression items in the HAD questionnaire focus on the anhedonic state, therefore eliminating physical aspects and avoiding measurement of depression affected by the physical condition. Zigmond and Snaith (1983) discuss the importance of separation of the emotional and physical symptoms of anxiety and depression, and all items in the HAD are related only to the psychological symptoms. This applies to chronic pain since it may lead to some physical symptoms associated with depression such as dizziness or headaches. The anxiety items were chosen according to research into manifestations of anxiety (Zigmond and Snaith 1983).

The HAD questionnaire is a reliable and valid instrument to assess clinically significant depression and anxiety in a medical setting having been validated against psychiatric interviews with outpatients (Zigmond and Snaith 1983). The HAD questionnaire has since been validated against other psychometric scales measuring anxiety and depression using a cohort of general hospital outpatients (Aylard 1987). A review of 747 papers using the HAD questionnaire addressed methodological concerns which included internal consistency, discriminant validity and comparison with other similar psychometric tests. It was concluded that the HAD questionnaire was a sensitive measure and suitable for assessing anxiety and depression in primary care patients and the general population (Bjelland et al. 2002). Internal consistency of the HAD scale has been examined with reports of Cronbach's alpha coefficients between 0.80 – 0.93 for the anxiety scale and 0.81 – 0.90 for the depression scale (Mykletun, Stordal and Dhal 2001). Re-test reliability was also investigated and established in several studies (Roberts et al. 2001; Prettyman, Cordle and Cook 1993). Zigmond and Snaith (1983) corroborate the instrument usefulness for repeated administration at sequential follow up clinics, which is the methodology undertaken in this research. Administration of this questionnaire allowed changes in depression and anxiety to be explored at six months and one year, allowing associations between treatment outcome and depression and anxiety to be investigated.

### *Pain Coping Strategies Questionnaire (appendix 5)*

Literature investigating psychological influences upon treatment outcomes has highlighted coping strategies as impacting not only on the experience of pain (Vlaeyen 2007; Esteve, Ramirez-Maestre and Lopez-Marinez 2007; Mercado et al. 2005) but also on treatment outcomes (Turk and Melzack 2001; Jensen, Turner and Romano 2007). Therefore, it is highly relevant to examine pain coping strategies and behaviours.

This instrument was developed as a result of a combination between clinical and laboratory studies investigating coping in low back pain patients (Rosenthal and Keefe 1983). Although assembled for use with the chronic low back pain population, the PCSQ has been applied and proven an accurate measure among other populations including sickle cell disease pain patients (Gil 1989), rheumatoid arthritis pain patients (Keefe et al. 1989) and different groups of chronic pain conditions such as diabetic neuropathy, cancer, headache and neuralgia (Geisser, Robinson and Henson 1994; Lawson et al. 1990; Snow-Turek, Norris and Tan 1996). The PCSQ comprises 44 items measured on a seven-point likert scale ranging from 0 (never do) to 6 (always do that), assessing six cognitive coping strategies (subscales): diverting attention (thinking of things that serve to distract from pain), reinterpreting pain sensations (imagining the pain as a sensation other than pain, numbness), coping self statements (stating to oneself that no matter how difficult the pain becomes you will always cope), ignoring pain sensations (denying that the pain hurts or affects one's life), praying or hoping (praying to God or hoping the pain will improve) and catastrophizing (negative self statements and thoughts). Also included are a measure of behavioural coping strategies [increasing activity level (engaging in active behaviours that divert attention away from pain)] and measures of perceived effectiveness of coping strategies [control over pain (belief about ability to control pain) and ability to decrease pain (belief about ability to decrease pain)].

Each subscale is calculated from the relevant items. The questionnaire takes approximately between five to eight minutes to complete. Rosenthal and Keefe (1983) found this instrument to have satisfactory internal reliability when tested with a cohort of 61 chronic low back pain patients. The alpha coefficients for all of the subscales were high ( $r = > 0.7$ ). An alpha coefficient  $\geq 0.7$  is considered acceptable when examining the internal consistency of subscales (Cronbach 1951). Snow-Turek, Norris and Tan (1996) also found the PCSQ to

have high internal consistency when comparing to the Vanderbilt pain management inventory, which demonstrated lower levels. When assessing coping strategies Main and Waddell (1991) found 86% of individual items in the PCSQ to have a higher test-retest reliability when compared to other questionnaires including the multidimensional health locus of control questionnaire, the pain responses self statements questionnaire and the pain responses coping statements questionnaire. The authors of this research including 120 patients with low back pain concluded that catastrophising assessment had the greatest ability to understand chronic low back pain, and the PCSQ was the best tool to measure this psychological factor. The PCSQ has also been found to have concurrent validity with variation in adjustment including psychological factors and pain reporting being elucidated by the PCSQ (Rosentiel and Keefe 1983; Main and Waddell 1991). Snow-Turek, Norris and Tan (1996) found the PCSQ to be a valid measure of active and passive coping when tested with 210 patients presenting different chronic pain conditions. Rosentiel and Keefe (1983) suggest that the pain coping strategies of chronic pain patients should be assessed and that they have an important relationship with adjustment. Using the PCSQ at baseline, six months and one year will allow identifying changes in coping associated with treatment outcome.

Using principal components analysis, the subscales were organised into three additional grouping factors or composite scores by Rosentiel and Keefe (1983). The three additional factors were found to account for 68% of the variance in responses. These were cognitive coping and suppression, which comprised reinterpreting pain, coping self-statements and ignoring pain sensations; helplessness (catastrophising, increasing activity level, control over pain, ability to decrease pain); and diverting attention and praying (diverting attention and praying or hoping). When examining the factor structure of the PCSQ in 152 chronic pain patients, the subscales were suggested to have greater utility in terms of examining coping than the composite scores (Geisser, Robinson and Henson 1994).

Some patients may see the PCSQ as time consuming because of its 44 items, which can be a limitation of this questionnaire. Withdrawal from the study will be supported if a patient finds completing the questionnaire difficult or too time consuming.

### *Oswestry Lower Back Pain Questionnaire* (appendix 6)

The Oswestry questionnaire comprises 10 sections each assessing limitations experienced during a number of daily life activities. The selection of activities to include in the questionnaire was made based on relevance to people suffering with low back pain. For each activity (pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, travelling) the patient selects one of six options to illustrate the level of limitation they experience during that activity. The activities considered in the questionnaire are also applicable to people experiencing chronic pain in other areas of the body. Each item is scored between zero to five, the total disability score is calculated by adding all the items, then dividing by the total possible score and multiplying by 100. Scores from zero to 20 represent minimal disability, 20 to 40 moderate disability, 40 to 60 severe disability and scores over 60 represent extremely severe disability during the majority of activities in daily life (Fairbank et al. 1980). The questionnaire takes between 3 to 5 minutes to complete.

This questionnaire was found to be a valid measure of disability, with good internal consistency and with high test re-test reliability correlation (0.99) in a study involving 25 low back pain patients (Fairbank et al. 1980). Internal consistency was observed by Fisher and Johnson (1997). These authors reported a Cronbach's alpha of 0.78 for this questionnaire when testing the instrument with low back pain patients. The receiver operating characteristic (ROC) curve of the Oswestry measure of disability has been reported to be 0.78 demonstrating it to be a valid measurement of clinically meaningful change (Fisher and Johnston 1997). Although intended for use with low back pain patients, in the research presented within this thesis, the Oswestry questionnaire was administered to all chronic pain patients, which reported diverse areas of pain. Participants were requested to associate the items on the questionnaire with their particular area of pain. This questionnaire has been recommended as a tool to measure pain related disability when considering areas other than and including low back pain (McDowell and Newell 1996). This questionnaire has been found to be a clinically meaningful measure of disability when assessing treatment effects among 30 patients with both back and lower extremity pain (Ferrari 2007). The use of the Oswestry questionnaire in the current research enabled tracking changes in perceived disability throughout the first year of treatment (baseline, six months, one year).

### *Visual Analogue Scale*

The visual analogue scale (VAS) is 100 mm in length with anchors at each end with the low end of the scale to the left and the high to the right ranging from 0 to 100. Although patients may find converting the sensation of pain to a gradient on a straight line difficult, previous research suggests that the VAS is a reliable and valid measure of subjective phenomena including pain for the chronic pain population (Gift 1989; Price et al. 1983; McCormack, Horne and Sheather 1988). Elton et al. (1979) used the McGill pain questionnaire to test the validity of the VAS, obtaining correlations from 0.60 to 0.63. Research reviewing 54 peer-reviewed papers revealed high correlations between the VAS and numerical rating scale (Hjermstad et al. 2011). The VAS is a reliable measure of subjective sensations and has been described as the most sensitive scale to measure pain (Luria 1975). The VAS has been found to be more sensitive than verbal rating scales and numeric rating scales (Huskisson 1974).

A vertical scale with gradations was used in the current research. Participants were asked to indicate on the scale where they felt their pain was for an average day. Patients' preference for the vertical scale has been observed when 175 adults were questioned in an exploratory study of pain measures (Herr et al. 2004). A vertical scale is also recommended for clinical testing because of increased sensitivity (Gift 1989). The VAS has also been found to be the most common measure of choice for pain intensity in a review conducted by Hjermstad and colleagues (2011).

### *EQ5D VAS (appendix 7)*

The Euro QoL group developed the EQ5D VAS as part of a measure to evaluate health. This group consists of international, multilingual and multidisciplinary researchers from the UK, Finland, The Netherlands, Norway and Sweden. The EQ5D VAS enables participants to rate their overall health. This scale ranges from 0 to 100 and is displayed vertically. The top of the scale (100) represents the best possible health and the bottom of the scale (0) represents the worst possible health an individual could have. Participants were asked to mark on the scale where they perceived their overall health, taking into account every health domain, not just their pain. The EQ5D VAS provides an idea of the participant's perception of their overall health at each data collection time point (baseline, six months and one year). These scores were used to correlate against percentage pain reduction, to explore if, as



pain reduces, the perceived overall health increases. The EQ5D VAS was found to be reliable, valid and responsive in terms of measuring clinically significant change in a study with 233 rheumatoid arthritis patients (Hurst et al. 1997).

#### *Calculation of clinical change*

The percentage pain reduction was calculated from the VAS scores (average pain relief report) measured at baseline assessment, six months and one year after SCS by the following method:  $[(\text{VAS pre-treatment} - \text{VAS post-treatment}) / (\text{VAS pre-treatment})] \times 100$  (Farrar et al. 2001).

An improvement of  $\geq 30\%$  was considered as a clinically moderate improvement in pain reduction (Dworkin et al. 2008). Clinical change in pain reduction was calculated at both six and 12 months and the SCS patients were divided into two groups ( $\geq 30\%$  and  $< 30\%$ ).

#### 5.2.3.2 Quantitative data analysis

Logistic regression is performed when the outcome variable is binary and the predictor variables are categorical or continuous (Field 2009). This research has a categorical outcome variable ( $\geq 30\%$  or  $< 30\%$  pain reduction). Therefore, the data will be analysed using binary logistic regression to attempt to predict allocation into these two possible categories. Logistic regression allows predicting the probability of a participant being allocated to one or other group. This research has several continuous predictor variables from the questionnaires HAD (anxiety and depression subscales) and PCSQ (diverting attention, reinterpreting pain, catastrophising, ignoring sensations, praying or hoping, coping self-statements, increased behavioural activity, control over pain, ability to decrease pain).

The use of logistic regression in this research allowed the formulation of a model incorporating the outcome variables that indicate whether an individual put forward for SCS is likely to get  $\geq 30\%$  reduction in pain. A backward stepwise method was employed with the analysis beginning with all the predictors included. The removal of a predictor was based on the least impact to how well the model fits the data. Stepwise methods are appropriate when proposing to construct a model to fit the data (Menard 1995). Previous studies have failed to highlight any definitive variables that should be included in such a model, making a backward stepwise method a seemingly appropriate method.

Logistic regression does not make assumptions regarding distribution of data, therefore, the predictors do not need to be equally distributed or have equal variance, however linearity may enhance the power (Tabachnick and Fidell 2007). Nevertheless, multicollinearity and outliers can be problematic (Pallant 2007). In logistic regression it is necessary to ensure high correlations among the predictor variables do not exist. Multicollinearity needs to be investigated before running the analysis and any variables demonstrating multicollinearity need to be reviewed (Moore 2010). Logistic regression also assumes that responses of different cases are independent, meaning that each data point is from an unrelated, independent case.

Since the objective of the research was to develop a predictive equation of psychological characteristics that may influence achievement of  $\geq 30\%$  reduction in pain, logistic regression was selected instead of other statistical analysis methods. This was despite the small number of events per variable. Logistic regression is selected when the outcome variable is categorical and the predictor variables are continuous. The literature review confirmed that no variables have been identified as consistently impacting upon successful SCS; therefore it was deemed necessary to include all continuous coping strategies, anxiety and depression variables in the regression analysis to further investigate possible impacting variables. Logistic regression in this study enabled a feasibility study to take place and a post-hoc power analysis to be run. The power analysis demonstrated the number of participants needed to obtain 0.8 power, for the variables found in the current analysis to be statistically significant.

#### *5.2.4 Qualitative methods*

There are however areas of social reality that quantitative methods are unable to provide clarity on. Quantitative data collection allows for a comparison of scores obtained from the selected questionnaires. Qualitative investigation via semi-structured interview allows exploration of the common experiences and the placing of the SCS experience within the context of the individuals' lives.

Data of a qualitative nature or data corpus are data collected for a particular research project. This could include interviews, observations, pictorials, texts or focus groups. The data set is the data from a particular data corpus which is being analysed, such as the text, the picture and transcription (Braun and Clarke 2006). Data collection of a qualitative nature involves describing and interpreting data to build upon theory (Leedy and Ormrod 2001). Discovery of the social phenomena is studied through the participants' outlook (Williams 2007). This process involves describing, explaining and interpreting the collected data. Contrasting to quantitative data collection, the observer is heavily involved in the data collection and not separate. This can lead to criticism about subjectivity. The generally smaller sample sizes in qualitative studies and the deep involvement of the researcher means the research may be less objective. Qualitative research aims to generate hypothesis rather than testing and provides high levels of detail and understanding of a particular observable fact. The use of qualitative data collection in this study enables the 'real life' story of the SCS experience to be explored. Description and interpretation of what participants experienced allows insight into improvements that may be necessary or what is currently being done well. The psychological characteristics highlighted by the quantitative research can be explored and interpreted by qualitatively exploring the individual experience, giving context to the research findings. This research focused on the content and themes, reporting the repeated patterns inductively generated from the interview data of SCS patients after one year of treatment. The analysis seeks to provide insight into the experience, recognising themes among participant experience with implications for practice and treatment selection.

The qualitative aspect of the research stems from a realist perspective, reporting experiences and reality for participants. This is conducive to the quantitative aspect of the research which sought to discover specific variables impacting upon treatment outcome. Alone the quantitative lacks explanation and description of personal patient experience. By additionally reporting experiences and reality for participants the quantitative aspect of the research can be explained more so, and either supported or challenged. The qualitative investigation sought to understand the reality of the treatment experience. By giving a voice to participants the journey of the treatment experience can be better understood. Aspects that patients found difficult or lacking in support can be highlighted and these may give colour and explanation to variables highlighted in the quantitative aspect of the research. Using a thematic analysis method was therefore deemed appropriate, outlining surface

themes and reality for patients. The qualitative exploration sought to fully understand the treatment experience and identify any gaps in the care received, it was therefore important to collect and analyse data up to saturation. By reaching saturation the researcher could feel confident that the treatment experience had been fully explored for this particular group of patients. Uncovering all important aspects that may contribute to treatment outcome could be considered to have been identified if saturation was achieved. Other methods of qualitative analysis were therefore rejected as thematic analysis from a realist perspective met the requirements of the study and supported the quantitative inquiry.

#### 5.2.4.1 Interviews

Interviews allow an insight into an individual's world, interpretation and opinion. Kvale (1996) provides a metaphor to demonstrate the purpose of the interview technique in research. This metaphor describes the interviewer as a miner, uncovering valuable metal seeking either objective facts, which are quantifiable or to understand meaning, the concept that knowledge is waiting to be revealed in its purest form. Open-ended interviews are often favoured in qualitative research to enable an insight into 'lived experience' (Silverman 2000). Interviews should not be seen as entirely truthful though as consideration of external variables needs attention. Just being interviewed can introduce tenuous issues. How people talk with one another on a daily basis is very different compared to a clinical interview setting (Silverman 2000). The researcher met with each participant on at least two occasions prior to the interview (baseline assessment and six month follow up), allowing for a level of rapport to be developed. The interview was also opened with casual discussion to enable the participant to settle and feel at ease.

A total of 13 patients were invited for an interview. Patients were recruited consecutively after one year of SCS therapy when attending the pain management clinic for follow up. Since the objective was to gain an understanding of the SCS experience from many perspectives and uncover as many issues and themes as possible, the sample size was not predetermined and recruitment continued until saturation was reached (Guba and Lincoln 1985). The concept of saturation in qualitative data collection implies that data collection should stop once new information is no longer being uncovered from the analysis of the data, new codes and themes are no longer developing and only repetitions are being recognized (Wray 2007). According to the data saturation concept, new participants should

be brought into a study until the data is complete and therefore codes and themes are no longer developing and changing (Bowen 2008). In the current study, once only repetition in the analysis started to be observed and no new themes were emerging, two further interviews were conducted to verify if saturation had been reached. The following two interviews did not introduce new themes and recruitment for interviews ceased. The analysis and all the codes from the last two interviews fitted into categories that had already been devised. A second and third researcher confirmed there were no omissions in the data analysis.

A room in the pain management clinic was chosen to conduct the interviews, as this is a familiar place for the participants. Although this setting may have an impact upon the nature of the participant's report, it was considered a suitable place. The participants visited the pain management clinic on numerous occasions (e.g. pre-assessment, implantation and follow ups). The patients were invited for an interview that would take place following a standard follow up appointment to try to limit disruption of the patients' daily routine. This setting would also take into consideration the researcher's safety. However, the clinical setting, with all the possible connotations such as white walls, medical instruments and equipment, and the presence of physicians and nurses in adjacent rooms may impact on the interview content. All the participants were interviewed in a closed room for privacy. All the invited patients' agreed to take part in the interview and stratification was monitored in terms of interviewing a group heterogeneous in their pain reports. All the participants invited for an interview had reached either one year of treatment or one year following trial (failed trial participants). Stratification was unnecessary as there was a wide range of pain reports. A wide range was also observed in age and gender. Research conducted on the efficacy of SCS treatment has detected changes most commonly around 12 months (Cameron 2004; Kupers et al. 1994). Therefore, interview at one year was considered as appropriate to investigate the participants' experience. The systematic review within this thesis revealed that few studies collected data at one-year, and several focused on cross-sectional data collection and short-term follow up (three and six months). This review also demonstrated the lack of qualitative enquiry, which would allow understanding of the treatment outcomes from a different perspective to questionnaires alone.

#### 5.2.4.2 Semi-structured interview schedule

A semi-structured interview allows the interviewer to deviate from the sequential order or follow up with further questions in response to the interviewees retort (Bryman 2004). The semi-structured interview approach adopted for this research sought to uncover information from preselected themes to further the understanding of the patient's SCS experience and psychological factors interacting with SCS treatment.

The semi-structured interview schedule (appendix 8) was derived from literature depicting topics suggested to be important when assessing chronic pain patients for treatments such as SCS. The topics covered in the interviews were as follows: pain description and experience/ pain history/ medication use/ specific pain behaviours/ SCS/ patients concept (beliefs/expectations) of pain and pain treatment (Doleys, Klapow and Hammer 1997; Turk and Melzack 2001; Turk and Okifuji 2002).

The patients were invited to talk openly about their pain experience and treatment. If the patients emphasized any issues considered important regarding the SCS experience not included within the interview schedule, these would be included in the subsequent interviews. Only one patient mentioned an additional topic, which was regarding the hospital in-stay experience following SCS implantation.

#### 5.2.4.3 Qualitative analysis

The interviews were transcribed verbatim and the transcripts stored on a password protected memory stick. On very few occasions, parts of the interview were not decipherable (black spots) and were transcribed as a question mark. The transcripts were uploaded onto the computer program QSR NVivo 2.0, which has been designed to aid researchers during the coding process. NVivo facilitates the process as it enables codes and themes to be generated and stored electronically amongst the data. The coded data can be collated and viewed at each node. NVivo enables organisation and electronically collated data into codes and themes, however the researcher is the facilitator of the analysis.

Thematic analysis has been described as a process that is followed within analytic traditions, but Braun and Clarke (2006) argued that it is a method in its own right. These authors were the first to show a clear methodological process and outline the theoretical

basis. Many qualitative analytic methods develop from a theoretical perspective following a rigid analysis process (interpretive phenomenological analysis, conversation analysis). Thematic analysis can be applied across many theoretical perspectives, providing potentially rich and detailed accounts (Braun and Clarke 2006). Thematic analysis was selected since the primary aim of the current research was to describe common themes for SCS patients, and describe their SCS treatment experiences, both positive and negative, to further inform practice. The aim was to understand what the SCS experience was like and to identify themes at a surface level. Using thematic analysis allows the researcher to provide a rich and detailed account of the data without subscribing to the implicit theoretical commitments of other analytic methods (Grounded theory/IPA).

Thematic analysis can be either essentialist/realist (reporting experiences and reality for participants) or constructionist (examining ways in which events and experiences affect a range of discourses within society) (Braun and Clarke 2006). The qualitative study within this thesis seeks to report themes and patterns reflecting the reality and experience of the SCS patient from a realist perspective. The themes are derived to capture and respond to the essence of the research question demonstrating an important aspect related to the overarching aims and objectives of the research. The determination of a theme is the researcher's responsibility and there are no rules as to what determines a theme (Braun and Clarke 2006). Reliability and validity of the results need consideration due to the potential subjectivity of the analytic process.

There is limited available literature depicting a clear structural outline and application of thematic analysis. Braun and Clarke (2006) have described a robust structure not only illustrating a clear and concise systematic process to follow, but also the important role of thematic analysis in research. Glaser and Strauss (1967) upheld the notion that meaning may emerge from the data. Thematic analysis implies that immersion into the data allows generating an inductive analysis, independent of predetermined hypotheses. However, Silverman (2000) argues that a researcher always enters the analysis process with some beliefs. Within the context of this research, prior collection of quantitative data meant that some knowledge was already held regarding the experience with some relevant psychological characteristics beginning to be identified. Moreover, holding knowledge of the research area may influence interpretation.

Thematic analysis allows for themes to be generated in an inductive way (Patton 2002). Although researchers are unable to free themselves of theoretical viewpoints the analysis process is data driven as themes may not bear resemblance to the specific questions asked and no pre-existing framework is developed (Braun and Clarke 2006). The qualitative study aimed to provide a rich account of the psychological processes and experiences for an SCS patient during the first year of treatment, however, the analysis was driven by the data and no pre-determined themes were introduced from previous research (deductive approach). Nevertheless, it should be acknowledged that the selection of questions in the interview might influence the participants' discussions.

The semantic approach taken forth in this current research identifies and codes the explicit surface meanings of the data in a unidirectional relationship with language reflecting and enabling to the researcher to articulate meaning and experience (Braun and Clarke 2006). As previously mentioned, the epistemological approach follows a realist perspective. The data was organised to show patterns and themes and then summarised, leading to interpretation, in an attempt to demonstrate the themes' broader meanings and implications, which can be useful when investigating an under-researched area and the viewpoints of those involved are not known (Braun and Clarke 2006; Patton 2002). Drawing out the predominant and important themes will accurately reflect the content of the data set.

The analysis process followed the six stage protocol as described by Braun and Clarke (2006). Interviews were transcribed and then re-read to allow familiarisation and closeness to the data to allow initial identification of patterns within the transcripts. Early ideas of possible codes were scripted at this stage informally. This helped to remain focussed on the data.

Coding of the data began after familiarisation following an open coding process where interesting features identified within the transcribed interviews were highlighted and given descriptive code names. While coding, a clear focus was maintained on uncovering the patients' experience of SCS and psychological factors, which may be affecting efficacy. A coding manual was developed where each time a code was assigned a clear definition for categorising data into that code was determined. This enabled the researcher to be sure of



suitability when assigning new data extracts to pre-existing codes. This process upholds some consistency when coding and also reduces repetitive coding. Transcripts were revisited to try to detect additional codes and themes, which may have been missed initially. Memos of any themes or interesting features of the data that were detected during the initial coding stage of the analysis were also made helping to remain focused on the aim and objectives of the research.

A second researcher reviewed the generated codes independently. The first three and the last three transcripts were reviewed and suitable codes were assigned, before reviewing the principal researcher's codes. Any fundamentally different coding by the researchers resulted in either re-categorisation of that particular word/phrase or agreement through discussion.

A repetition and lack of new codes were identified while coding the tenth interview. Three further interviews were conducted to investigate if saturation had been reached. These additional interviews did not generate any new codes and hence data collection ceased after interview thirteen. A second and third researcher also failed to find new codes emerging from the transcripts confirming saturation.

Codes relevant to emergent themes were collated together as themes started to be noticed within the coded data. The researcher also reviewed codes that could be combined to form overarching themes and subthemes. Relationships between the codes and overarching themes were explored in a repetitive process, to ensure the codes were suitably assigned to the overarching themes. The coding manual was revisited when developing themes and grouping codes to ensure the correct grouping was taking place. The analysis generated two core categories with sub-themes.

A negative case analysis was performed where the themes were revisited to verify if the data/codes fitted into the themes. This is a process to ensure there is enough meaningful data to support the generated theme and subtheme and to investigate as to whether several themes could collapse into one. The entire dataset was re-read to check that the themes adequately reflected the data, and to ensure all relevant data had been coded. The themes were then defined and its essence is described in the results section of this thesis.

### *Rigor of the analysis process*

Qualitative research is regularly criticised for its possible lack of trustworthiness and concern that findings are presented in an untrustworthy fashion (Braun and Clarke 2006). This concern is due to the analysis being reduced to the researchers own interpretation of the data. To improve the rigor of the analysis, several considerations were taken into account during the analysis process. Qualitative research emphasises the consideration for trustworthiness when analysing the data. Guba (1981) outlines the criteria to improve the rigor of qualitative research such as credibility, transferability, dependability and confirmability.

Credibility can be understood as how accurate the phenomenon under study has been recorded. In this research, consideration for credibility was initially taken into account by following the process for thematic analysis described by Braun and Clarke (2006). In terms of the interview process, rapport was improved by meeting the participants on two occasions before the interview took place. Participants were also supported to withdraw from the study should they wish to. Confidentiality was discussed and participants were reassured that the interviews would not have any impact upon their future treatment. These factors permitted the development of some trust and rapport between the researcher and participant, which may have encouraged participants to feel more at ease while expressing their experiences. Stages of the analysis were scrutinised by peers to challenge assumptions and ensure coding and development of themes were representative of the interviews. Specific quotes are provided alongside the findings to support the argument put forward, allowing the reader to appreciate how representative of the data a particular theme may be (Silverman 2004).

Transferability is recognised as the extent to which findings can be applied to a wider population. Small studies limit the applicability of the findings to a wider population. Nevertheless, the group of patients studied in this research were recruited from a population of chronic pain patients selected for SCS with varied socio-economic backgrounds. The pain management clinic, protocol for SCS selection, participants' demographics, data collection methods and analysis, length of interviews and contributors that participated in the study are described to allow judgement of transferability; the boundaries of the study were outlined by providing these details (Cole and Gardner 1979).

Dependability concerns the reliability of the findings. Silverman (2000) explains two important considerations of reliability. Firstly, how a researcher devises the categorisation of words and phrases into specific groups when analysing qualitatively. Secondly, researchers need to make sure the transcription consistently captures the conversation in the context it was meant when recorded. Despite Marshall and Rossman (1989) arguing that social reality is always in flux and therefore it makes little sense to concern over measurement of reliability, this issue needs to be taken seriously. To ensure the data was captured consistently, the principal researcher transcribed the interviews verbatim. Each interview was analysed prior to the subsequent interview, so important topics generated could be introduced into future interviews. As mentioned in the previous segment, a second and third researcher ensured reliability of the process by independently reviewing the generated codes, themes, omissions or inconsistencies and discussing possible disagreements.

Confirmability can be recognised as being considered in the current research by the clear process depicted and paradigm perspectives discussed. The coding and development of themes is illustrated by the tables in chapter 7. The shortcomings of the research methodology are also discussed.

### **5.3 Ethical approval**

The World Medical Association aims to achieve the highest standards in medical education, science, ethics and health care. Formally established in 1947, this organisation developed the declaration of Helsinki in 1964 at the 18<sup>th</sup> World Medical Assembly. The main objective of the declaration of Helsinki is to provide an ethical framework to safeguard those voluntarily participating in medical research. This declaration underlies the duty to protect life, health, dignity, integrity, right to self-determination, privacy and confidentiality of personal information of those participating in medical research. The document is morally binding and should be abided by even if describing higher standards of protection in comparison with local regulations. Six amendments have been made since its inception to maintain relevance to current medical practice. The latest update of the declaration occurred in 2008 during the 59<sup>th</sup> World Medical Assembly in Seoul, South Korea (World Medical Association 2008). In summary, the document provides the following considerations for patient protection stating that it is the right of the individual to make informed decisions when

partaking in research, the participants' welfare must come before any interests of science and, ethical concerns take precedence over local laws. The declaration also outlines the principles that must be considered when carrying out the practicalities of research declaring that research must be supported by scientific rationale, the risks must be carefully considered, there should be benefit of the research to the population under study, those conducting the research must be trained and skilled in doing so, research investigation is subject to peer ethical review by a convened committee, information detailing the study should be publically available, conflict of interest must be declared, the study must enable patients to the best proven care and unproven methods may be tested where there is possibility of benefit.

Ethics are defined as the scientific study of the morals and rules of behaviour (British Psychological Society 2009). Prior to starting a study the protection of the public needs to be anticipated, clear ethical principles, values and standards expressed (British Psychological Society 2009). The British Psychological Society (BPS) sets out standards to uphold the highest standards in terms of professionalism. Ethical concerns collected from surveys raise the following issues, which impinge on ethical principles; multiple relationships (where psychologists have an allegiance to several stakeholders), personal relationships, infringement or violation of trust, inadequate standards of practice, breach of confidentiality, competence, misleading claims, falsifying data, lack of informed consent, plagiarism, personal health problems which impact on professionalism and disrepute of profession (British Psychological Society 2009). The principles and considerations addressed to ensure an ethical conduct in this research are described below.

According to the BPS, several areas of ethical implications need consideration before embarking on professional work (research in this case). The following need careful consideration throughout professional work to ensure ethics are adhered to: ethical behaviours, information seeking, reflective practice, peer support and transparency of professional activity. The studies presented within this thesis adhered to these guidelines by going through an ethical peer review process for the proposed research. The research project was carefully prepared and protocols, participant information sheets and consent forms were developed for scrutiny by a convened ethical board. The BPS code of conduct follows four clear ethical principles:

- 1) Respect - psychologists must value the dignity and worth of all individuals, regarding individual rights, privacy and self-determination. The ethical review process confirmed that the proposed research would do no harm to the participants. All participants were taken through an informed consent process, where they were able to ask any questions. The patients were also informed of the option to withdraw from the study at any time without prejudice to their treatment, should they wish to.
- 2) Competence - recognise the importance of continued development, ability to function optimally within recognised limits of knowledge, skill, training, experience and education. Competence was guaranteed by the support of two PhD supervisors, skills developed during the PhD journey and knowledge of carrying out research previously acquired during an MSc in Health Psychology. Competency in working with a patient group had also been developed by previous work experience in health care settings within public and mental health.
- 3) Responsibility - remember responsibility to clients, the public and other professionals, avoid harm and prevent any misuse or abuse.
- 4) Integrity - remember honesty, accuracy, clarity and fairness in all interventions.

These ethical principles were taken into consideration throughout the research process via peer review and by providing participants with clear information regarding the research. Participants were supported to ask questions about the research or withdraw from the process if they wished to do so, without consequence.

### *5.3.1 Confidentiality issues*

Participant confidentiality was assured by assigning identification numbers to each patient. The written informed consent form had both the participant name and study ID code to be used as a master reference. All written informed consent forms were kept separate from the data collection forms, to minimize opportunity of individual identification. All data collected were kept in locked cupboards and on a password protected database. Publication of the collected data will not reveal individual information, therefore maintaining the confidentiality and anonymity of all participants.

### *5.3.2 Sponsorship and NHS REC ethical review*

Sponsorship was granted from Birmingham City University for this research to take place (appendix 11). Ethical approval was sought and obtained before data collection commenced by Birmingham, East, North and Solihull Research Ethics Committee (REC reference: 08/H1206/183, appendix 12). In order for the ethical process to be carried out a set of documentation was required. An application form was completed detailing the research process. Copies of the participant information sheet (appendix 9), consent form (appendix 10) and University sponsorship agreement (appendix 11) were included with the application. Several questions regarding study design, recruitment process, protection of participants, patient information sheets and consent form were made during the meeting by different members of the ethics committee board. Ethical approval was granted (appendix 12) with minor amendments to the participant information sheet (use of an everyday language to facilitate patients' understanding). The entire process from beginning of application to formal ethical approval took approximately six months.

## **5.4 Participant recruitment**

### Patient selection criteria

The Midlands Regional Centre for Spinal Cord Stimulation is based at Russells Hall Hospital, Dudley. It follows a screening protocol with patients. Patients are considered for SCS when their pain is neuropathic and/or ischemic and have not responded or have experienced intolerable side effects to more conservative treatments.

The psychologist has an important role within the multidisciplinary assessment. A psychological evaluation of suitability for SCS must be conducted in the short time allocated with the patient. The circumstances can be pressurising considering the emotions the patient displays due to the urgency to be treated. Currently, patients are excluded on the grounds of unrealistic expectations of the treatment, lack of comprehension or unrealistic beliefs surrounding their pain. Those patients who are perceived as unsuitable or are not successful during SCS trial are treated by the pain clinic via other methods of treatment or medication. Although the patients selected for SCS by the pain management team were considered as suitable candidates, research shows that even after selection for suitability, high rates of reduction in anaesthesia can be observed (Cameron 2004; Kupers et al. 1994).

Once selected for SCS, the patients are requested to attend a pre-admission appointment with the pain nurse one week before the trial. This appointment is to confirm that the patients are prepared for hospitalisation, answer any questions/doubts and take swabs for infectious diseases. During this appointment, the pain nurse would inform the patients that met the inclusion criteria, that the current study was taking place and ask if they would be happy to meet with the researcher following the appointment. No patients refused to meet with the researcher. The research would be explained to the patients and a copy of the participant information sheet and consent form would be provided for the patient to read. The patient information sheet outlined the relative advantages and disadvantages to participation in the study as well as the study objectives.

#### Inclusion and exclusion criteria

Patients were invited to participate in the current research if selected for SCS for neuropathic or ischemic limb pain after initial assessment by the pain management multidisciplinary team and if they were 18 years of age or over. Participants were excluded if they did not meet the inclusion criteria or if they did not wish to participate.

#### Consent process

After addressing any queries the patient might have, the consent form would be signed and some demographic information would be asked and recorded on a pro forma. Participants were given the baseline psychological questionnaires to complete at home and asked to return them when they attended the hospital for their trial period. The patients' were informed that they could withdraw from the study at any time. Participants were supported to withdraw from the study if they wished to do so without jeopardising their treatment. The participants would be signposted for appropriate support if they experienced any discomfort while discussing any of the issues. Only one patient chose to withdraw from the study, explaining that the questionnaires were tedious.

All patients who were selected by the pain management clinic at Russells Hall Hospital for SCS (n=56) were invited sequentially to take part in the research within a 12 month period. Participants were recruited at baseline (during preadmission assessment), prior to the SCS trial (three to five days). If the trial was unsuccessful, patients would be invited to continue in the research for a one year period following initial assessment.

## **5.5 Data collection**

The interviews were conducted and questionnaires collected during scheduled clinic appointments taking into account the protocol and patient information sheet procedures. Data collection at baseline, six and 12 months included a demographic questionnaire (baseline only), self-rating visual analogue scales (VAS) (Price et al. 1983), pain coping strategies questionnaire (Rosentiel and Keefe 1983), hospital anxiety and depression questionnaire (Zigmond and Snaith 1983), Oswestry low back pain questionnaire (Fairbank et al. 1980) and the EQ5D thermometer (Hurst et al. 1997).

At one-year post SCS implantation patients were invited to participate in a 45-60 minute semi-structured interview. The clinic took place between 9am and midday and participants were interviewed following their appointment. The interview lasted between 45 and 60 minutes and was recorded and transcribed. All interviews were conducted by the same researcher (E.S). In combination with the interview, patients were asked to rate their average daily pain using the VAS. This score was used together with their pain score reported at baseline (prior to SCS trial), to compute the percentage pain reduction (Farrar et al. 2001).

The principal researcher had no clinical involvement in the patients' treatment or clinical assessment, as this could influence treatment outcomes and potentially lead to bias. Bias can occur due to the interviewer or interviewee where expectancies and interpersonal interactions can produce new dimensions to the interview, influencing the results (Kvale 1996). A number of interpersonal effects could have influenced the research, had the participants been interviewed by a member of the pain management clinic, such as the patient feeling a need to reflect a positive experience due to ongoing treatment or not wanting to affront their health care team. On the other hand, the healthcare team may influence the interview unknowingly through questions influenced by their own experiences and knowledge of the patient.

The next chapter of this thesis will present a prospective longitudinal study evaluating potential psychological characteristics impacting on SCS treatment outcome.



## **Chapter 6**

**Quantitative study of psychological factors  
affecting SCS efficacy**

## **6.1 Introduction**

Although a successful trial may initially be achieved for SCS, this does not appear to guarantee long-term success (Cameron 2004; Kupers et al. 1994). Generally, research carried out into factors affecting the efficacy of the treatment has tended to focus on mechanical aspects of SCS. It is not uncommon for the wires to migrate resulting in a loss in analgesia (Mutagi et al. 2006). The review of the literature investigating the psychological factors affecting SCS efficacy (chapter 4), observed that there was a lack of consistent evidence to confirm any psychological factors linked with SCS efficacy. The majority of the studies that fitted the inclusion criteria for the literature review identified depression as a possible impacting factor. However, it was observed that successful SCS treatment could modify the level of depression if it was a state in reaction to the pain rather than a trait characteristic. The studies ranged in methodologies employed and follow up periods and a clear conclusion about which psychological factors impacted upon the efficacy of SCS was not possible. A prospective longitudinal study using more rigorous methods of assessment could potentially provide some insight into this topic.

As previously discussed, cognitions about illness and treatment can modify coping styles. The pain coping strategies and behaviours that individuals demonstrate may be linked to outcome for both pain and treatment. Therefore, it can be hypothesised that certain psychological factors may interact with the experience of pain and response to SCS. This research aimed to identify psychological factors affecting the long-term success of SCS.

## **6.2 Study design**

Psychological factors and functional measures were evaluated in a prospective longitudinal cohort study in order to investigate psychological factors impacting upon the efficacy of SCS. Ethical approval was obtained from Birmingham, East, North and Solihull Research Ethics Committee (REC reference: 08/H1206/183, appendix 12). SCS patients were administered questionnaires followed up at baseline, six months and one year.

### **6.3 Data collection**

The data collected at each time point (baseline, six months and one year) included the self-rating VAS (Price et al. 1983), EQ5D thermometer (Hurst et al. 1997), pain coping strategies questionnaire (Rosentiel and Keefe, 1983), hospital anxiety and depression questionnaire (Zigmond and Snaith 1983) and the Oswestry low back pain questionnaire (Fairbank et al. 1980). All the data were collected during routine follow up appointments at Russells Hall Hospital. Demographic data was taken orally at pre-assessment appointment one week before the trial. The patients were asked a series of demographic questions including age, pain area, duration of pain and diagnosis.

The data was entered into Microsoft Office Excel and SPSS for analysis, following each completed questionnaire. The data was checked a second time after being entered for any possible errors. An example of the data entry is presented in appendix 13. Logistic regression was carried out on the data resulting in the development of an equation to allow prediction of probability of  $\geq 30\%$  pain reduction.

### **6.4 Results**

#### *6.4.1 Demographic data*

Fifty-six patients were trialled for SCS. Nine of these patients were subsequently excluded. Eight due to failed trial of SCS (seven female, one male with a mean pain duration of  $6.5 \pm 2$  years (range 2-15) and a mean age of  $44 \pm 7$  years (range 24-70). Pain areas of the excluded patients included leg/knee (two), arm (one), foot/ankle (one), multiple (one), and other (three). One patient requested to be withdrawn from the study due to finding the process of completing the questionnaires tedious. Forty-seven patients were included in the final analysis at six months and 40 patients at one year. The demographic information for the patients included at each time point is presented in Table 6.1 and Table 6.2.

Table 6.1 Six months demographics by Percentage Pain Relief grouping

	< 30% n = 25	≥ 30% n = 22	Homogeneity
Gender	M (12); F(13)	M (13); F(9)	$\chi^2(1) = 0.578, p = 0.447$
Age (years)	46 ± 2 (32-70)	50 ± 2.5 (30-70)	$t(45) = -1.243, p = 0.220$
Duration of pain (years)	10.3 ± 1.8 (1.5-40)	10 ± 2 (2-40)	$t(45) = 0.070, p = 0.945$
Topography of pain			
Back	3	3	
Arm/hand	3	1	
Buttock/leg/foot	12	11	
Head/neck	1	1	
Multiple	6	6	
Mean ± SEM (range)			

Table 6.2 Twelve months demographics by Percentage Pain Relief grouping

	< 30% n = 26	≥ 30% n = 14	Homogeneity
Gender	M (11); F(15)	M (8); F(6)	$\chi^2(1) = 0.803, p = 0.370$
Age (years)	46 ± 2 (32-69)	50 ± 3 (34-70)	$t(38) = -1.388, p = 0.173$
Duration of pain (years)	10 ± 1.4 (1.5-25)	9.1 ± 2.8 (2-40)	$t(38) = 0.337, p = 0.738$
Topography of pain			
Back	2	2	
Arm/hand	2	3	
Buttock/leg/foot	14	6	
Head/neck	1	1	
Multiple	7	2	
Mean ± SEM (range)			

#### 6.4.2 Correlations

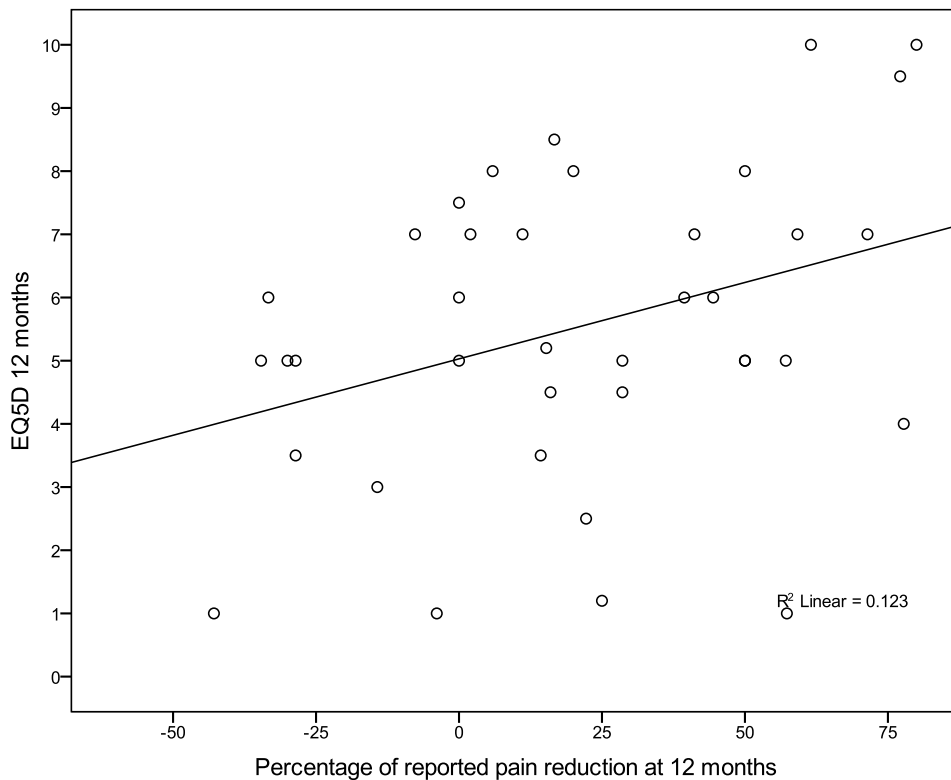
##### *Percentage pain reduction, EQ5D and Oswestry questionnaire*

The relationship between percentage pain reduction score with EQ5D scores and Oswestry questionnaire scores was explored using bivariate correlations at six months and one year.

### EQ5D and percentage pain reduction

Percentage pain reduction and EQ5D score were not significantly correlated at six months,  $r = 0.098$ ,  $p = 0.544$  (2-tailed). At 12 months there was a significant positive correlation between percentage pain reduction and EQ5D score,  $r = 0.351$ ,  $p = 0.031$  (2-tailed), indicating that as pain reduction increases, the EQ5D score increases (figure 6.1). The  $R^2 = 0.123$ , is a measure of the amount of variance in one variable shared by the other variable. The  $R^2$  value can be converted to percentage (12.3%). This result indicates that pain reduction accounted for only 12.3% of the variation in EQ5D scores and 87.7% of the variance is still to be accounted for.

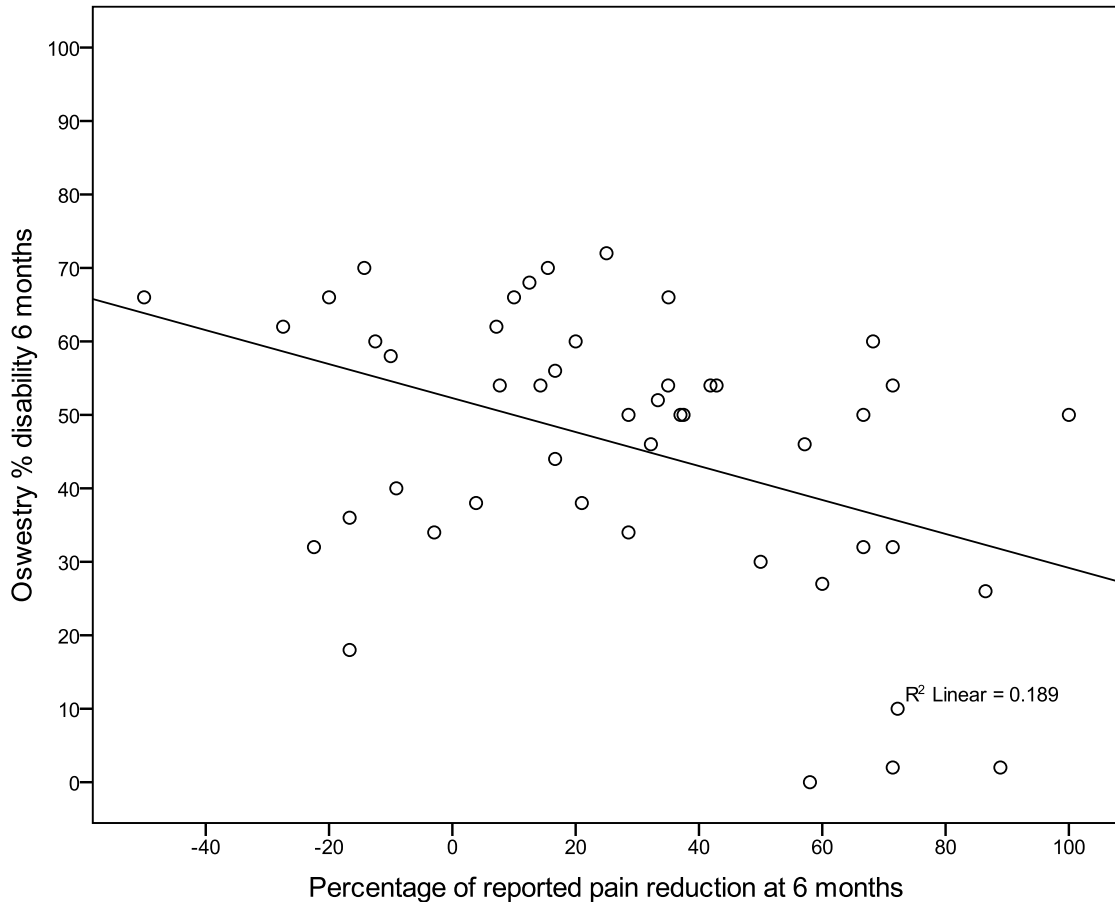
The findings from the correlations demonstrate that 12 months after SCS implantation, as percentage pain reduction scores increase, reported EQ5D scores also increase. This indicates an improved quality of life score alongside an improved pain relief report.



**Figure 6.1 Correlation between EQ5D and reported % pain reduction at 12 months**

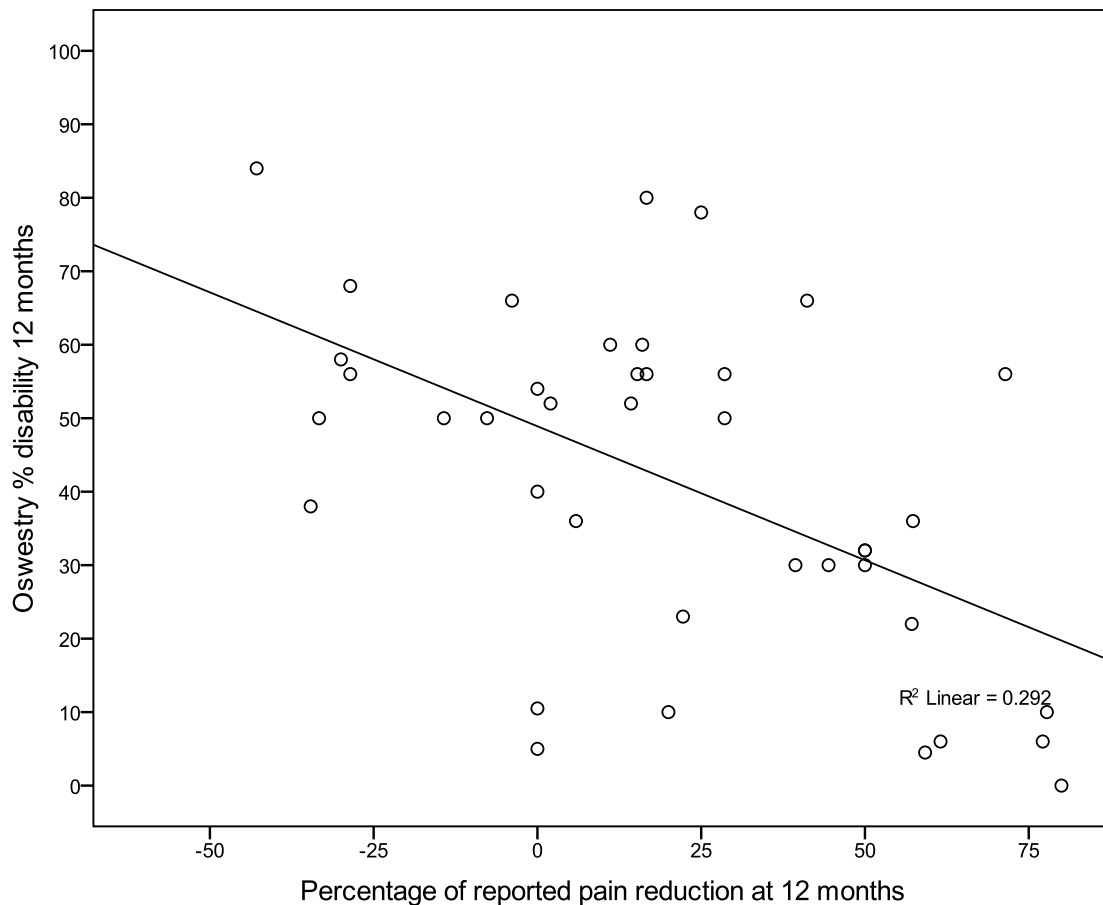
### Oswestry questionnaire and percentage pain reduction

At six months there was a significant negative correlation between percentage pain reduction and the Oswestry questionnaire score,  $r = -0.434$ ,  $p = 0.002$  (2-tailed) (figure 6.2). For this correlation, the  $R^2 = 0.189$  (18.9%), indicating that pain reduction accounted for only 18.9% of variation in the Oswestry questionnaire scores (81.1% of the variance still to be accounted for).



**Figure 6.2 Correlation between ODQ score and reported percentage pain reduction at six months**

At 12 months there was also a significant negative correlation between percentage pain reduction and the Oswestry questionnaire score,  $r = -0.552$ ,  $p < 0.001$  (2-tailed) (figure 6.3). At 12 months, the  $R^2 = 0.292$  (29.2%). Therefore, pain reduction accounted for 29.2% of variation in Oswestry questionnaire scores with 70.8% of the variance still to be accounted for.



**Figure 6.3 Correlation between ODQ score and reported percentage pain reduction at 12 months**

#### 6.4.3 Logistic regression

Binary logistic regression is undertaken when the outcome variable is categorical and the predictor variables are categorical or continuous. The outcome variable in this research has two categories ( $\geq 30\%$  or  $< 30\%$  pain reduction) and several continuous predictor variables from the questionnaires HAD (anxiety and depression subscales) and PCSQ subscales (diverting attention, reinterpreting pain, catastrophising, ignoring sensations, praying or hoping, coping self-statements, increased behavioural activity, control over pain, ability to decrease pain), and composite scores (cognitive coping/suppression, helplessness, diverting attention/hoping and praying). Logistic regression does not make any assumptions regarding the distribution of scores for the independent variables (Field 2009). Logistic regression is sensitive to multicollinearity, and outliers may also influence the results (Pallant

2007). Tests carried out to evaluate if the assumptions for logistic regression were met, are presented throughout the results section. Multicollinearity was tested to investigate which dependent variables could be included in the logistic regression. Multicollinearity occurs when two or more dependent/predictor variables are highly correlated. Following logistic regression, analysis tests to investigate the assumptions for logistic regression were carried out, which included linearity in the logit, absence of outliers and independence of errors, and a post hoc power analysis to examine ratio of cases to variables (Field 2009).

The use of binary logistic regression in this study allowed to develop a model incorporating the outcome variables that determine whether an individual put forward for SCS is likely to get  $\geq 30\%$  reduction in pain. The method employed was a backward stepwise method and the analysis began with all predictors included and removal of a predictor was dependent upon having the least impact on how well the model fitted the data (examination of significance values  $< 0.05$ ). The backward stepwise method is considered a better method than the forward method since the latter runs a high risk of type II errors (Field 2005). Stepwise methods are appropriate when proposing to construct a model to fit the data (Menard 1995).

The following segment begins with the investigation of the relationships between the predictor variables (PCSQ subscales and HAD subscales) at baseline and the outcome variable, percentage pain reduction ( $<30\%$  or  $\geq 30\%$  pain relief) at both six month and 12 months follow up. Correlations were carried out to assess the strength of relationship between the variables.

#### *6.4.3.1 Correlations*

Correlations between pain reduction and baseline variables at six and 12 months were conducted.

##### Six months

At six months there were no significant correlations between percentage pain reduction and the PCSQ and HAD baseline variables (Table 6.3). Taking into account that  $r \geq 0.7$  constitutes a strong correlation (Moore 2010) there were a number of baseline variables evidencing strong correlations. Correlations  $\geq 0.7$  were observed in the following variables:



PCSQ diverting attention and hoping/praying with PCSQ diverting attention, PCSQ reinterpreting pain with PCSQ cognitive coping and suppression, PCSQ helplessness with PCSQ catastrophising, PCSQ ignoring sensations with PCSQ cognitive coping and suppression, PCSQ coping self-statements with PCSQ cognitive coping and suppression. These correlations indicate multicollinearity, which is investigated in more detail in section 6.5.4.

The PCSQ composite variables were generated from a combination of PSCQ subscales, which can explain the correlations observed. The score of the composite variable cognitive coping and suppression is derived from the combination of the variables reinterpreting pain sensation, coping self statements and ignoring sensations; the diverting attention and hoping/praying composite score is derived from the grouping of the variables diverting attention and praying or hoping; and the helplessness composite score results from a combination of the variables catastrophising, increasing behavioural activity, control over pain and ability to decrease pain. When examining the factor structure of the PCSQ, the subscales were suggested to have greater utility in terms of examining coping than the composite scores (Geisser, Robinson and Henson 1994). The composite scores were therefore excluded from the analysis.

Table 6.3 Correlation of six month percentage pain reduction with baseline assessment

	Percentage of pain reduction	PCSQ diverting attention	PCSQ reinterpreting pain	PCSQ catastrophising	PCSQ ignoring sensations	PCSQ praying or hoping	PCSQ coping self-statements
PCSQ diverting attention	$r = -0.151$ $p = 0.311$						
PCSQ reinterpreting pain	$r = 0.570^{**}$ $p < 0.001$						
PCSQ catastrophising	$r = -0.057$ $p = 0.703$	$r = 0.250$ $p = 0.090$					
PCSQ ignoring sensations	$r = 0.025$ $p = 0.865$	$r = 0.533^{**}$ $p < 0.001$	$r = -0.020$ $p = 0.895$				
PCSQ praying or hoping	$r = -0.055$ $p = 0.711$	$r = 0.581^{**}$ $p < 0.001$	$r = 0.414^{**}$ $p = 0.004$	$r = 0.192$ $p = 0.197$			
PCSQ coping self-statements	$r = -0.021$ $p = 0.886$	$r = 0.385^{**}$ $p = 0.008$	$r = -0.164$ $p = 0.271$	$r = 0.685^{**}$ $p < 0.001$	$r = 0.363^{*}$ $p = 0.012$		
PCSQ increased behavioural activity	$r = -0.038$ $p = 0.797$	$r = 0.498^{**}$ $p < 0.001$	$r = 0.133$ $p = 0.375$	$r = 0.464^{**}$ $p = 0.001$	$r = 0.593^{**}$ $p < 0.001$	$r = 0.588^{**}$ $p < 0.001$	
PCSQ control over pain	$r = 0.164$ $p = 0.272$	$r = -0.110$ $p = 0.460$	$r = -0.055$ $p = 0.712$	$r = 0.231$ $p = 0.118$	$r = -0.204$ $p = 0.168$	$r = 0.381^{**}$ $p = 0.008$	
PCSQ ability to decrease pain	$r = 0.201$ $p = 0.176$	$r = -0.118$ $p = 0.431$	$r = -0.078$ $p = 0.603$	$r = 0.222$ $p = 0.134$	$r = -0.160$ $p = 0.282$	$r = 0.327^{*}$ $p = 0.025$	
PCSQ cognitive coping/suppression	$r = 0.033$ $p = 0.827$	$r = 0.493^{**}$ $p < 0.001$	$r = 0.788^{**}$ $p < 0.001$	$r = 0.020$ $p = 0.896$	$r = 0.884^{**}$ $p < 0.001$	$r = 0.428^{**}$ $p = 0.003$	$r = 0.830^{**}$ $p < 0.001$
PCSQ helplessness	$r = -0.106$ $p = 0.478$	$r = -0.133$ $p = 0.373$	$r = -0.034$ $p = 0.820$	$r = 0.765^{**}$ $p < 0.001$	$r = -0.310^{*}$ $p = 0.034$	$r = -0.004$ $p = 0.978$	$r = -0.526^{**}$ $p < 0.001$
PCSQ diverting attention/ hoping and praying	$r = -0.069$ $p = 0.647$	$r = 0.852^{**}$ $p < 0.001$	$r = 0.645^{**}$ $p < 0.001$	$r = 0.330^{*}$ $p = 0.023$	$r = 0.307^{*}$ $p = 0.036$	$r = 0.865^{**}$ $p < 0.001$	$r = 0.455^{**}$ $p = 0.001$
HAD anxiety	$r = 0.142$ $p = 0.341$	$r = 0.267$ $p = 0.069$	$r = 0.157$ $p = 0.290$	$r = 0.624^{**}$ $p < 0.001$	$r = 0.009$ $p = 0.953$	$r = 0.147$ $p = 0.325$	$r = -0.152$ $p = 0.309$
HAD depression	$r = 0.021$ $p = 0.891$	$r = 0.154$ $p = 0.303$	$r = 0.002$ $p = 0.990$	$r = 0.569^{**}$ $p < 0.001$	$r = -0.185$ $p = 0.213$	$r = -0.053$ $p = 0.726$	$r = -0.305^{*}$ $p = 0.037$

\* Correlation is significant at the 0.05 level (2-tailed) / \*\* Correlation is significant at the 0.01 level (2-tailed)

Table 6.3 (continued) Correlation of six month percentage pain reduction with baseline assessment

	PCSQ increased behavioural activity	PCSQ control over pain	PCSQ ability to decrease pain	PCSQ cognitive coping/suppression	PCSQ helplessness	PCSQ diverting attention/ hoping and praying	HAD anxiety
PCSQ control over pain	$r = 0.199$ $p = 0.179$						
PCSQ ability to decrease pain	$r = 0.162$ $p = 0.278$	$r = 0.689^{**}$ $p < 0.001$					
PCSQ cognitive coping/suppression	$r = 0.592^{**}$ $p < 0.001$	$r = 0.235$ $p = 0.112$	$r = 0.201$ $p = 0.175$				
PCSQ helplessness	$r = -0.423^{**}$ $p = 0.003$	$r = -0.654^{**}$ $p < 0.001$	$r = -0.444^{**}$ $p = 0.002$	$r = -0.338^*$ $p = 0.020$			
PCSQ diverting attention/ hoping and	$r = 0.586^{**}$ $p < 0.001$	$r = -0.097$ $p = 0.517$	$r = -0.079$ $p = 0.598$	$r = 0.568^{**}$ $p < 0.001$	$r = -0.105$ $p = 0.481$		
HAD anxiety	$r = 0.124$ $p = 0.405$	$r = -0.276$ $p = 0.060$	$r = -0.048$ $p = 0.750$	$r = 0.002$ $p = 0.988$	$r = 0.475^{**}$ $p = 0.001$	$r = 0.186$ $p = 0.210$	
HAD depression	$r = -0.315^*$ $p = 0.031$	$r = -0.361^*$ $p = 0.013$	$r = -0.201$ $p = 0.175$	$r = -0.182$ $p = 0.221$	$r = 0.627^{**}$ $p < 0.001$	$r = 0.049$ $p = 0.746$	$r = 0.577^{**}$ $p < 0.001$

\* Correlation is significant at the 0.05 level (2-tailed) / \*\* Correlation is significant at the 0.01 level (2-tailed)

### Twelve months

At 12 months there were significant correlations between percentage pain reduction and the PCSQ and HAD baseline variables (Table 6.4). A significant negative correlation was observed between pain reduction and the PCSQ catastrophising score,  $r = -0.378$ ,  $p = 0.016$ , indicating that as pain reduction increases, the catastrophising scores decrease. Pain reduction was also positively correlated with the PCSQ control over pain score,  $r = 0.424$ ,  $p = 0.006$ , which suggests that as pain reduction increases, the control over pain scores increase. A significant positive correlation was also observed between pain reduction and the PCSQ ability to decrease pain subscale,  $r = 0.317$ ,  $p = 0.046$ , which implies that as pain reduction increases, the ability to decrease pain score also increases. The percentage pain reduction variable was negatively correlated with the PCSQ helplessness score,  $r = -0.471$ ,  $p = 0.002$ , therefore suggesting that as pain reduction increases, the helplessness subscale scores decrease. These correlations demonstrate medium strength relationships ( $r \geq 0.3$ ) (Moore 2010).

Similarly to the six month analysis, there were a number of baseline variables indicating strong correlations with one another ( $r \geq 0.7$ ). These correlations were observed between composite variables and their associated subscales: PCSQ diverting attention and hoping/praying with PCSQ diverting attention; the composite score PCSQ cognitive coping and suppression with PCSQ reinterpreting pain, PCSQ ignoring sensations and PCSQ coping self statements; and PCSQ helplessness composite with the PCSQ catastrophising subscale. These composite variables will not be included in the logistic regression, due to being an amalgamation of the subscale variables included in the PCSQ and since the subscales were suggested to have greater utility in terms of examining coping than the composite scores (Geisser, Robinson and Henson 1994).

Table 6.4 Correlation matrix of twelve month percentage pain reduction with baseline assessment variables

	Percentage of pain reduction	PCSQ diverting attention	PCSQ reinterpreting pain	PCSQ catastrophising	PCSQ ignoring sensations	PCSQ praying or hoping	PCSQ coping self-statements
PCSQ diverting attention	$r = -0.210$ $p = 0.194$						
PCSQ reinterpreting pain	$r = -0.019$ $p = 0.906$	$r = 0.591^{**}$ $p < 0.001$					
PCSQ catastrophising	$r = -0.378^*$ $p = 0.016$	$r = 0.425^{**}$ $p = 0.006$	$r = 0.429^{**}$ $p = 0.006$				
PCSQ ignoring sensations	$r = 0.020$ $p = 0.901$	$r = 0.336^*$ $p = 0.034$	$r = 0.499^{**}$ $p = 0.001$	$r = 0.111$ $p = 0.495$			
PCSQ praying or hoping	$r = -0.088$ $p = 0.588$	$r = 0.638^{**}$ $p < 0.001$	$r = 0.622^{**}$ $p < 0.001$	$r = 0.580^{**}$ $p < 0.001$	$r = 0.221$ $p = 0.170$	$r = 0.362^*$ $p = 0.022$	$r = 0.496^{**}$ $p = 0.001$
PCSQ coping self-statements	$r = 0.162$ $p = 0.317$	$r = 0.323^*$ $p = 0.042$	$r = 0.381^*$ $p = 0.015$	$r = 0.045$ $p = 0.783$	$r = 0.637^{**}$ $p < 0.001$	$r = 0.584^{**}$ $p < 0.001$	$r = 0.344^*$ $p = 0.030$
PCSQ increased behavioural activity	$r = 0.016$ $p = 0.920$	$r = 0.502^{**}$ $p = 0.001$	$r = 0.539^{**}$ $p < 0.001$	$r = 0.393^*$ $p = 0.012$	$r = 0.483^{**}$ $p = 0.002$	$r = 0.584^{**}$ $p < 0.001$	$r = 0.403^{**}$ $p = 0.010$
PCSQ control over pain	$r = 0.424^{**}$ $p = 0.006$	$r = -0.120$ $p = 0.460$	$r = -0.144$ $p = 0.377$	$r = -0.480^{**}$ $p = 0.002$	$r = 0.192$ $p = 0.234$	$r = -0.190$ $p = 0.240$	$r = 0.344^*$ $p = 0.030$
PCSQ ability to decrease pain	$r = 0.317^*$ $p = 0.046$	$r = -0.124$ $p = 0.445$	$r = -0.148$ $p = 0.361$	$r = -0.407^{**}$ $p = 0.009$	$r = 0.210$ $p = 0.193$	$r = -0.134$ $p = 0.412$	$r = 0.403^{**}$ $p = 0.010$
PCSQ cognitive coping/suppression	$r = 0.068$ $p = 0.678$	$r = 0.496^{**}$ $p = 0.001$	$r = 0.773^{**}$ $p < 0.001$	$r = 0.222$ $p = 0.170$	$r = 0.872^{**}$ $p < 0.001$	$r = 0.467^{**}$ $p = 0.002$	$r = 0.792^{**}$ $p < 0.001$
PCSQ helplessness	$r = -0.471^{**}$ $p = 0.002$	$r = -0.041$ $p = 0.800$	$r = 0.093$ $p = 0.568$	$r = 0.670^{**}$ $p < 0.001$	$r = -0.249$ $p = 0.121$	$r = 0.099$ $p = 0.544$	$r = -0.371^*$ $p = 0.019$
PCSQ diverting attention/ hoping and praying	$r = -0.124$ $p = 0.448$	$r = 0.863^{**}$ $p < 0.001$	$r = 0.674^{**}$ $p < 0.001$	$r = 0.488^{**}$ $p = 0.001$	$r = 0.330^*$ $p = 0.037$	$r = 0.863^{**}$ $p < 0.001$	$r = 0.432^{**}$ $p = 0.005$
HAD anxiety	$r = -0.036$ $p = 0.824$	$r = 0.377^*$ $p = 0.017$	$r = 0.273$ $p = 0.088$	$r = 0.597^{**}$ $p < 0.001$	$r = 0.093$ $p = 0.566$	$r = 0.349^*$ $p = 0.027$	$r = 0.061$ $p = 0.708$
HAD depression	$r = -0.233$ $p = 0.148$	$r = 0.284$ $p = 0.076$	$r = 0.105$ $p = 0.518$	$r = 0.558^{**}$ $p < 0.001$	$r = -0.147$ $p = 0.364$	$r = 0.121$ $p = 0.457$	$r = -0.172$ $p = 0.290$

\* Correlation is significant at the 0.05 level (2-tailed) / \*\* Correlation is significant at the 0.01 level (2-tailed)

Table 6.4 (continued) Correlation matrix of twelve month percentage pain reduction with baseline assessment variables

	PCSQ increased behavioural activity	PCSQ control over pain	PCSQ control decrease pain	PCSQ cognitive coping/suppression	PCSQ helplessness	PCSQ diverting attention/ hoping and praying	HAD anxiety
PCSQ control over pain	$r = 0.199$ $p = 0.217$						
PCSQ ability to decrease pain	$r = 0.209$ $p = 0.197$	$r = 0.745^{**}$ $p < 0.001$					
PCSQ cognitive coping/suppression	$r = 0.597^{**}$ $p < 0.001$	$r = 0.172$ $p = 0.289$	$r = 0.191$ $p = 0.237$				
PCSQ helplessness	$r = -0.277$ $p = 0.083$	$r = -0.729^{**}$ $p < 0.001$	$r = -0.662^{**}$ $p < 0.001$	$r = -0.211$ $p = 0.190$			
PCSQ diverting attention/ hoping and	$r = 0.576^{**}$ $p < 0.001$	$r = -0.079$ $p = 0.628$	$r = -0.064$ $p = 0.695$	$r = 0.597^{**}$ $p < 0.001$	$r = -0.017$ $p = 0.919$		
HAD anxiety	$r = 0.400^*$ $p = 0.011$	$r = -0.322^*$ $p = 0.043$	$r = -0.182$ $p = 0.261$	$r = 0.157$ $p = 0.334$	$r = 0.346^*$ $p = 0.029$	$r = 0.342^*$ $p = 0.031$	
HAD depression	$r = -0.102$ $p = 0.529$	$r = -0.427^{**}$ $p = 0.006$	$r = -0.381^*$ $p = 0.015$	$r = -0.079$ $p = 0.627$	$r = 0.573^{**}$ $p < 0.001$	$r = 0.210$ $p = 0.194$	$r = 0.479^{**}$ $p = 0.002$

\* Correlation is significant at the 0.05 level (2-tailed) / \*\* Correlation is significant at the 0.01 level (2-tailed)

### Comparison of six and 12 month correlations

The majority of correlations between percentage pain reduction and the independent variables continued in the same direction (positive or negative correlation) when comparing six and 12 months. However, the correlations of pain reduction with PCSQ reinterpreting pain, HAD anxiety and HAD depression changed from positive correlations at six months to negative correlations at 12 months. As pain reduction increases at 12 months PCSQ reinterpreting pain, HAD anxiety and HAD depression scores decrease. The opposite occurred at six months. The correlations of pain reduction with PCSQ coping self-statements and PCSQ increased behavioural activity changed from negative correlations at six months to positive correlations at 12 months. This suggests that at 12 months, as pain reduction increases so do PCSQ coping self-statements and PCSQ increased behavioural activity, whereas at six months, the results suggest that as pain reduction increased PCSQ coping self-statements and PCSQ increased behavioural activity decreased. It should be noted however, that none of the variables that changed direction were significantly correlated with pain reduction at either six or 12 months.

#### *6.4.3.2 Multicollinearity*

The statistics for tolerance and variance inflation factor (VIF) were run for the six and 12 months variables to test for multicollinearity among the independent variables (appendix 14). Menard (1995) suggests that a tolerance value  $< 0.1$  is problematic. The tolerance values for the variables entered into the logistic regression were all  $> 0.1$  for the six month data (range 0.306 to 0.471) and for the 12 month data (range 0.281 to 0.496). Myers (1990) proposes that a VIF value  $> 10$  is problematic. The VIF results for the variables entered into the logistic regression were all  $< 10$  for the six-month data (range 2.122 to 3.270) and for the 12 month data (range 2.017 to 3.558).

Following investigation of multicollinearity, the predictor variables (diverting attention, reinterpreting pain, catastrophising, ignoring sensations, praying or hoping, coping self statements, increased behavioural activity, control over pain, ability to decrease pain, anxiety and depression) were entered into the logistic regression analysis. Predictive Analytics SoftWare (PASW) (version 17.0, SPSS Inc., Chicago, IL, USA) was used to carry

out a backward stepwise logistic regression analysis of the relationships between percentage pain reduction at six and 12 months and the baseline psychological variables.

#### *6.4.3.3 Logistic regression at six and 12 months*

A backwards-stepwise logistic regression was performed to analyse the relationship between the baseline psychological variables and  $\geq 30\%$  pain improvement at six months and 12 months. Variables were removed from the model based on the strength of relationship they had with the model. The criterion for remaining in the model was set at an alpha level of 0.05 for all predictor variables (Field 2009). This process resulted in no significant predictors remaining in a model at six months. Therefore, it can be concluded that no psychological predictors of outcome could be identified with the six month analysis in this cohort. The analysis for the 12 months data resulted in the identification of three psychological predictors for the model: catastrophising, control over pain and anxiety (appendix 15).

#### *6.4.3.4 Tests for the assumptions for logistic regression*

##### Linearity in the logit

Logistic regression assumes a linear relationship between continuous predictors and the logit transform of the predictor variables. To test for linearity in the logit, interaction terms were created and a logistic regression was run, including the predictors that are an interaction between each predictor and the log of itself (Field 2009). The interaction terms did not generate any significant results ( $< 0.05$ ), which indicated that the assumption of linearity of the logit had been met and not violated (appendix 14).

##### Absence of outliers

Outliers can result in a model that does not fit the data satisfactory. Outliers were investigated by examining the residuals (appendix 16). The standardised residuals were checked for no more than 5% of cases having absolute values  $> 2$  and no more than 1% of cases having absolute values  $> 2.5$  (Field 2009). These criteria resulted in the removal of one patient case. Cook's distance was examined for any values  $> 1$  as these could result in single cases influencing the model (Field 2009). All the values were  $< 1$ . The average leverage was calculated (number of predictors plus one, divided by the sample size) and values were verified to ensure that no values were superior to three times the average



leverage value (Field 2009). The DfBeta values were explored to ensure that no values were > 1 (Field 2009). The DfBeta values allow identifying any cases that have a large influence on the parameters of the regression model.

Independence of errors

Another assumption for logistic regression is that different cases are independent of each other. All the data originated from different individuals and is therefore unrelated, confirming a between-subjects strategy (Tabachnik and Fidell 2007).

All assumptions were investigated and met, which indicated that the data were satisfactory to be analysed in a logistic regression (appendices 14, 15 and 16).

*6.4.3.5 Description of the developed model*

The model successfully predicted 21 of the 26 participants with < 30% reduction in pain (80.8%) and nine of the 13 participants with ≥ 30% improvement in pain (69.2%), giving an overall prediction rate of 76.9%. Table 6.5 depicts the model statistics for the predictive variables. The odds ratio can be calculated if we exponentiate the beta coefficient. Therefore a one point increase in anxiety multiples the odds by a factor of 1.448, a one point increase in control over pain score increases the odds by a factor of 3.456, whereas a one point increase in catastrophising multiplies the odds by a factor of 0.723, which reduces the odds of successful ≥ 30% reduction in pain by 28%. The odds are gained by dividing the probability of ≥ 30% pain relief by the probability of < 30% pain relief.

Table 6.5 12 month backwards stepwise logistic regression

	β (SE)	95% CI for Odds Ratio		
		Lower	Odds Ratio	Upper
Constant	-3.441 (1.997)			
Catastrophising	-0.324* (0.142)	0.547	0.723	0.955
Control over pain	1.240* (0.609)	1.047	3.456	11.405
Anxiety	0.370* (0.185)	1.007	1.448	2.082

R<sup>2</sup> = 0.318 (Hosmer & Lemeshow); 0.388 (Cox & Snell); 0.538 (Nagelkerke)

Model X<sup>2</sup>(2) = 19.120, p < 0.001

\* p < 0.05

According to this model, to have a higher probability of a  $\geq 30\%$  improvement in pain after 12 months, a patient would need to score lower for the PCSQ variable catastrophising, and higher for the variables HAD anxiety and PCSQ control over pain.

#### *6.4.3.6 Power analysis*

A post hoc power analysis was calculated using G\*Power 3 (G\*Power 3) to estimate the sample size required (based on the coefficients of the presented model) for an 80% chance of avoiding a type II error at the  $p = 0.05$  significance level. That is if the relationships between the three predictor variables and the criterion variable are genuine. Based on the post hoc calculations, it was estimated that for the variable control over pain, 36 participants would be required (appendix 17a and 17b). In the current study 39 participants were included in the final analysis. Based on the anxiety variable, 51 patients would be needed (appendix 18a and 18b), whereas 119 participants would be necessary for the variable catastrophising (appendix 19a and 19b). Thus, based on the coefficient gained for the weakest predictor (catastrophising) a minimum sample size of 119 would be required to obtain a power of 0.8.

An alternative calculation suggested by Peduzzi et al. (1996) was also used to estimate the required sample size. Peduzzi and colleagues suggest that the number of covariates (three in this case) should be divided by the smaller proportion of positive or negative cases in a population or sample. In the present study, the mentioned proportion would refer to those participants with percentage of pain  $\geq 30\%$  (one third of the sample). Therefore,  $3 / 0.33 = 9.09$ . The resultant figure should then be multiplied by 10,  $9.09 \times 10 = 90.9$  (which would be rounded up to 91).

The two presented estimates are approximate (85 and 91). Nevertheless, Long (1997) recommends that if estimates of required sample size fall below 100 participants, then they should be increased to this figure. Therefore, for validation of the present model, a minimum of 100 participants should be recruited. The developed model is underpowered and should remain tentative until further analysis can be made.

#### 6.4.3.7 Use of the model for prediction

Using the information provided in table 6.5 we can tentatively predict the likelihood that an individual will get  $\geq 30\%$  improvement in pain relief after 12 months of treatment with spinal cord stimulation.

$$\text{Probability } (\geq 30\% \text{ improvement in pain relief}) = \frac{e^{k_1 + k_2(c) + k_3(co) + k_4(a)}}{1 + e^{k_1 + k_2(c) + k_3(co) + k_4(a)}}$$

In this equation  $\underline{e}$  symbolises the logarithm,  $\underline{k}_1$  represents the constant value of -3.441,  $\underline{k}_2$  the change in the outcome resulting from a unit change in the catastrophising variable, which is represented by the constant value of -0.324,  $\underline{c}$  signifies the individual catastrophising score derived from the PCSQ,  $\underline{k}_3$  is the change in the outcome resulting from a unit change in the control over pain variable represented by the constant value of 1.240,  $\underline{co}$  symbolises the individual control over pain score derived from the PCSQ;  $\underline{k}_4$  is the change in the outcome resulting from a unit change in the anxiety variable represented by the value of 0.370, and  $\underline{a}$  denotes the individual anxiety score resultant from the PCSQ. The patient scores replace the corresponding symbols in the equation for the variables catastrophising, control over pain and anxiety. This will indicate the probability for the likelihood that a patient will obtain  $\geq 30\%$  reduction in pain at 12 months following SCS.

#### Twelve month worked example 1

The following two worked examples use the tentative model to demonstrate that predictions of outcome with high levels of anxiety scores are moderated by levels of catastrophising and control over pain. A poorer outcome is expected if anxiety and catastrophising are moderately high and control over pain is low.

**Patient with <30% pain reduction**

Scores on Pain Coping Strategies Questionnaire (catastrophising and control over pain variables) and Hospital Anxiety and Depression questionnaire (anxiety variable).

Catastrophising **15**

Control over pain **1**

Anxiety **8**

$$Prob (\geq 30\% \text{ improvement in pain relief}) = \frac{e^{-3.441+(-0.324)(cat)+(1.240)(C.O.P)+(0.370)(anx)}}{1+e^{-3.441+(-0.324)(cat)+(1.240)(C.O.P)+(0.370)(anx)}}$$

$$Prob (\geq 30\% \text{ improvement in pain relief}) = \frac{e^{-3.441+(-4.86)+(1.24)+(2.96)}}{1 + e^{-3.441+(-4.86)+(1.24)+(2.96)}}$$

$$Prob (\geq 30\% \text{ improvement in pain relief}) = \frac{0.017}{1.017}$$

$$Prob (\geq 30\% \text{ improvement in pain relief}) = 0.02$$

This patient has a very low probability of obtaining  $\geq 30\%$  pain reduction (0.02). The probability of this individual obtaining  $< 30\%$  pain reduction is  $(1 - 0.02) = 0.98$ .

Twelve month worked example 2

When the anxiety variable remains at a score of eight, but catastrophising decreases and control over pain increases, the probability of outcome is much improved.

**Patient obtaining  $\geq 30\%$  pain reduction**

Scores on Pain Coping Strategies Questionnaire (catastrophising and control over pain variables) and Hospital Anxiety and Depression questionnaire (anxiety variable).

Catastrophising **6**

Control over pain **3**

Anxiety **8**

$$Prob (\geq 30\% \text{ improvement in pain relief}) = \frac{e^{-3.441+(-0.324)(cat)+(1.240)(C.O.P)+(0.370)(anx)}}{1+e^{-3.441+(-0.324)(cat)+(1.240)(C.O.P)+(0.370)(anx)}}$$

$$Prob (\geq 30\% \text{ improvement in pain relief}) = \frac{e^{-3.441+(-1.944)+(3.72)+(2.96)}}{1 + e^{-3.441+(-1.944)+(3.72)+(2.96)}}$$

$$Prob (\geq 30\% \text{ improvement in pain relief}) = \frac{3.651}{4.651}$$

$$Prob (\geq 30\% \text{ improvement in pain relief}) = 0.78$$

This individual has a very high probability of obtaining  $\geq 30\%$  pain reduction (0.78). The probability of this patient obtaining  $< 30\%$  pain reduction is  $(1 - 0.78) = 0.22$ .

#### Failed trial patients

Failed trial patients were not included in the follow up at six and 12 months. This was due to the distress they experienced following the failed trial. When questioned, participants did not want to be part of a follow up. However, baseline data is available for comparison. For interest, the mean baseline scores for the eight failed trial patients were also entered as a worked example to determine probability of success.

*Scores on Pain Coping Strategies Questionnaire (catastrophising and control over pain variables) and Hospital Anxiety and Depression questionnaire (anxiety variable).*

Catastrophising; N=8, mean score  $20.38 \pm 8.67$  (range 9-32)

Control over pain; N=8, mean score  $1.75 \pm 1.39$  (range 0-4)

Anxiety; N=8, mean score  $11.13 \pm 3.04$  (range 6-15).

$$Prob (\geq 30\% \text{ improvement in pain relief}) = \frac{e^{-3.441+(-0.324)(cat)+(1.240)(C.O.P)+(0.370)(anx)}}{1+e^{-3.441+(-0.324)(cat)+(1.240)(C.O.P)+(0.370)(anx)}}$$

$$Prob (\geq 30\% \text{ improvement in pain relief}) = \frac{e^{-3.441+(-6.60)+(2.17)+(4.12)}}{1 + e^{-3.441+(-6.60)+(2.17)+(4.12)}}$$

$$Prob (\geq 30\% \text{ improvement in pain relief}) = \frac{0.023}{1.023}$$

$$Prob (\geq 30\% \text{ improvement in pain relief}) = 0.02$$

In this example, the probability of obtaining  $\geq 30\%$  pain reduction is very low (0.02). Contrarily, a very high probability of obtaining  $< 30\%$  pain reduction is observed [(1 – 0.02) = 0.98]. This result suggests that the tentative model identifies correctly those patients who are likely to fail the trial.

#### 6.4.3.8 Exploration of variables included in the equation

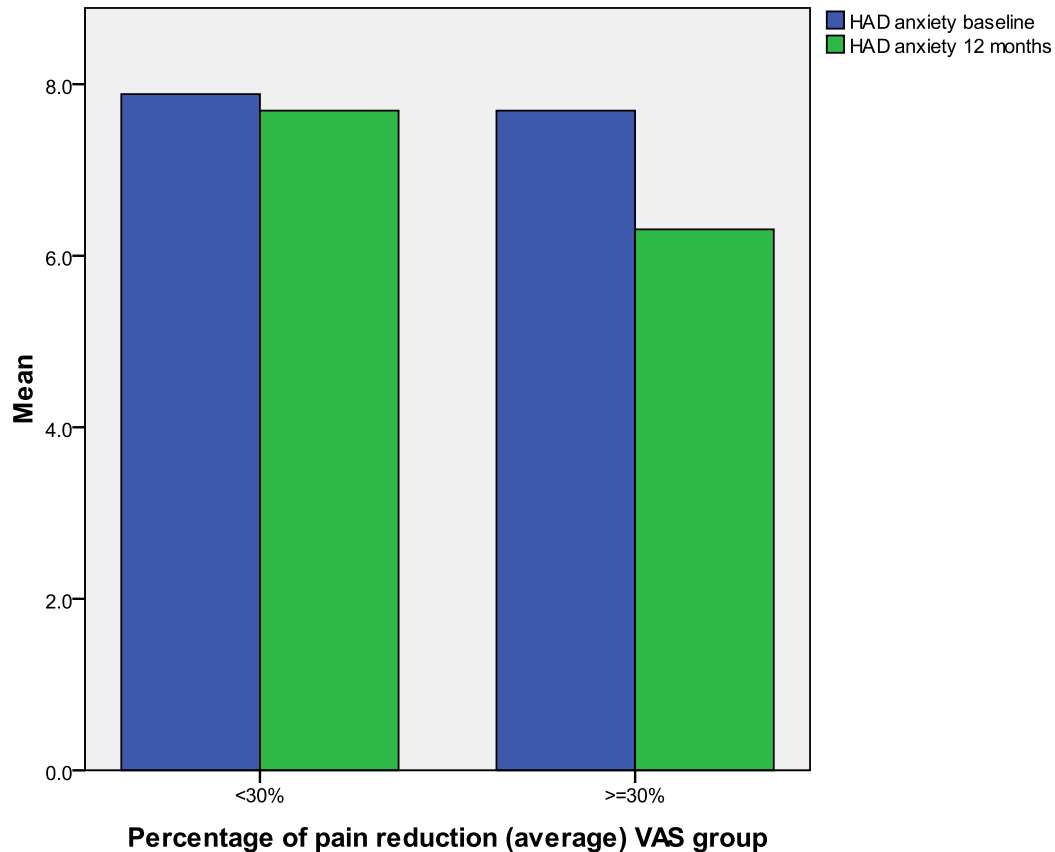
The following section provides the descriptive statistics for the variables of interest (catastrophising, control over pain and anxiety) that as a result of the analysis were included in the predictive equation for probability of success with SCS treatment ( $<30\%$  and  $\geq 30\%$  pain reduction). The printouts of the t-tests in the following section are included in appendix 20.

Table 6.6 Descriptive statistics for anxiety variable

Anxiety	N	Minimum	Maximum	Mean	Std.Deviation
Baseline $< 30\%$	26	2	16	7.89	4.38
Baseline $\geq 30\%$	13	2	16	7.69	4.01
12 months $< 30\%$	26	0	16	7.69	3.89
12 months $\geq 30\%$	13	0	13	6.31	3.27

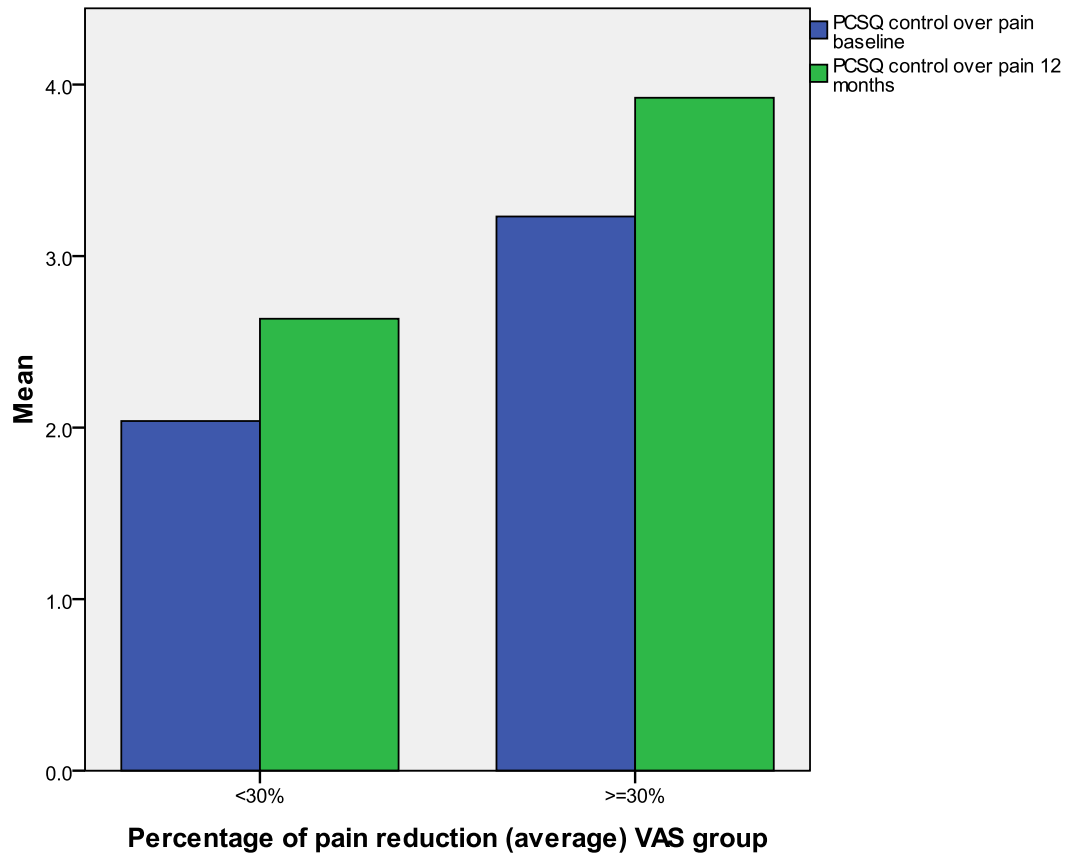
On average, the patients that obtained  $<30\%$  pain reduction, experienced greater anxiety at baseline than participants in the  $\geq 30\%$  pain reduction group (figure 6.4, table 6.6). This difference was not statistically significant  $t(37) = 0.133$ ,  $p = 0.895$ , and the effect size was small  $r = 0.002$  (figure 6.4, Table 6.5). Likewise at 12 months on average participants in the

<30% pain reduction group experienced greater anxiety than the patients who obtained  $\geq$  30% pain reduction. This difference was not significant  $t(37) = 1.10$ ,  $p = 0.279$ , with a small effect size  $r = 0.178$ .



**Figure 6.4 Mean HAD anxiety scores by pain reduction group at baseline & 12 months**

On average, participants in the  $\geq$  30% pain reduction group experienced greater control over pain at baseline than participants in the < 30% pain reduction group (figure 6.5, table 6.7). This difference was significant  $t(37) = -3.61$ ,  $p = 0.001$ , with a medium effect size  $r = 0.51$ . At 12 months, the participants in the  $\geq$  30% pain reduction group experienced on average greater control over pain than participants in the < 30% pain reduction group ( $M = 2.64$ ,  $SE = 0.28$ ). This difference was statistically significant  $t(37) = -2.83$ ,  $p = 0.008$ , with a medium effect size  $r = 0.42$ .



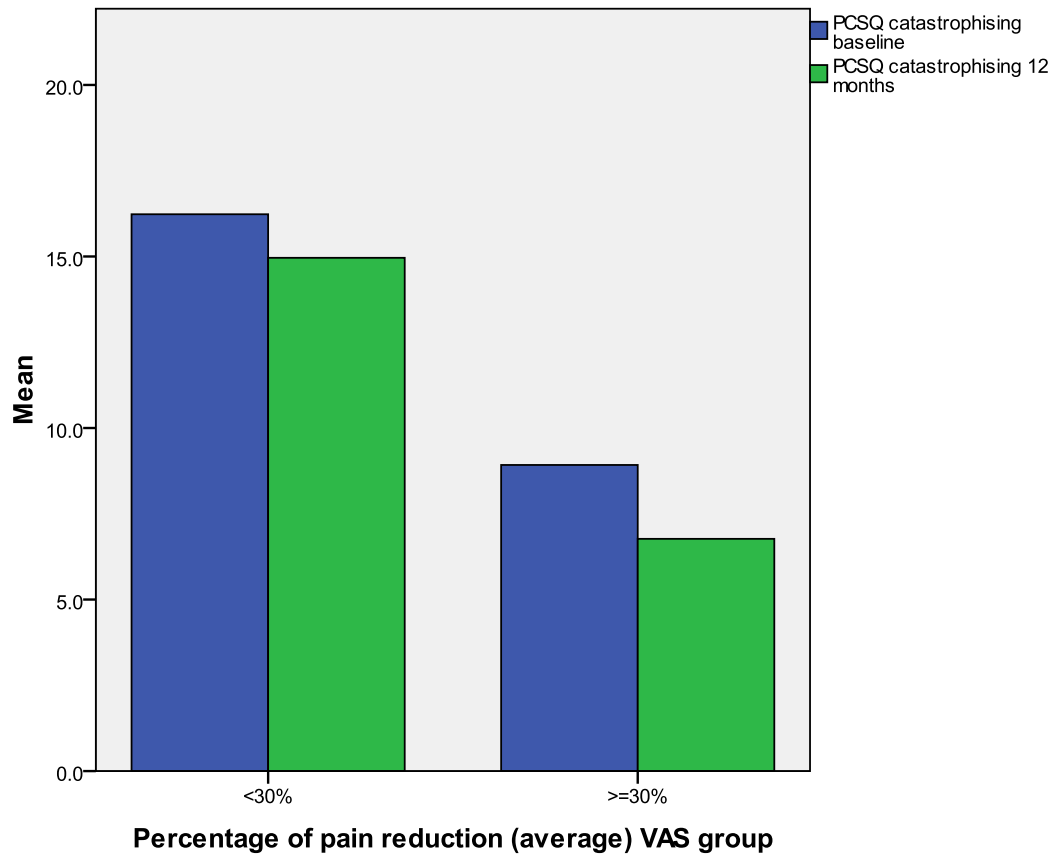
**Figure 6.5 Mean PCSQ control over pain scores by pain reduction group at baseline & 12 months**

**Table 6.7 Descriptive statistics for control over pain variable**

Control over pain	N	Minimum	Maximum	Mean	Std.Deviation
Baseline < 30%	26	0	4	2.04	1.46
Baseline ≥ 30%	13	2	4	3.23	0.59
12 months < 30%	26	0	5	2.64	1.41
12 months ≥ 30%	13	3	6	3.92	1.19

The patients in the < 30% pain reduction group experienced greater catastrophising at baseline than participants in the ≥ 30% pain reduction group (figure 6.6, table 6.8). This difference was significant  $t(37) = 2.70, p = 0.010$ , with an effect of medium size  $r = 0.41$ . After 12 months, the patients in the <30% pain reduction group experienced on average greater catastrophising than participants in the ≥ 30% pain reduction group. This difference was statistically significant  $t(37) = 2.72, p = 0.010$  and the effect size was medium  $r = 0.40$ .

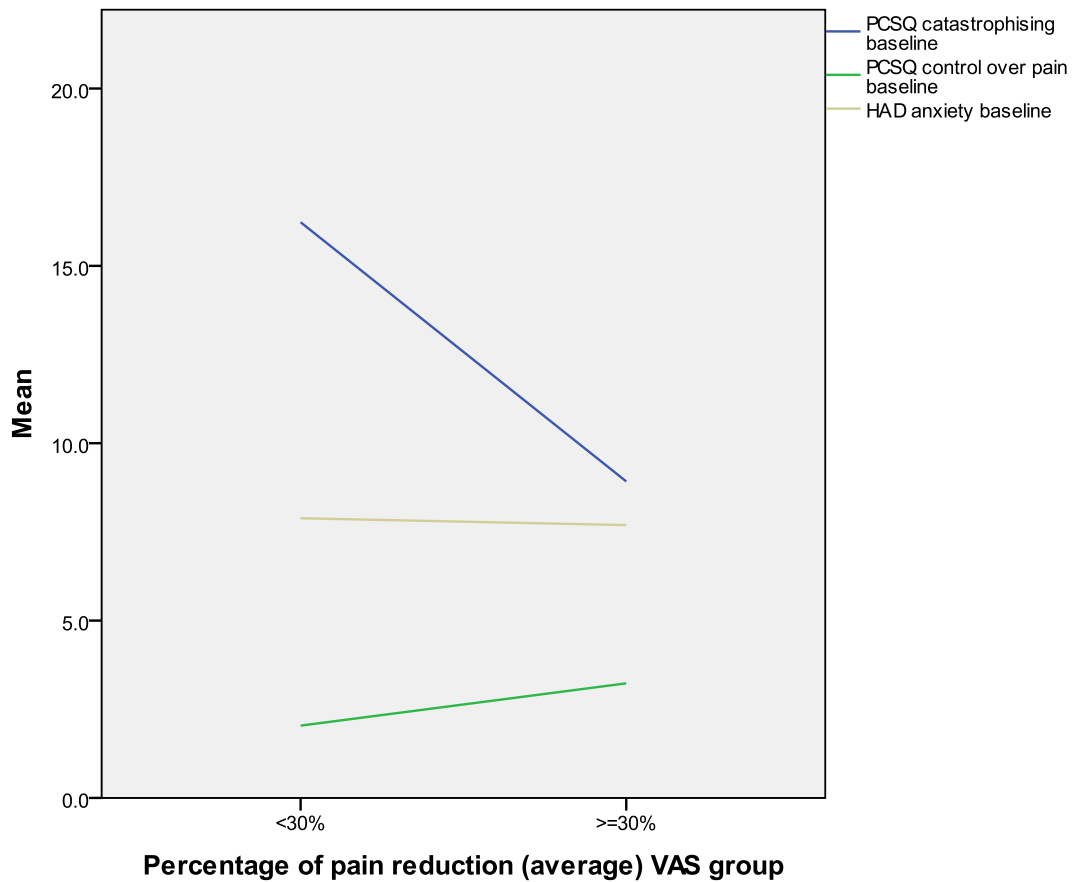




**Figure.6.6 Mean PCSQ catastrophising scores by pain reduction at 12 months**

**Table 6.8 Descriptive statistics for catastrophising variable**

Catastrophising	N	Minimum	Maximum	Mean	Std.Deviation
Baseline < 30%	26	2	36	16.23	8.81
Baseline ≥ 30%	13	0	22	8.92	5.75
12 months < 30%	26	2	36	14.96	9.28
12 months ≥ 30%	13	0	22	6.76	7.87



**Figure 6.7 Mean scores at baseline by pain reduction group**

Figure 6.7 illustrates the relationship between the variables anxiety, catastrophising and control over pain. As illustrated in the figure, moderate anxiety scores paired alongside higher control over pain and lower catastrophising scores result in a higher probability of  $\geq 30\%$  pain reduction.

### 6.5 Discussion

A review of previous studies was inconclusive in relation to predictive psychological variables of SCS efficacy. This study followed patients throughout their SCS treatment for one year, recording variables at baseline, six months and one year to investigate relationships between psychological variables and  $\geq 30\%$  pain reduction following one year of SCS treatment.

### Correlations

Correlations of percentage pain reduction with EQ5D and Oswestry disability questionnaire revealed results that would be expected. Apart from the correlation between EQ5D score and percentage pain reduction at six months, the other three correlations were significant (Oswestry with percentage pain reduction at six and 12 months, and EQ5D score with percentage pain reduction at 12 months). This suggests that as the percentage pain reduction increases, the disability score decreases and EQ5D score increases. It can be hypothesised that the correlation between EQ5D and percentage pain reduction was not statistically significant after six months due to the short time period and the possibility that perceptual changes in overall health may not have been obvious to individuals at this early stage.

### Six month analysis

Analysis of the data at six months revealed that none of the Pain Coping Strategy questionnaire variables or the Hospital Anxiety and Depression questionnaire variables were predictive of  $\geq 30\%$  pain reduction. It appears that it is too early in the treatment to be able to establish predictors of  $\geq 30\%$  pain reduction.

Placebo effects are not uncommon, especially for pain relief treatments (Evans 1974). There are huge expectations on the treatment (SCS) being a success. Often expectations may be high due to the cost of the equipment, invasive nature and the desperation individuals may experience due to having unsuccessfully tried many other treatments to obtain pain relief. The expectations about the placebo will interact with effectiveness of treatments (Shapiro and Shapiro 1997). It can be hypothesised that a placebo effect may be present during this six month period, hence the non-observation of potential predictors of pain reduction.

### Twelve month analysis

Analysis of data at 12 months resulted in two of the PCSQ variables (catastrophising and control over pain) and one of the HAD variables (anxiety) being predictive of  $\geq 30\%$  pain reduction when included in a logistic regression analysis. Unlike the analysis of the six months data, the 12 months analysis resulted in the identification of predictors. The logistic regression analysis demonstrated that an individual who scored lower on catastrophising and higher on the variables control over pain and anxiety at baseline would have a higher

probability of obtaining  $\geq 30\%$  reduction in pain at 12 months. The power analysis revealed that the statistical analysis was underpowered. The model remains tentative.

However, anxiety was negatively correlated with control over pain and positively correlated with catastrophising indicating that as anxiety increases, control over pain decreases and catastrophising increases. This demonstrates anxiety levels to have a potentially negative impact if they increase due to the relationship with control over pain and catastrophising. The 12 month worked examples reveal that moderate levels of anxiety may be acceptable, but higher scores on control over pain alongside lower scores on catastrophising are needed for a higher probability of success according to the developed model.

#### Failed trial patients

Although not included in the final analysis due to low numbers and patients choosing not to participate in the follow ups, baseline data was available for failed trial patients. The mean baseline scores for failed trial patients demonstrated a poor probability of outcome when included in the equation to predict  $\geq 30\%$  pain reduction. Failed trial patients had a high mean catastrophising score, a high mean anxiety score ( $> 11$  which is classed as anxiety), and lower mean control over pain score in comparison to non-failed trial patients. Although the analysis of patients who underwent full implantation of SCS revealed that a moderately high score for anxiety may not reduce treatment efficacy, failed trial patients presented high mean anxiety scores, coupled with low control over pain and high catastrophising. It can be hypothesised that the trial has high specificity for SCS suitability selection when considering the psychological variable mean scores included in the predictive equation for failed trial patients. The failed trial patients mean baseline scores predict a very low chance of successful outcome according to the developed equation. However the trial may have low sensitivity as not all the patients who have a successful trial achieve  $\geq 30\%$  pain relief when measured at one year. Specificity and sensitivity of the equation require further testing.

#### Catastrophising

Catastrophising was one of the variables identified as a predictor for the model at 12 months with a lower score on this variable being required to increase the probability of obtaining  $\geq 30\%$  pain reduction after 12 months of SCS therapy. Although the results demonstrate that catastrophising scores reduced for both groups over the one year period, those that

obtained < 30% reduction in pain have higher scores at baseline, which remain higher at 12 months than in the  $\geq$  30% pain reduction group.

As previously discussed, catastrophising is renowned for impacting on attention to pain resulting in more attention to unpleasant sensations and therefore increasing pain intensity reporting. One element of catastrophising can be recognised as giving and maintaining attention to pain, leading to rumination over the pain sensations and to magnification of these sensations (Sullivan, Rodgers and Kirsch 2001). Catastrophising can be influenced by social factors since individuals' pain will often be responded to with the offer of help and sympathy/empathy and therefore, they may rely more heavily upon others for help and support rather than their own self-efficacy. This has been suggested to impact upon disability and increase avoidance behaviours (Turk, Meichenbaum and Genest 1983; Vlaeyen and Linton 2000; Vowles, McCracken and Eccleston 2008). However, those who catastrophise less and adopt other coping strategies may respond better to SCS treatment.

Acceptance of pain has been suggested to be imperative for a higher efficacy in continuing daily life with lower pain reports (Esteve, Ramírez-Maestre and López-Marínez 2007). Acceptance has been defined as individuals paying less attention and a reduced use of catastrophisation behaviours in response to pain (Esteve, Ramírez-Maestre and López-Marínez 2007). In accordance with previous research, catastrophising remains as a predictor for pain intensity and treatment efficacy (Jensen, Turner and Romano 2001; Spinhoven et al. 1989). In the literature review presented earlier in this thesis, the study presented by Schocket et al. (2008) also reported elevated levels of catastrophising as impacting negatively upon SCS outcome during the trial period. The psychological variables were measured using Coping Strategies Questionnaires, a similar questionnaire to the PCSQ.

According to the model produced, a lower level of catastrophising at baseline assessment is likely to result in an improved outcome in SCS treatment ( $\geq$  30% pain reduction). A substantial amount of literature supports the role of catastrophising in increasing pain intensity reporting and reducing efficacy of treatment (Jensen, Turner and Romano 2001; Keefe 1989; Spinhoven et al. 1989; Turk, Meichenbaum and Genest 1983; Vowles, McCracken and Eccleston 2008). As to whether this characteristic is state or trait is

unknown. The effectiveness of CBT prior to SCS treatment to encourage reduction of catastrophisation and uptake of more positive coping skills would need to be studied further.

### Control over pain

Higher scores in control over pain were found to be of importance for an increased probability of  $\geq 30\%$  pain reduction following 12 months of SCS implantation. How an individual interprets their pain, the evaluation of their ability to reduce and improve pain, will have subsequent effects on pain processing (Verhoeven et al. 2010). Specific beliefs moderate the behavioural reaction to pain, therefore, if an individual is engaging in positive cognitions for reduction in pain, this may underpin the positive expectations and more positive behavioural reactions to pain. The beliefs an individual holds regarding their illness will interact with coping and outcome (Leventhal, Mayer and Nerenz 1980). Control over pain scores reported by patients remained relatively constant for both groups when comparing baseline and 12 months within the groups. This demonstrates the importance of higher levels of perceived control over pain prior to SCS implantation. Perceived level of control may enable individuals to engage in more positive cognitions about their ability to reduce their pain, impacting on a better response to treatment. As discussed earlier in the introductory chapter, mental processes alter the plasticity of the brain, potentially impacting on pain intensity reporting (Beauregard 2007; Villemure and Schweinhardt 2010). It would appear and can be hypothesised from this particular cohort that the individual needs to perceive an element of ability to control their pain to increase response to SCS treatment.

### Anxiety

The results demonstrated little differences between anxiety scores for individuals with  $\geq$  or  $<$  30% reduction in pain at both baseline and one year. Although a one point reduction in mean anxiety score between baseline and one year can be observed for those who obtained  $\geq 30\%$ , this was not significantly different to those receiving  $< 30\%$ . Based on the results, it would appear that individuals with moderately high anxiety scores, combined with higher control over pain scores and lower catastrophising scores, fare better in SCS treatment when compared with individuals presenting moderately high anxiety scores, in conjunction with lower control over pain scores and higher catastrophising scores.

Previous research found elevated anxiety levels to have a negative impact upon SCS efficacy at 3.5 year follow up as measured by the DABS (North et al. 1996) and during trial period as measured by the MMPI-2 (Schocket et al. 2008). However, we can consider that moderate levels of anxiety are to be expected due to the recurrent pain and fear of pain onset. It may be that anxiety also acts as a motivator to seek out treatment and suitable coping strategies to improve quality of life. Moderate levels of anxiety may not affect efficacy if individuals employ coping strategies that increase control over pain and reduce catastrophising. During exploratory analysis it was noted that as anxiety increased so did catastrophising, and control over pain decreased. Contrary to the findings mentioned earlier in the systematic literature review, moderate anxiety may not necessarily be a contraindication for successful SCS outcome.

In a study investigating locus of control and coping strategies among chronic pain patients, Crisson and Keefe (1988) reported that clinicians needed to be wary when treating patients with strong views that outcomes are controlled by external factors. They found that those who relied on external factors for reduction in pain used more maladaptive strategies to cope and experienced more anxiety and depression than those without an external locus of control. The current study observed that patients who believe that they have little control over their pain do not respond as well to SCS as those patients who believe they have moderate control over their pain. Anxiety was also found to have a relationship with control over pain and catastrophising. The equation developed and the worked examples demonstrate that if a moderately high anxiety score is coupled with a high control over pain and lower catastrophising score, there would be a higher probability for successful outcome.

It should be noted that changes in psychological characteristics over time may result from improved pain relief, therefore being classed as state characteristics rather than trait (Fishbain et al. 2006). It is not clear as to whether the psychological factors observed for participants in this study are pre or post morbid to the onset of pain. This could only be explored by analysing measures prior to the onset of pain.

#### Limitations of the study

The limitations of the study need to be acknowledged. The number of patients recruited is limited due to SCS being an invasive treatment that is only suggested to individuals once

more conservative non-invasive pain relief treatments have been unsuccessful. There were few failed trial patients not willing to be followed up. However when entered into the predictive equation the mean baseline scores for trial patients indicated a poor probability of successful outcome. The use of the mean baseline scores suggests that the psychological factors found to affect efficacy of SCS at 12 months may also be specific to trial.

A non-clinical researcher, not involved in the treatment process, administered the questionnaires to patients, removing some possible bias effects where patients modify their answers due to the person administering the questionnaire. However, the questionnaires were completed in the hospital environment and therefore, the answers might have been influenced by the surroundings (e.g. memories of uncomfortable experiences having an impact on responses to questions). Moreover, although patients were told that the results were confidential and would have no impact upon their treatment, they may still have a concern that their answers may lead to changes in their treatment, further influencing their responses.

It should also be considered that the cohort invited to take part in the research were recruited from a single centre, therefore the predictive equation would need to be tested in additional cohorts, from other hospitals and areas. A new cohort or selection of cohorts of patients selected for SCS would be required to test the reliability of the equation.

## **6.6 Conclusion**

In this cohort of patients, the combination of higher scores of control over pain, with lower scores of catastrophising and moderate levels of anxiety were found to be predictors of successful responses to SCS ( $\geq 30\%$  pain reduction). Control over pain, anxiety and catastrophising also appear to have a clear relationship. The belief in an ability to have some control may result in more capacity to engage in normal daily activities and less helplessness and catastrophising behaviours, which have been known to lead to withdrawal and activity avoidance, which can potentially lead to further disability (Keefe et al. 1989). Anxiety appears to be an unavoidable factor in pain that does not necessarily lead to a poor SCS outcome. This research suggests that moderate levels of anxiety are not contraindicative to a successful SCS outcome, depending on the levels of perceived control,



catastrophising and their interaction with anxiety. Preparation for SCS needs to consider these factors. Enabling patients to reduce catastrophic thoughts and behaviours and increase perceived control via CBT may decrease anxiety to moderate/low levels and further improve outcome. These conclusions need further exploration, alongside the testing of the equation on other SCS patients' cohorts.

## **Chapter 7**

### **Qualitative study of patient experience of SCS treatment**

The current chapter details the qualitative study findings, which investigated psychological factors and the SCS experience through semi-structured interviews.

## **7.1 Introduction**

Patients' responsiveness to SCS is usually investigated during a trial period prior to permanent implantation. Nevertheless, 25 to 50% of patients selected as suitable for full implantation report loss of analgesia within 12-24 months following SCS implantation (Cameron 2004; Kupers et al. 1994). Theories for the decline in pain relief have focused mainly on the technical issues of SCS procedure such as position of the leads and electrical parameters as indicators for paraesthetic location (Mutagi et al. 2006) However since pain is a multidimensional experience, psychological factors may impact upon efficacy.

Previous studies using quantitative methods have not identified consistent psychological indicators for the prediction of long-term SCS success (Sparkes et al. 2010). In a study of 100 patients in Belgium investigating prediction of outcome through a psychiatrist interview, the success rate was three times greater for those considered suitable via the psychiatric interview (investigating psychiatric contra-indications) when compared with those who had reservations (Kupers et al. 1994). This raises interest in the potential value of the addition of interview for selection for SCS treatment, rather than reliance on questionnaire methods alone. However, psychiatric diagnoses as described by Kupers et al. (1994) do not take into consideration the more common psychological characteristics found in chronic pain patients. Specific pain behaviours (response to symptoms), cognitions (beliefs, attitudes, expectations) and mood (anxiety, depression) have been demonstrated to impact on the treatment outcome for an individual with chronic pain (Turk et al. 2010).

The aim of this study was to explore the patients' experience during SCS treatment to provide an insight into factors that may influence the reduction of SCS efficacy over time. The use of a qualitative method may enable other aspects to be uncovered in addition to the variables identified as impacting upon efficacy in the quantitative study (chapter 6). A qualitative approach was felt to be appropriate for this study, as the purpose was not to generalise the findings to a wider population but to understand how participants experienced SCS and lived with chronic pain following SCS. Qualitative interviews allow for the collection

of richer and more salient data, from which experience may be explained. Through the conduction of semi-structured interviews participants were enabled to report on issues and concerns of importance to them regarding SCS, and how they made sense of chronic pain and SCS treatment within the context of their lives. Thematic analysis was carried out to analyse the data (Braun and Clarke 2009).

## **7.2 Analysis trail**

The following pages illustrate the analysis process followed based on the methods described in chapter 5, section 5.2.4. The free codes developed from participant data are presented in table 7.1. The transcripts were read, reread and coded when the researcher felt particular areas of interest were noticed. Table 7.1 demonstrates the amount of sources relating to that code (number of participants who spoke about the topic coded), the overall number of references made by participants regarding that code, when the codes were created/modified and the researcher that developed the code. Table 7.2 presents the themes developed and allocated codes.

Table 7.1 Codes developed from participant data

Name	Sources	References	Created On	Created By	Modified On
Acceptance	9	19	07/06/2010 20:36	LS	05/08/2010 15:36
Activity avoidance	5	16	30/07/2010 10:32	LS	02/08/2010 16:13
Adapting to the pain	5	12	07/06/2010 15:25	LS	05/08/2010 15:36
Anger and frustration due to pain	9	19	07/06/2010 18:22	LS	05/08/2010 15:43
Anxiety	2	5	21/07/2010 16:02	LS	05/08/2010 12:44
Apprehensive about activities due to pain	7	8	07/06/2010 15:27	LS	05/08/2010 12:00
Being strong for themselves and others	2	4	02/08/2010 10:52	LS	02/08/2010 14:03
Blame health system for onset	1	2	02/08/2010 11:50	LS	05/08/2010 15:23
Can't drive with stim	2	2	30/07/2010 11:26	LS	30/07/2010 14:35
Carry on, not letting the pain stop you.	7	14	07/06/2010 15:21	LS	02/08/2010 12:01
Catastrophising	5	11	09/06/2010 12:31	LS	05/08/2010 15:39
Choosing to have a procedure	1	2	02/08/2010 13:49	LS	02/08/2010 13:50
Control over the pain	2	3	09/06/2010 12:35	LS	30/07/2010 14:58
Controlled by the pain	5	20	30/07/2010 10:33	LS	05/08/2010 12:40
Coping strategies (Positive)	9	20	07/06/2010 15:10	LS	02/08/2010 16:12
Description of maladaptive pain behaviours	4	4	30/07/2010 10:40	LS	02/08/2010 16:16
Difficult life events	9	19	07/06/2010 18:59	LS	05/08/2010 12:14
Emotional expression	3	7	30/07/2010 10:37	LS	05/08/2010 16:03
Envious of others not in pain	2	2	07/06/2010 15:28	LS	02/08/2010 15:05
Fear of the pain	4	6	09/06/2010 12:33	LS	02/08/2010 11:11

Table 7.1 (continued) Codes developed from participant data

Name	Sources	References	Created On	Created By	Modified On
Fear, experience in hospital	4	9	09/06/2010 11:49	LS	05/08/2010 12:47
Feel responsible for controlling pain	1	1	21/07/2010 15:28	LS	21/07/2010 15:28
Feeling helpless	11	41	07/06/2010 13:24	LS	05/08/2010 12:14
Feeling low	9	20	07/06/2010 15:09	LS	05/08/2010 12:14
Guilt	6	11	09/06/2010 12:30	LS	05/08/2010 15:50
Ignoring the pain, carry on	3	3	07/06/2010 15:15	LS	02/08/2010 16:18
Illness, poor health generally	7	7	07/06/2010 19:02	LS	05/08/2010 15:35
inability to hide the pain	1	2	07/06/2010 18:45	LS	07/06/2010 19:06
Independence increased	2	2	09/06/2010 12:41	LS	30/07/2010 14:10
Information from other SCS patients	7	16	07/06/2010 19:12	LS	05/08/2010 15:41
Inspired by others	3	5	09/06/2010 11:18	LS	05/08/2010 15:45
Isolating oneself	10	14	07/06/2010 19:13	LS	05/08/2010 12:20
Lack of control over pain	4	5	07/06/2010 13:59	LS	30/07/2010 17:44
Lack of coping skills	1	1	21/07/2010 14:47	LS	21/07/2010 14:47
Lack of social support	2	2	21/07/2010 14:18	LS	21/07/2010 14:38
Lack of support from medical staff	3	3	21/07/2010 13:50	LS	02/08/2010 12:15
Life events exacerbate pain	1	1	30/07/2010 12:39	LS	30/07/2010 12:39
Lonely	4	7	21/07/2010 14:08	LS	05/08/2010 12:12
Losing faith in Dr's	4	6	07/06/2010 15:33	LS	05/08/2010 15:54
Loss of independence	7	20	07/06/2010 18:23	LS	05/08/2010 12:49

Table 7.1 (continued) Codes developed from participant data

Name	Sources	References	Created On	Created By	Modified On
Loss of job due to pain	3	3	21/07/2010 14:28	LS	05/08/2010 15:24
No control over pain origin	11	15	07/06/2010 13:25	LS	02/08/2010 15:17
No firm diagnosis	3	4	14/06/2010 10:15	LS	05/08/2010 15:40
Not adapting to pain	1	2	05/08/2010 12:38	LS	05/08/2010 12:49
Not being believed by Dr's	6	8	07/06/2010 19:11	LS	05/08/2010 15:49
Not being believed by people generally	5	7	07/06/2010 20:34	LS	30/07/2010 12:42
Not compensated	2	2	09/06/2010 11:22	LS	30/07/2010 13:55
Not fully informed about stimulator	3	4	07/06/2010 15:41	LS	02/08/2010 12:15
Operation uncomfortable	8	13	09/06/2010 12:46	LS	05/08/2010 15:39
Pain causes life events	1	2	30/07/2010 12:36	LS	30/07/2010 12:37
Pain description	11	17	07/06/2010 13:24	LS	05/08/2010 11:55
Pain is part of them	1	1	02/08/2010 12:02	LS	02/08/2010 12:02
Prof Raphael really understands	3	4	07/06/2010 15:33	LS	30/07/2010 14:49
Programming causes fear of stim changing	1	1	21/07/2010 14:01	LS	21/07/2010 14:01
Realistic expectation	3	3	02/08/2010 10:24	LS	02/08/2010 15:34
Reliance on medication	10	19	07/06/2010 14:03	LS	05/08/2010 12:15
Researching stim	2	4	02/08/2010 10:20	LS	02/08/2010 13:42
Responsibility for pain relief lies with Drs	5	13	21/07/2010 15:55	LS	05/08/2010 15:54
Satisfied with care from health professionals generally	2	3	30/07/2010 11:13	LS	05/08/2010 12:11
Satisfied with pain relief	1	1	30/07/2010 11:28	LS	30/07/2010 11:28

Table 7.1 (continued) Codes developed from participant data

Name	Sources	References	Created On	Created By	Modified On
SCS and the affect on body image	3	10	07/06/2010 14:05	LS	05/08/2010 15:53
SCS expensive	2	2	09/06/2010 11:28	LS	09/06/2010 11:46
SCS information from health professionals	11	21	07/06/2010 14:02	LS	02/08/2010 16:31
SCS not very successful	5	9	07/06/2010 14:00	LS	05/08/2010 12:04
SCS restricts desired activities	3	4	30/07/2010 12:47	LS	02/08/2010 11:12
SCS uncomfortable	2	2	07/06/2010 20:37	LS	30/07/2010 11:19
SCS works	8	22	07/06/2010 15:39	LS	30/07/2010 17:43
Self blame for pain	3	5	02/08/2010 10:17	LS	05/08/2010 15:37
Side effects of pain killers	3	6	21/07/2010 13:57	LS	05/08/2010 12:15
Sleeping	10	13	07/06/2010 14:09	LS	05/08/2010 12:07
Social support	10	15	07/06/2010 15:11	LS	05/08/2010 12:12
Tearful due to pain	2	3	07/06/2010 14:10	LS	05/08/2010 15:51
There is nothing more that can be done	5	7	07/06/2010 15:14	LS	05/08/2010 15:51
Time to navigate the health system	3	9	30/07/2010 11:10	LS	02/08/2010 16:26
Told the pain would go	3	3	30/07/2010 10:42	LS	02/08/2010 15:18
unable to seek compensation	1	1	30/07/2010 11:04	LS	30/07/2010 11:04
Unrealistic expectation	3	5	21/07/2010 15:45	LS	05/08/2010 15:44
Ward nurses don't understand the seriousness of op	2	6	30/07/2010 11:25	LS	02/08/2010 16:32



Table 7.2 Free coding sorted and mapped into themes and overarching themes

<b>Coping and pain</b>	<b>Frustration and anger</b>	<b>Responsibility for pain relief</b>
Helplessness, controlled by pain	Anger and frustration due to pain	Blame health system for onset
Activity avoidance	Emotional expression	Losing faith in Dr's
Anxiety	Guilt for not being able to carry on normally	No control over pain origin
Apprehensive about activities due to pain	Envious of others not in pain	No firm diagnosis
Catastrophising	Life events exacerbate pain	Responsibility for pain relief lies with Drs
Control over the pain	Not being believed by Dr's	Time to navigate the health system is lengthy
Controlled by the pain	Not being believed by people generally	Told the pain would go
Fear of the pain	Description of maladaptive pain behaviours	
Feeling helpless	Self blame for pain	
Feeling low		
Illness, poor health generally		
Inability to hide the pain		
Isolating oneself		
Lack of control over pain		
Lack of coping skills		
Lack of social support		
Lonely		
Loss of independence		
Loss of job due to pain		
Pain description		
Reliance on medication		
Side effects of pain killers		
Sleeping		
Tearful due to pain		
There is nothing more that can be done		

Table 7.2 (continued) Free coding sorted and mapped into themes and overarching themes

<b>SCS treatment</b>		
<p>Information provision</p> <p>Choosing to have a procedure</p> <p>Information from other SCS patients</p> <p>Inspired by others with SCS</p> <p>Lack of support from medical staff</p> <p>Not fully informed about stimulator</p> <p>Prof Raphael really understands</p> <p>Programming causes fear of stim changing</p> <p>Researching stim</p> <p>SCS expensive</p> <p>Unrealistic expectation</p>	<p>Regaining control</p> <p>Independence increased after SCS</p> <p>Satisfied with care from health professionals generally</p> <p>Satisfied with pain relief</p> <p>SCS works</p>	<p>Unexpected experiences</p> <p>Can't drive with stim</p> <p>Fear, experience in hospital</p> <p>SCS and the affect on body image</p> <p>SCS information from health professionals</p> <p>SCS not very successful</p> <p>SCS restricts desired activities</p> <p>SCS uncomfortable</p> <p>Operation for SCS uncomfortable</p> <p>Ward nurses don't understand the seriousness of op</p>

## **7.3 Results**

### *7.3.1 Participants*

The participants were recruited as an opportunity sample at the follow up SCS clinics and consisted of six males and seven females with ages ranging from 32 to 70 years (average 45.4 years). All participants were white British. Two participants had failed the trial and did not proceed to full implantation of SCS. For those proceeding to full implantation of SCS, eight participants reported less than 30% pain relief and three participants reported at least a 30% reduction in pain at one year follow up. Pain topography included back, anus, legs, ankle and feet. Time in pain prior to implant ranged from two to 21 years (average 18.2 years).

### *7.3.2 Analysis*

Analysis of the interviews revealed themes in seven domains, which were categorised into two sub-themes: coping and pain, and SCS treatment:

#### **Coping and pain**

Helplessness, controlled by pain

Frustration and anger

Responsibility for pain relief

Acceptance of pain

#### **SCS treatment**

Information provision

Regaining control

Unexpected experiences

### *7.3.3 Coping and pain*

Living with chronic pain induces a mixture of emotional responses including frustration, anger, sadness and fear. The emotions that an individual experiences have huge impacts upon coping ability. Often the lack of a distinct diagnosis leaves individuals feeling helpless and unsure about the future. These intense emotions often impact on an individual's ability to cope and continue with daily life and it was evident that participants wanted to express the helplessness they experienced. All participants disclosed feeling helpless and controlled by pain to some degree. Coping and pain was a significant theme among all participants. Regardless of whether their pain was managed, emotional coping was still of importance.

There was frequent discussion regarding who was responsible for the individual's pain relief. It became apparent that many individuals felt that it was the health care practitioners' responsibility. There was a sense that they were waiting for someone to show them a cure for their pain. This was less frequent amongst those who described managing and accepting their pain.

***Feelings of helplessness and being controlled by pain: 'I'm stuck in a hole'***

Feelings of helplessness were described almost unanimously. Patients who experienced both successful and unsuccessful SCS expressed feelings of helplessness; however those who had not obtained successful relief from SCS made more regular reference to an inability to cope and feelings of incapacity to know what to do. There was an emphasis among the patients on feeling unable to move forward and being stuck.

*"...It's just like I'm stuck in a hole and I don't... don't know how to get out of it."* (Interview 5)

Often participants described how they focused on what they were no longer able to do; there was a sense of the mental torture that was experienced.

*"...I can just sit there thinking like, well I could be dancing like and you can't, you sit there, it's terrible."* (Interview 2)

Participants described that they could not find a way to move on or cope with the pain when it became extreme. Often an external locus of control was described in relation to any possibility of the pain improving (waiting for someone to cure their pain). An external locus of control is understood as an individual belief that an improvement will only be achieved via external factors independent of their individual control or ability. It became clear that there was a strong sense of feeling out of control. One woman in her fifties who had been out of work for sometime due to pain remarked:

*"...I've resigned myself you know, this is as good as it gets and erm, short of somebody coming up with a miracle cure then well that's it."* (Interview 11)

There was a sense that participants felt helpless due to the very nature of the control that pain had over their lives. Difficult life events were also discussed as impacting upon the inability to cope. The ability to be able to carry on was often related to medication use, although difficult side effects were regularly reported; this dependency was evident among many participants. There were strong beliefs that medication was the only way to continue functioning.

*"...You can't live a normal life when you are constantly in pain because your whole life revolves around taking the next pain killer."* (Interview 1)

The concept of feeling controlled by pain was also evident in the inability to follow certain goals individuals had for their lives. One woman described how she had been advised against having a child, as it was suggested that her pain would not be controlled whilst pregnant.

*"...he'd said 'I would be extremely concerned if she got pregnant with you know the, the metal work, the amount of pain that she's in, the fact that she's, you know she's still suffering because we're not going to be able to manage the pain properly because you're going to have to stop taking various things.'" (Interview 12)*

There was also a regular discussion of a lack of control over pain origin, leaving participants feeling helpless and fearful. Participants described having no idea where the pain originated.

*"...I don't know what I'd done you know, I don't know, you know it was err, I'd always been very active you know, I'd had an active job. Never worried about lifting or bending or anything like that, there'd never been any problems you know and it was just there."* (Interview 10)

### ***Frustration and anger: 'I just explode'***

Frustration and anger in response to the control that pain had over individuals' lives was a recurrent experience for the participants. Participants described isolating themselves or feeling isolated due to the emotional turmoil, frustration and anger they felt. There was a sense that pain could occur at any moment and without any expected triggers.

*“...I get frustrated, you know because sometimes I don’t know what I’ve done extra to cause the extra pain you know. I know if I’ve been on my feet a lot you know, I can expect to ache more, I know if I’ve been busy at home, I can expect to ache more but some days it’s a case of well, what have I done you know so, I get frustrated, I get angry with myself that I can’t sort it, you know but it’s there and it’s not going to go, so...”* (Interview 10)

The sense of helplessness leading to frustration continues in the amount of reliance on others that is developed due to pain. Participants often described how frustrating it was not being able to be independent and involved in family life. One male participant aged 44 years old displayed feelings of guilt that he relied heavily on his wife, leading to angry outbursts.

*“...Well like I said, my wife has to do most, everything for me. Like I said I had my independence before but now she’s got everything on her plate, plus everything else. It just mounts up, you know what I mean, it’s like anybody else I assume, but at the time like it gets so far and then I just explode.”* (Interview 2)

### ***Responsibility for pain relief***

Patients frequently made reference to responsibility for pain relief lying with the doctors. One younger woman who considered herself very active before the onset of chronic pain described waiting for something to cure her pain.

*“...Erm, still hoping that somebody else invents something else or something else, you know every time I come here and play with the computer I’m always thinking well I don’t know what they’ve done with that computer programme since they were last there, there might be something new and brilliant.”* (Interview 12)

There was also evidence of losing faith in doctors when anticipated pain relief was not obtained. Participants on occasions displayed anger towards doctors not ‘curing’ their pain. The idea that pain relief was external responsibility appeared to increase angst and anger.

*“... Well first off I thought Drs will help me, then, I lost faith in them.”* (Interview 1)

There was a general sense that participants focused on external sources as responsible for their pain relief. Some participants reported that they had no control over their pain reduction and an external locus of control was observed regarding their pain. One participant described feeling that her family and friends thought not enough was done to help her reduce the pain. The cognitions that pain reduction was the responsibility of external sources was reinforced by those close by.

*“...I think they get, maybe get, sort of annoyed. Cos the quality of life that I had, I no longer have. Everything is restricted for me. I feel they think, they feel more should be done for me. That’s the only sort of thing that comes across to me. They think that more could be done for me.”* (Interview 7)

### **Acceptance of pain**

There was mention of acceptance from some of the participants. This was more common amongst those who reported more pain relief from the SCS and generally displayed a positive self-perception. The impression was that acceptance came from realising that the pain could not be beaten but managed as a normal part of their lives. This acceptance was noted by participants reporting they had realistic expectations about the future and felt supported by those around them.

*“...It’s just something that, something that lives with me. I you know, I don’t live with it, it lives with me, it’s what I am trying to make of it is that I know I am not going to beat it but you know, I’ve got it, it’s under my umm, you know my control to an enth, to a degree.”* (Interview 3)

*“... I’ve learnt to live with it, it’s an everyday thing, it’s normal for me.”* (Interview 9)

Some of the participants who reported being less accepting of their condition reported seeking compensation or the inability to receive compensation, which they felt they were owed.

#### 7.3.4 SCS treatment

Separate issues arise when describing the experience of SCS. Participants regularly felt they needed more access to information. It became clear that those who were satisfied with their knowledge of SCS had researched on their own via internet resources. There was a desire from participants to speak to individuals already with an SCS prior to participation in the trial. The trial and initial experience of the SCS introduced body image concerns for the majority of the female participants. Women disclosed that they experienced dissatisfaction with their individual perceptions of their bodies (body image) in relation to the SCS being implanted and the wires visible during the trial. Also scarring due to the implantation was described by some women as upsetting. There was discussion that health professionals did not seem to recognise the somewhat traumatic experience of the trial. Participants also reported feeling guilty for moaning about the discomfort after SCS was implanted due to the cost of the system and nurses telling them that they should be grateful as not everyone was lucky enough to have an SCS. Those that achieved successful pain relief described regaining some control, independence and a reduction in helplessness.

#### ***Access to information, professionals and expert patients please!***

It became evident that those who felt relatively satisfied with the information received prior to SCS treatment had taken upon themselves to research via the internet as well as receiving information from health professionals.

*“...I started doing some homework then, you know, on the internet to find out exactly what it was, what it did, erm then I was referred here, sat and talked it through with the consultant who was you know, very informative.” (Interview 10)*

*“...So when I came in yes I did find, feel I had enough information because I'd made it my business to find out.” (Interview 11)*

One participant who had been in pain for 20 years and been unsuccessful in receiving satisfactory analgesia with the fully implanted SCS described how she was not completely aware of what was actually going to happen when she went in for the SCS trial.



*“... Yeah and I think in the future I would be a bit more pushy and I would ask a few more questions about what they are actually giving me.” (Interview 1)*

This was in contrast to another participant who obtained successful pain relief. The experience was described as much improved when compared to other places where he had sought treatment.

*“... They’re caring people, and everything that I had done, everything was explained well in advance. I knew what was going on whereas, what happened at other places it’s not been like that, you’re kept in the dark sort of thing.” (Interview 9)*

On occasions participants reported that they received contrasting information and advice. Participants made reference to feeling confused about the right action to take with their SCS device.

*“...and you ask questions, ‘oh yeah’ blahblahblah, you ask somebody else, they tell you something completely different and just confused all the time.” (Interview 2)*

There was an almost unanimous desire to have the opportunity to speak to an SCS patient before having the trial themselves. Participants described feeling disappointed when they did not get the opportunity to talk to someone who already had an SCS.

*“...I actually asked if I could speak to somebody who’d had the stimulator but that never happened erm, but I did come up and speak to err one of the sisters here and had a chat with her but, I found that useful, but I was a bit disappointed not to speak to somebody who’d err, who’d had a stimulator.” (Interview 11)*

Speaking to an expert patient was seen as a factor that would have greatly improved the information provision among many of the participants. Participants wanted to be able to discuss the experience with someone who had been in their situation and have the opportunity to ask questions that they felt they could not ask the consultant.

*“...Even if it’s you know getting in touch with someone who has had it done. You know like myself, so somebody coming in and you know they have no experience of it whatsoever and then to be put in touch with somebody who has had it done and for them just to have a chat about it.” (Interview 3)*

### ***Independence and regaining control***

Participants who were obtaining successful pain relief made regular reference to regaining control over their lives. There was mention of improved ability to cope. Although pain was not completely eliminated, participants were able to reduce the medication and still manage their pain. One lady who worked as a barmaid had been able to maintain her job throughout her experience of chronic pain.

*“...The implant has helped greatly because I’ve been able to reduce the medication that I’m taking, but err yeah it’s just there all the time you know, there’s good days and bad days but never very good days when it goes away.” (Interview 10)*

It was clear that the SCS gave participants some freedom back. The ability to go out and walk every day was something that one patient had greatly missed.

*“...I think it’s given me a little more independence back, because I do go out walking every day, umm and I think that’s where I have lost the weight. Umm so I think yeah from that side, you know, it’s given me independence, you know.” (Interview 3)*

Participants clearly felt an increased ability to be able to carry out their lives. The SCS gave the participants security that the use of the SCS would enable them to carry on when pain became unbearable.

*“...I think now that I’ve got the implant, I can cope with the pain more. It’s not as severe when the machine is running. I look forward to the day to begin. Whereas before I didn’t want to wake up in the morning because I knew I’d got the same thing to look forward to everyday. I know it’s still there now, and it’s, it’s not nice but I know I can go and do something about it when it gets bad. I can go shut myself away in the room, put the machine on and the helps there.” (Interview 9)*

### ***The unexpected experiences of SCS***

There were several issues for patients that emerged along the lines of unexpected experiences. The majority of participants did not expect the trial to be so painful and felt unprepared for the experience. It also became evident that the participants felt that health professionals were not aware or empathetic of the experience of the trial and the subsequent feelings after the trial. Body image also was an unexpected issue amongst their women, with several commenting on the impact SCS had on their body perception.

### **The uncomfortable trial**

The majority of participants found the trial painful and often participants declared that they had not expected the experience to be quite so uncomfortable. Individuals explained that they were prepared to be uncomfortable but were completely unaware of how painful the experience would be for long periods of time.

*“...I knew what you know, I was going to feel some discomfort, pressure, pushing but I didn’t expect to feel the pain that I did. You know erm, whether they normally put people to sleep I don’t know, whether they give more local, leave it a little bit longer, I don’t know, but for me it wasn’t a good experience.”* (Interview 10)

*“...When I spoke to him (consultant), when he said about it, I asked him, he said I should be awake and I said well is it very painful, he said it’s uncomfortable which I expected, but it was very painful when it was hitting the nerves.”* (Interview 13)

Participants made reference to feeling that health professionals on the wards during the trial in hospital were not empathetic of their experience during the operation. Ambivalence was felt by some patients, as they wanted to express their gratitude for the SCS but at the same time felt a need for acknowledgment for the difficult experience.

*“...’lots of people would love to be in your position’ was one of the phrases that was used and I was sort of saying I’m so grateful I am in my position but actually right now this is the way I feel about it.”* (Interview 12)

*“...Whilst actually in hospital having it done, I did get the feeling that some of the nurses didn't quite understand the severity of the operation that we'd had.” (Interview 8)*

#### Body image 'I wasn't expecting that!'

Women disclosed negative body image issues in a number of areas related to the SCS. There was a sense of shock described by some of the female patients when the SCS was fully implanted. The idea of a machine being implanted into their body caused some concern, as did the visibility of wires during the trial. They were also not expecting the scars caused by the implantation surgery, which some found upsetting.

*“...the only shock I had was the size of the scars. I wasn't expecting that. The big scars, you know that don't you, and on your back, you've got all the scars on your back, so I think for some women, I think that might be a major problem.” (Interview 1)*

One woman was really disturbed by the presence of the 'holes' in her body for the wires during the trial period. She discussed how unprepared she was for this. She also pointed out how she was unable to look at the physical change, scarring, on her body for two months.

*“...so, probably the worst thing was how freaked out I was. Erm, first of all, I suppose I hadn't really realised after that first stage of the operation that you'd have like, what in my head always looked like, I've got holes in me, you can go from the outside to the inside and that's just wrong and that kind of shook me up a bit but it was actually when I, after the second one where erm, I could feel the thing and even though it was all stitched up I probably couldn't look, oh yeah I probably couldn't even turn round and look at where the scar was or anything for about two months.” (Interview 12)*

## **7.4 Discussion**

This study explored patients' experiences of SCS with the aim of providing a descriptive analysis of the findings. To our knowledge the findings in this study have not been previously reported. The impact of psychological factors upon SCS has generally been investigated via questionnaires. The interviews have enabled some wider areas of interest that have not been investigated by questionnaire studies to be explored, which may be

important to consider when preparing individuals for SCS. Two core themes were generated through thematic analysis of 13 interviews, coping and pain, and SCS treatment.

Coping and pain encompassed the sense of helplessness that patients experienced in response to chronic pain, alongside other negative coping strategies (passing responsibility to doctors, feeling controlled by pain, and frustration and anger). The theme SCS treatment comprised three main topics. These included information provision and a desire for contact with expert patients; regaining independence when SCS was successful; and also the unexpected experiences of the treatment (i.e. uncomfortable trial and body image concern).

Emotional coping and a sense of helplessness was experienced by all patients in response to pain, more so by those who had not achieved successful pain relief through SCS. The recurrent theme of the effect of emotion upon coping was evident throughout the findings. The data suggests that some participants were hoping for a 'miracle'. This is an example of negative coping, as helplessness and negative outcome expectancies were found to be related to uptake of passive pain coping strategies (Den-Boer et al. 2006). Passive coping includes aspects such as inactivity and an overreliance on medication with patients absolving themselves of personal responsibility for the reduction of pain. Passing responsibility to others can adversely affect individuals' lives (Sullivan, Rodgers and Kirsch 2001). The results demonstrate how some of the participants experienced an inability to move past the pain, resulting on a focus of what cannot be done rather than what can be achieved. There was also evidence of responsibility being passed to external sources for reduction in pain. The findings of helplessness in response to pain was not new knowledge. However, it further demonstrates the importance of enabling patients to develop and use active coping strategies.

The sense of feeling controlled by pain was regularly mentioned. Pain is a conscious process with internal and external factors influencing the experience. Individual interpretations of the painful experience interact with the affective component of pain. The attention and evaluation given to the pain experience appears to be central to the perception and subsequent experience (Verhoeven et al. 2010). CBT may be helpful in reducing the negative attributions and increasing active coping, which may lead to a further reduction in pain when being treated (McCracken and Turk 2002).

The results highlighted an acceptance of pain, more so by those with successful pain relief. Acceptance has increasingly become an important consideration for successful pain management. Acceptance can be understood as not employing avoidance, fear of movement beliefs or control behaviours, continuing with an individual's life and following personal goals (López-Martínez, Esteve-Zarazaga and Ramírez-Maestre 2008). CBT may encourage a move away from feelings of lack of control and more towards acceptance, potentially influencing outcome of treatment.

Unexpected experiences came to light in the interviews. Patients felt on occasions they were not prepared for the painful experience of the trial. Disclosure of the possible amount of pain experienced from this procedure could cause an increase in anxiety prior to trial. There is, therefore, a tension which clinicians must manage. Some participants also alluded to feeling that health professionals on the hospital ward were not aware of the difficult experience of the trial. Ensuring staff are aware of the procedure may be important to improve care. The trial and initial experience of the SCS introduced body image concerns for the majority of the female participants, which was apparently something they were not expecting. This concern however was not mentioned by any of the male patients. Body image is not merely a personal perception of the body, but is mediated by social and cultural context (Nettleton and Watson 1998). An altered body image may undermine the confidence people feel in the presence of others, and the way in which they feel they are perceived, and it appeared in this study to have affected women more than men. These aspects need further consideration during information provision sessions.

Information provision was a topic that generated several considerations for clinical practice. There was a desire among the participants for the opportunity to discuss SCS treatment with expert patients. Some participants reported a lack of information and those who felt they had enough information had often researched the subject themselves, usually via the internet. A question/answer session may be helpful in determining if patients are well informed about what an SCS procedure involves. Cognitions impact upon the pain experience and therefore interact with response to treatment (Melzack, Casey and Kenshalo 1968). Feeling confident and knowledgeable about the treatment, thus increasing self efficacy may enhance

outcome. Ensuring patients are appropriately informed and enabling discussion with an expert patient may prepare them for potentially unpleasant experiences.

For those who achieved successful pain relief, a sense of regaining control was experienced. The possibility to obtain relief at any given moment provided participants with confidence that they could continue with their goals in life and no longer be controlled by pain that often occurred without warning. This was connected with an understanding that SCS treatment was not a cure for pain. Ensuring patients are aware that SCS is a treatment to enable increased pain management and not cure chronic pain seems imperative for realistic expectations.

The study recruited participants sequentially upon reaching one year following SCS trial (for those who failed trial) or implantation. No participants declined participation in the interview. A particular strength to this study is the non-involvement of the researcher in the treatment process. This may have encouraged participants to speak openly. The cohort included patients who had failed the trial, those who had full SCS implantation receiving successful pain relief and those who did not obtain successful pain relief from SCS. Interestingly, the themes generated were common across all the patients. Participants who were receiving satisfactory pain relief from SCS expressed feeling more control over pain and expressed improved coping and acceptance of pain. The nature of this qualitative study does not allow conclusion as to whether improved coping and acceptance led to increased efficacy of SCS or improvement in pain enabled improved coping and acceptance.

Limitations of the study include the setting since participants were interviewed in an office on the hospital site, which could inadvertently have influenced the interviews by having pain management staff in the close vicinity. Moreover, the participant group was white British and therefore the findings lack an element of transferability to other patient populations. The centre where the study was conducted serves a mixed demographic area with some participants from deprived areas and others from more affluent regions. The sample was relatively small, although new themes ceased to emerge indicating saturation. A more ethnically diverse, multicentre-based sample has the potential to lead to verification or to allow further findings. The data was collected from a single centre and findings may be specific to this hospital, especially when considering information provision. This centre,

however follows the British Pain Society national guidelines (Simpson, Stannard and Raphael 2009). Therefore all patients were assessed by a multidisciplinary team including a psychologist, physiotherapist, consultant and specialist pain nurse prior to SCS treatment. The findings may be influenced by how successful the treatment was. Negative attributions may therefore be influenced by the outcome of the treatment. Interviews prior to one year following initiation of SCS treatment may allow further insight into this aspect.

## **7.5 Conclusion**

The current study provides a context for understanding the experience of SCS from a patient's perspective. The findings may contribute to the practical implications for SCS preparation. Enabling patients to learn active coping strategies and reduce maladaptive coping through CBT may lead to improved outcome. Information provision needs consideration, particularly regarding the potentially uncomfortable experience of the trial and body image concerns raised by the female participants. Additional information via expert patients may be of value, to cover issues of what to anticipate and ensure correct levels of understanding and expectation are achieved before treatment. Further investment in preparation prior to SCS surgery is warranted. Additional investigation is needed as to whether such changes in SCS preparation lead to increased SCS efficacy. This study provides new areas for more rigorous exploration. The use of the emerging themes to develop a questionnaire and subsequently validation could also be considered.



## **Chapter 8**

## **Conclusion**

This chapter provides a concluding summary encompassing the findings of both the qualitative and quantitative studies. The results from both studies have produced conclusions that complement each other. This final chapter will summarise the findings and make suggestions for clinical practice and future research.

### **8.1 Summary of the research**

The aim of this research was to investigate the contribution of psychological factors to the efficacy of SCS treatment outcome 12 months following implantation. This research has accomplished its aim by undertaking the three objectives summarised below.

The first objective was to review the current literature investigating the psychological factors affecting the efficacy of SCS. The varied range of methodologies employed in the studies identified precluded a meta-analysis. The review highlighted the need for a longitudinal prospective study and that there were inconclusive findings regarding the psychological factors affecting the efficacy of SCS. Depression was the only factor that was regularly highlighted as an influential psychological factor. However, the review allowed noticing that depression may improve in response to successful SCS therapy and therefore may not be a complete contra-indication. This review was accepted for publication in the journal *Pain* (appendix 1).

After reviewing the literature the subsequent objective was to carry out a longitudinal prospective study investigating potential psychological factors affecting the efficacy of SCS over a one year period. The patients completed questionnaires to evaluate psychological characteristics at baseline, six months and one year. Analysis of the data at one year resulted in the development of a predictive equation. Based on the baseline scores, this equation allows predicting the likelihood that a patient will achieve  $\geq$  or  $<30\%$  reduction in pain at one year. Analysis of the data at six months did not result in the identification of predictive psychological characteristics possibly because this was a time where placebo responses may be occurring. Three psychological factors were identified and included in the equation at one year: catastrophising, control over pain and anxiety. Contrary to what was expected based on the literature review, depression was not a significant predictor. However, this study is underpowered and therefore the model developed remains tentative.

An additional objective was to explore the experience of SCS via a qualitative method, to understand the experience from the patients' perspective. Moreover, the questionnaires may not highlight all of the important factors regarding the SCS experience so by interviewing patients their views and experiences can be uncovered and understood at a deeper level. This study highlighted some important and insightful themes, which added to the understanding of the factors that may influence SCS efficacy. Coping with the pain and issues of helplessness and acceptance were highlighted. Important patient concerns surrounding the treatment process were uncovered, including information provision and a host of unexpected experiences when having SCS, such as a lack of psychological preparation for scarring and the painful trial. This study was accepted for publication in the journal *Chronic Illness* (appendix 2).

The results from the quantitative and qualitative studies complemented each other. The qualitative investigation outlined some important considerations, which may help to moderate levels of catastrophising, control over pain and anxiety, which were outlined by the quantitative study. These considerations include coping and control issues, described in both studies and for which information provision and expert patient support seem crucial to help with these matters. Decreasing and raising awareness of concerns such as body image distortions or unexpected scarring may enable individuals to develop improved ways to cope with the difficult trial. This may also reduce catastrophising and anxiety and increase perceptions of control. The studies presented within this thesis have been successful in highlighting psychological factors for consideration when selecting for SCS treatment. The equation needs to be further tested to confirm the variables mentioned as predictors or for possible recalculation. This research has also outlined the patients' personal views and desires to improve the patient experience.

## **8.2 Coping and control**

Acknowledging patients' scores of catastrophising, anxiety and control over pain may enable an insight into aspects of the patient's psychological status that may need addressing prior to SCS implantation.

The findings from both the qualitative and quantitative studies demonstrate the importance of consideration for coping strategies affecting pain experience in relation to SCS treatment. The quantitative research outlined control over pain as an important variable for prediction of success and the qualitative research allowed the complexity of this issue to be uncovered through exploration of the SCS experience. It became apparent that the patients wanted to feel more in control of their pain and this could be potentially achieved by certain perceptions and beliefs being modified and changed. The interviews highlighted that patients were making regular reference to feeling controlled by pain and this resulted in feelings of helplessness. Participants displayed beliefs that they could not carry on with their normal lives and that they were trapped. Perceptions of a lack of control appeared to stem from numerous factors including a lack of clear diagnosis for their pain complaint, unknown pain origins and unknown onset of pain. Similarly, the quantitative study findings identified higher scores on the variable control over pain to be predictive of SCS efficacy at one year.

The interviews demonstrated evidence of an external locus of control for pain reduction amongst many participants. Participants reported perceiving physicians and other health care professionals as responsible for successful pain relief and there was even mention of awaiting a miracle. The perceived control that individuals have over their pain was a common theme and variable throughout the findings of the separate studies. It would appear from the results of the quantitative and qualitative studies that SCS patients do better when assuming some responsibility for their pain relief. Crisson and Keefe (1988) reported that clinicians should be careful when treating patients with strong views that outcomes are controlled by external factors. These authors observed that those who described external factors as responsible for any reduction in pain used more maladaptive strategies to cope and experienced more anxiety and depression than those who did not have an external locus of control. An internal locus of control was also demonstrated in the current research by those patients obtaining better pain reduction by being more accepting of the pain and seeing it as something to be managed as part of their lives rather than something to be cured purely by external sources of help.

Catastrophising was a coping mechanism found to impact negatively upon SCS when investigated via questionnaires. Catastrophising is a psychological factor that could be hypothesised as likely for individuals perceiving external sources as responsible for pain

reduction. Catastrophising attracts the attention of others and also the help and empathy of those around. Interviews explored the beliefs participants held regarding inability to cope due to lack of perceived control over pain. Participants described lack of control resulting in helplessness and forms of catastrophisation. The interviews allowed insight into the types of catastrophic behaviours. The behaviours included angry outbursts and women described catastrophic reactions to changes in their body image as a result of the SCS being implanted. There was also evidence of catastrophic thinking in terms of not being able to carry on and waiting for a miracle. This research has found that catastrophising and control over pain are influential in the efficacy of SCS. Catastrophising alongside a lack of perceived internal control is associated with the onset and continuation of chronic pain (Jensen, Turner and Romano 2001; Spinhoven et al. 1989; Sullivan, Rodgers and Kirsch 2001; Turk and Okifuji 2002).

Anxiety was also a recurrent response to pain. This research has highlighted the importance of equipping patients with the knowledge and skills regarding the use of adaptive coping skills. Adaptive coping will reduce anxiety to some degree and therefore according to the results of the current research, increase response to SCS treatment. The quantitative findings demonstrated, however, that moderate levels of anxiety were not a contraindication for SCS suitability if moderated by better coping (lower catastrophising) and perceived control. It could be considered that certain levels of anxiety may motivate individuals to help themselves and move forward. However, higher levels may have an opposing effect, increasing fear and helplessness.

Lazarus and Folkman (1984) described the theory of stress appraisal. According to this theory, the result of incorrect or lack of information can result in individuals feeling vulnerable and lacking in control, therefore experiencing stress and anxiety. Not being fully prepared for SCS treatment could result in increased anxiety levels. Patients disclosed on occasions feeling they were lacking in information. There was also discussion in the interviews that patients were unaware of potential experiences, such as a possibly painful trial and body image changes. These experiences are likely to increase and maintain anxiety. A problem may often be resolved through the weighing up of pros and cons (Rosenstock, Strecher and Becker 1988). To weigh up the pros and cons, correct information regarding a situation is required. Ensuring that patients hold the correct beliefs

about their pain and their treatment will improve coping and perceived control, therefore reducing levels of anxiety (Leventhal, Meyer and Nerenz 1980).

SCS may provide individuals with an ability to regain elements of control over their lives. This was demonstrated by reports during the interviews of the ability to switch the system on and off in response to pain onset. Individuals experiencing chronic pain for long periods of time have often developed maladaptive coping behaviours. Information provision and time with expert patients may be extremely helpful for the preparation, but long term learnt behaviours may be hard to change. The introduction of CBT strategies to patients referred for SCS treatment, with a clear focus on coping and enhancement of locus of control, may improve patients' preparation for this treatment. Being knowledgeable about strategies to use when feeling out of control could well be vital to success. It was noticed during the interviews that many patients did not have strategies in mind for difficult situations. Specific strategies explained by a CBT instructor will improve self-efficacy when coping. Patients need to be fully supported and educated on how thoughts and behaviours interact, to be able to go on and make changes to their behaviour. Self-efficacy is important when making changes in an individual's life (Rogers 1975). Enabling participants to feel confident about making changes in their thoughts and behaviours will result in a higher chance of change occurring (Ajzen and Maddon 1986).

### **8.3 SCS information**

Interviews conducted to generate themes regarding the SCS experience revealed important insights not shown by the selected questionnaires. The interviews allowed for an elaboration of the specific issues faced by those participants. A clearer and more detailed understanding of the topics was gained through the interviews. This supported the quantitative findings, giving meaning and a developed understanding to the psychological factors highlighted by the questionnaires. A common and repetitive theme was that access to information and methods of information provision during preparation for SCS could be improved for this particular cohort of patients. Inconsistencies were observed in terms of satisfaction with information received prior to SCS trial. Interestingly those who received better pain relief were generally more satisfied with their knowledge before SCS treatment commenced. There was mention by participants that this was due to information seeking by their own

initiative via sources such as the internet. Having correct and clear information about treatment may reduce anxiety alongside reduction of catastrophising and also increase feelings of control, the three psychological factors deemed important as a result of the quantitative research. Thorough information sessions may also ensure that realistic expectations about the SCS treatment are established. Expectations may also interact with the perception of control and levels of anxiety experienced.

This need for improved information may be further enabled by the introduction of expert patients. This was suggested by several patients interviewed for the qualitative study. Some patients are expert at managing their conditions and this can be helpful for other patients to observe. Expert patients can communicate their experiences, skills and management decisions to other patients, providing them with insight and a different level of understanding to that of a health professional (Tattersall 2002). Being able to talk to an individual who has experienced the treatment may provide patients with a chance to ask questions that they may not ask their consultant. The information will come from someone in a similar situation, someone who they may be able to identify with. An expert patient may address the treatment and procedure in a way that the health professional may find more difficult, due to not having the patient experience. The unexpected experiences that patients reported may also be reduced by talking with an expert patient, which may lead to a possible reduction in psychological distress. Selection of the expert patients should be done with caution to ensure that patients referred for SCS are receiving correct and useful supportive information. The introduction of an expert patient session could be included within a tailored CBT pre-operation programme for SCS. As suggested by the quantitative findings a CBT programme targeting maladaptive coping in the form of catastrophising and lack of perceived control over pain may enhance a patient's probability of obtaining good pain relief with SCS treatment.

#### **8.4 Recommendations for future research**

Future research should focus on testing the model for confirmation of these variables as predictors or recalculation if necessary. The predictive equation formulated from psychological factors affecting the efficacy of SCS needs further testing on a new cohort or several cohorts of patients to test reliability. It would be of interest to include a larger cohort

of failed trial patients to allow investigation of potential psychological variables affecting these patients. In addition, a multicentre study would allow verifying if this equation is generalisable to other pain management treatment centres where SCS treatment is provided. A centre in Sweden has expressed interest in collaboration and the testing of the equation with their patients. This collaboration was suggested following the publication of the qualitative investigation of the SCS experience.

Research on the impact of a tailored CBT course, targeting perceived control and maladaptive coping prior to SCS treatment may also be of interest. This would allow investigation of whether individuals with higher scores of catastrophising and lower control over pain scores can achieve  $\geq 30\%$  reduction in pain from SCS treatment, if appropriately prepared via a suitable CBT programme. Moreover, it could confirm the efficacy of CBT to modify a patient's perception of their chronic pain further increasing the probability of success in SCS.

### **8.5 Implications of the findings**

The clinical implications resulting from the research carried out within this thesis are presented below.

#### *Implications for practitioners*

The qualitative findings underpinned the quantitative findings. Specific ways to enhance and improve the quantitatively identified psychological variables were outlined. The research has highlighted that improved preparation and enhanced educational provision for patients selected for SCS may reduce some of the psychological discomfort (anxiety/catastrophising/perceived low control over pain) potentially experienced during the treatment period. The published qualitative section of this research has been cited by Campbell, Jamison and Edwards (2013), the authors state that 'Sparkes and colleagues found that coping with pain and emotional impact on coping was a major determinant of SCS outcomes for patients. The authors suggest improved education/preparation and CBT for patients prior to undergoing SCS, as these approaches may serve to minimise and buffer the effects of negative affect during treatment period'.



#### *Administration of HAD and PCSQ questionnaires at baseline assessment*

To allow calculation of catastrophising, anxiety and control over pain scores. The scores would be entered into the predictive equation, generating a probability of success. Identification of individual scores on each of these psychological factors would allow insight into possible areas where patients may need additional support and education to assist them to benefit from the treatment. It should be noted that this equation needs further testing and it is not the author's intention to state that the future treatment of a patient should be decided based on a mathematical model. This model should be seen as an auxiliary tool used to assist a physician's work.

#### *Appropriate CBT*

A tailored CBT course including an information session and expert patient session prior to SCS treatment may increase adaptive coping skills, thereby reducing catastrophising and increasing perceived levels of control. Suitably preparing individuals for SCS treatment may increase the efficacy of this treatment. The tailored CBT course would be advised to focus on exercises that reduce catastrophising and anxiety, educating patients on the relationship between psychological factors, pain and treatment outcome and providing patients with skills to facilitate enhanced feelings of control over their pain. A web based CBT course could also be made available for patients to use in their own time, which would mean it is available at times when patients most need support. Some patients may prefer a course that is not group based. Helping patients to increase perceived control may be a matter of enabling a change in cognitions and using exercises that reframe an external locus of control to a more balanced view including internal locus of control. The kind of activities that may allow patients to increase an internal locus of control include goal setting, considering ways to improve daily life and further development of knowledge over their condition and treatment. Moreover, enhancing decision making and problem solving skills may increase perceptions of control.

#### *Health care staff information*

Providing the healthcare team involved with the care of SCS patients with information about the SCS experience which will further equip the healthcare staff with the necessary knowledge to understand the procedure. Patients reported feeling on occasions that health care staff directly involved with their treatment and recovery were not aware of the treatment

process. It is important to explain the SCS trial and implantation, as well as potential psychological factors patients may experience. This may enhance the communication and improvement of experiences between staff and patients.

#### *Long term implications*

The findings from this thesis represent a feasibility study. The psychological variables identified will now be further explored through a larger scale study. The developed equation remains tentative until a sufficient number of patients are recruited to achieve 0.8 power. The findings of the current thesis were presented at the recent NSUKI ASM and German Neuromodulation Society Joint Meeting in Berlin, Germany on the 23-24 November 2012. This oral presentation generated much interest amongst the pain consultants and resulted in the participation of two other hospital sites implanting SCS. The addition of two other sites in the research will increase participant numbers and participant diversity for further testing of the equation.

### **8.6 Reflections of the research**

This thesis has undoubtedly furthered my knowledge and skills in a number of different ways, which will now be briefly detailed. This final section of the thesis provides the reflections of my journey.

The start of the process involved an understanding of the treatment pathway and procedure undertaken by the patients selected for SCS. The initial period was spent in the pain management clinic, working with other colleagues collecting data for a number of different small research projects. This period provided an opportunity to expand the understanding about the SCS treatment and the journey patients made to get to that point of treatment. A number of one to one patient appointments with the consultant were attended to gain further insight into the patient experience. On frequent occasions the impact of chronic pain upon individuals' lives lead to feelings of shock and sadness. The opportunity to engage at this level also provided time to develop working relationships with the health care staff involved in patient treatment, acquire a clear understanding of the SCS treatment and the process followed by the pain management team. There was also opportunity to attend theatre sessions where SCS was implanted. This experience allowed furthering the necessary

understanding of the treatment from a holistic point of view, facilitating an understanding of every step of the SCS treatment process.

The first year of the PhD involved the development of the research protocol, university sponsorship and NHS ethics application. This progression allowed cementing the initial thoughts and ideas for the PhD. The feedback from a panel at Birmingham City University that evaluated the research proposal and the Birmingham, East, North and Solihull Research Ethics Committee provided confidence in the research and considerations for enhancement of the research proposed. The few changes suggested included tracking patients' psychological factors via questionnaire at six months as well as 12 months. After discussion it seemed that an opportunity would potentially be missed by not collecting a six months follow up as changes could be occurring at this time point. As observed after the analysis, at this time there were no clear indications of the effect of psychological factors upon outcome.

Collecting participant data at baseline, six and 12 months provided a challenge, as patients often missed scheduled appointments. A good working relationship was essential with the health care staff in order to arrange patient follow ups that coordinated with the research needs. The consultant's medical secretary engaged with the researcher by contacting patients at the necessary times for follow up within the research. It became clear that it was important to maintain good working relationships with the SCS patients, to allow compliance in filling the questionnaires three times throughout the first year of their treatment. Patients were willing to engage in the process viewing it as giving something back in return for their treatment. Only one patient refused to take part, claiming that the process was too time consuming.

The follow up of patients at six and 12 months was extremely time consuming but a strict regime was maintained with patients who failed to attend receiving gentle reminders. The analysis process took some time with investigation of the data being repeated to ensure errors at any stage during the analysis were avoided. The results allowed the generation of a predictive model for probability of outcome for SCS treatment. The six month analysis indicated no clear predictors for SCS efficacy, further illustrating possible placebo effects. The analysis process enabled an understanding of statistical analysis to be developed. The

development of the predictive equation provides an opportunity for further investigation with a new cohort of patients from other centres.

During the progress in the PhD journey there was opportunity to submit numerous abstracts to national and international conferences. Attending the World Institute of Pain conference in New York was one of the many highlights of this journey. Attendance at conferences provided the opportunity to receive feedback on the work carried out and be inspired by my peers' work. Working with colleagues and supervisors to develop the abstracts and poster presentations was an essential learning process. It proved an opportunity to learn from others and also spawn interests and understanding of areas outside my immediate research interests.

The systematic literature review confirmed that this research would be enhanced by both quantitative and qualitative investigations. By investigating the experience of living with pain and the SCS treatment experience through a qualitative approach, additional aspects that questionnaires did not highlight were uncovered. Patients were willing to attend an interview after follow up clinics to discuss their experience of the first year of treatment. In addition to the quantitative findings, the qualitative study enabled a clear understanding of what the patient experienced during SCS treatment. The data management software NVIVO proved valuable help and assisted a well-defined data analysis to be undertaken. The semi-structured interviews were a complement to the quantitative findings, highlighting additional insights into the patients' needs for the pre-treatment process.

During the final year, as write up was commencing I had to unexpectedly have major surgery. Although this was a difficult time, the recovery was fairly rapid and as unpleasant as the surgery was, I gained some very personal insight into pain and the debilitating effect of pain. Due to the nature of a personal experience of major surgery, a hospital stay and a recovery period littered with all manner of unexpected experiences, this enhanced the writing up and understanding of the implications of the research findings. This experience has further enhanced the understanding of the psychology of pain and recovery.

This thesis has allowed the development of an understanding of the effect of psychological factors upon pain and more importantly SCS treatment. An understanding of the historical

process of how knowledge and understanding of pain developed as well as physiological knowledge was gained. Writing a systematic literature review, planning and conducting independent research were all valuable learning experiences. The knowledge acquired with this research process has been both precious and undoubtedly indispensable. Understanding the research process in such depth and learning from mistakes can only be useful for all future research prospects. Pain is most certainly a challenging and problematic area for medicine and psychology. Treatments such as SCS provide a fantastic opportunity to regain some control over individual lives. What seems imperative to successful SCS outcome is acknowledging psychological factors (anxiety, catastrophising and control over pain), which may affect efficacy. Psychological factors may be treated before or as part of a treatment for optimum outcome. The selection and preparation process provides patients and health care staff with the opportunity to target and modify psychological factors.

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## Appendices