A FEASIBILITY RANDOMISED CONTROL TRIAL OF ACCEPTANCE AND COMMITMENT THERAPY FOR SPINAL CORD STIMULATION SURGERY PATIENTS

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Thesis Abstract

Introduction: This thesis explored the feasibility of conducting a randomised control trial (RCT) of Acceptance and Commitment Therapy (ACT) within patient's Spinal Cord Stimulation (SCS) treatment pathway. Previous ACT literature has reported that this is an effective intervention with persons with chronic pain, even when in a self-help format. Whilst this growing body of ACT literature is promising, chronic pain is a broad term used for a number and varying levels of disability. Chronic neuropathic pain (CNP) is usually more complex and resistant to treatment. According to NICE guidelines SCS should be the last treatment option for CNP sufferers. However, there is currently a dearth of literature exploring the effectiveness of the addition of a psychological interventions with the SCS population.

Objectives: The aim of this thesis was to explore the parameters of interest in ACT with SCS patient population including recruitment, acceptability of intervention and treatment signals.

Design: A mixed between-within group design with repeated measures. There were three conditions in the study.

Methods: Ethical and NHS trust approval was obtained. SCS participants were recruited from one Neuromodulation clinic during their routine appointment. Fourteen SCS patients that consented to the study were randomised to either SCS combined with an ACT self-help intervention (SCS-ACT) or SCS and treatment as usual (SCS-TAU). A third arm of the study was included to gain additional information on the ACT self-help intervention. This arm had been assessed for SCS surgery at the same neuromodulation clinic but deemed to be not suitable for the surgery. They were invited to the study via a letter from the clinic. All participants completed outcome measures pre and post-intervention.

The participants in the two ACT arms (SCS-ACT and ACT-only) were given an ACT self-help manual and received telephone support sessions over six consecutive weeks. These participants also completed an interview at the end of the intervention.

Results: Recruitment to the study was lower than expected and the majority of the participants in the ACT conditions (77%) did not complete the self-help manual. All the participants in the SCS-ACT condition had reliable improvement on at least two outcome domains, however, due to the small sample size it was not possible to assess whether these improvements were due to the SCS surgery or the ACT intervention. The interviews identified a number of barriers that prevented participants completing the manual.

Discussion: The study demonstrated that a number of amendments need to be made to the study design and the self-help manual before a full-scale RCT is justified. Therefore it is recommended that a number of alterations are implemented in another feasibility study to assess whether this improves recruitment, retention and outcomes.

Acknowledgments

I would like to thank all the people who took the time to participate in this study and the Neuromodulation staff that helped me with recruitment and made me feel welcome in attending the clinic. Thanks also to my supervisors Roshan das Nair, Nima Moghaddam and Surajit Basu for all their advice and support throughout the duration of the project.

On a personal level, I wish to thank my family for always supporting me in my academic endeavours. I wish to dedicate this thesis to my amazing wife for her patience and tolerating my temporary absence of a social life throughout this process and always believing in me.

Statement of Contribution

I, Samantha Akiens, declare that this thesis is the product of my own original work which I have carried out whilst enrolled on the Trent Doctorate in Clinical Psychology. Throughout the course of the research I have received regular input and supervision from my supervisors, Dr Roshan das Nair, Dr Nima Moghaddam and Mr Surajit Basu. I applied for ethical approval and wrote the review of the literature. I arranged with the Consultant Neurosurgeon, Surajit Basu that the department of neurosurgery would disseminate the information packs and initially approach potential participants regarding the study. I carried out all of the telephone support sessions and completed the data collection for the study. Dr Roshan das Nair and Dr Nima Moghaddam offered consultation during the telephone support sessions, data analysis, and interpretation stages.

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SYSTEMATIC LITERATURE REVIEW

Cover Sheet

The author will aim to publish this systematic review in “The Clinical Journal of Pain” journal. The Journal’s guidelines for authors are available from this website: http://edmgr.ovid.com/cjp/accounts/ifauth.htm

The layout of this assignment therefore follows these guidelines.

Are Self-Help Psychological Interventions Effective in Treating Chronic Pain? A Systematic Review

Abstract

Objectives: Chronic pain affects a large proportion of the population. Psychological therapies have been suggested as an effective way of managing these difficulties. However, the psychological services do not always have the capacity to meet the increasing demand for this therapy; therefore there has been an emergence of self-help interventions. The objective of this current review is to critically appraise the research on the effectiveness of self-help interventions for chronic pain in reducing pain intensity.

Methods: Electronic searches were conducted in EMBASE, PsychINFO, Medline, Web of Knowledge and Cochrane, and reference lists were examined. Fifteen studies met inclusion criteria and were assessed for methodological quality.

Results: There was mixed evidence on efficacy of psychological interventions in reducing pain intensity, however, results were more positive regarding the participants developing skills and/or strategies to manage their pain. There was also good evidence that these interventions improved mood, although the evidence for CBT improving mood was mixed. There was variation in the amount of studies that included telephone support as part of the intervention, but this did not appear to add any benefits to outcomes.

Discussion: The current review provides additional support for chronic pain sufferers benefiting from self-help psychological interventions although the evidence base for these needs to be increased before any definite conclusions can be drawn.

Key words: self-help, psychological intervention, therapy, chronic pain,

Introduction

Chronic pain is defined by the International Association for the Study of Pain as pain that persists past the healing phase after trauma or surgery.[1] Due to the difficulty in determining when the end of the healing phase is, so it is common for clinical definitions to set an arbitrary interval of time since the onset of the pain. The two most commonly used markers are three and six months[2]. It is likely that this lack of uniformity in the definition has impacted on the variations in reported prevalence rates of chronic pain. Although, it is stated that 37% of people in developed countries experience chronic pain[3] the prevalence estimations differ between countries. In Denmark the chronic pain prevalence is 20%[4] whereas Sweden reports this to be 55%[5]. Regardless of the exact prevalence rate or definition of chronic pain it is universally accepted that it is a deliberating condition, with 60% of sufferers living with the pain for up to 15 years[6] and is associated with social isolation[7], depression[8] and reduced quality of life[9]. In addition to the individual cost of chronic pain it is also costly to health care systems, disability compensations and work productivity[10]. Therefore, it is contested that chronic pain is a significant public health problem.

The predominate treatment for chronic pain is pharmacological[11]. However, this can cause deliberating side effects and patients may still report inadequate pain relief[12]. The next treatment option is usually corrective surgery[11], yet this also has mixed results and is associated with high costs to healthcare systems[11].Consequently, psychological treatments are being increasingly used as an additional treatment for chronic pain in order to provide a more holistic care package[13].

Cognitive Behaviour Therapy (CBT) focuses on helping patients manage their pain and distress by challenging negative, catastrophising beliefs and modifying unhelpful behaviours such as avoidance[14] . Meta-analyses have reported moderate effect size for patients with chronic pain[15-16]. More recently, therapies such as Acceptance and Commitment Therapy (ACT) have been applied to the chronic pain domain. The aim of ACT is to assist chronic pain sufferers to develop acceptance of their pain, rather than trying to control or stop it existing. ACT practitioners argue that while the pain hurts it is the struggle with attempting to control the pain that causes the real suffering[17]. Therefore ACT interventions work on increasing psychological flexibility in the presence of negative thoughts and feelings and increasing engagement in valued activities. A systematic literature review of ACT interventions for chronic pain reported that in general, patients with chronic pain responded reasonably well to acceptance based therapy[18]. Although, they concluded that this type of intervention was not superior to CBT but was a good alternative.

Despite the increasing literature examining the effectiveness of psychological therapies in treating chronic pain there are a number of barriers in people accessing these interventions. In the current economic climate there is limited psychological services available in public health settings and current capacity is not able to meet this demand[19-20]. This problem is particularly prominent in rural areas. Even if services were available, research has demonstrated that less than 40% of those experiencing clinical distress choose to attend therapy[19]. Therefore it has been proposed that the use of self-help as a delivery format for psychological interventions could overcome some of these barriers. The advantages of this approach are that it reduces therapist time and waiting lists, allows the patients to work at their own pace, it is available to more patients and is cost effective[21].

There have been two systematic literature reviews that have investigated the effectiveness of CBT delivered via the internet for chronic pain[21-22]. The first review[21] investigated chronic pain within its review of health problems; therefore the review also included patients with tinnitus[23] and cancer[24]. The authors reported that the effects for internet interventions that targeted pain were comparable to the effects found in face-to-face CBT. They predicted that the internet would play a major role in delivering CBT for people with health problems in the future. However, this review only explored CBT as a psychological intervention despite growing literature on third wave approaches.

The second review[22] also focused purely on internet based CBT for chronic pain. This review reported small pain reductions in the intervention groups compared with waiting list controls. Hence providing further support for self-help interventions in the treatment of chronic pain. However, from closer inspection of this review, it appears that the authors did not follow a clear definition for chronic pain when selecting their studies. Two of the studies[25-26] included in the review had chronic pain mixed in with other health related conditions, rather than exclusively focusing on pain. For example one study[26] investigated web based CBT for diabetes, hypertension, lung disease, heart disease and arthritis. Therefore contaminating the data when trying to ascertain the effectiveness of CBT self-help interventions for chronic pain.

Objectives

The primary aim of this systematic review was to investigate whether psychological self-help interventions are an effective tool in treating chronic pain. Secondary aims included:

1. to review any differences in outcomes of chronic pain in the different modalities of self-help psychological intervention, with particular attention being focused comparing CBT and ACT.
2. To ascertain if there are any differences in outcomes in the locations of the chronic pain.
3. To assess whether telephone support in addition to self-help improves treatment outcomes.

Materials & Method

A systematic review of the literature of self-help interventions for treating chronic pain was conducted using five main electronic databases: Cochrane Library (1991-July 2013), EMBASE (1980-July 12013), Medline (1950-July 2013), PsychInfo (1806-July 2013) and Web of Science (1900-July 2013). The DART- Europe Etheses and Dissertations were used to search for grey literature to reduce publication bias. The Cochrane database and other search engines were initially used to identify whether any systematic reviews had already been published in this field. Systematic literature reviews that had previously encompassed chronic pain and/or self-help interventions were used to identify specific search terms. A list of keywords falling within three key search strategies were used: terms related to chronic pain, terms related to self-help and terms related to psychological intervention. An example of the PsychInfo search strategy is provided in Appendix A. Minor modifications were made for other databases.

Selection

Inclusion and Exclusion Criteria

Randomised control trial (RCT) are considered to be the 'gold standard' on the hierarchy of evidence for quality of study designs, followed by controlled clinical trials[27]. The initial scoping review identified that the majority of the studies in this area had used these methodological approaches therefore only RCTs and CCTs were only included in the review. Studies that used methodological approaches at the bottom of hierarchy such as single case studies and case reports were excluded from this current review. In addition only studies that were published in English were included.

Intervention

All modalities of psychological therapy were included as long they were delivered in a self-help format. Previous reviews had restricted interventions to either one psychological model and/or delivered via the internet[21]. Whereas in this current review there was no restriction on how the self-help intervention was delivered, whether that be via the internet, a book, audio tape or DVD. In addition studies that included telephone and email support sessions alongside the self-help intervention were included.

Population

Studies identifying their patient population as adults experiencing chronic pain were included. The definition of chronic pain may vary between studies; however this review is following the British Pain Society definition of chronic pain (lasting more than 12 weeks or beyond the normal tissue repair). Therefore participants in the studies must meet this definition to be included in the review. Studies were excluded if they did not explicitly state how long participants must be experiencing pain to participate in their study. There were no restrictions on the location of the pain; therefore headaches were included as long as they met the other inclusion criteria.

Outcomes

Pain intensity was chosen as the primary outcome measure based on the IMMPACT recommendations[28.] Therefore only studies that included a pain intensity measure pre and post intervention to evaluate treatment effectiveness were included. Secondary outcomes included mood, management of pain, functional impairment and attrition rates.

Data Extraction and Quality Assessment

Data was extracted from studies meeting the full inclusion criteria to a standardised coding sheet based on the Cochrane library's recommendations for data extraction[29]. Information that was extracted related to the design of the study, the participants primary diagnosis, participant characteristics, method of treatment and outcome measures.

The quality of the research design was assessed using a chronic pain specific measure of psychological treatments[30] (see Appendix B for Quality Rating Scale scoring template). The quality rating adopted in this current review has previously

been used in two Crochrane reviews investigating the effectiveness of psychological therapies (face-to-face) in the management of chronic pain with adults[15] and children and adolescents[31]. However, the therapist training item was removed from the quality ratings due to it not being applicable to the reviewed studies. The amended Quality Rating Scale provides an overall total quality (zero to 33) and two subscales: a treatment scale score (zero to seven) that cover the stated rationale for treatment, manualisation, and patient engagement; and a design and methods scale (zero to 26) that cover inclusion/exclusion criteria, attrition, sample description, minimisation of bias (randomisation, allocation bias, blinding of assessment and equality of treatment expectations), selection outcomes, follow up analysis and control group.

The quality of reporting was also assessed using the Crochrane Collaboration 'risk of bias' assessment tool[29]. This tool assessed possible sources of bias in reporting the outcomes of a RCT (see Appendix C for scoring template).

Data synthesis

A meta-analytic procedure was not used to synthesis the data due to the heterogeneity in study designs, populations, type of intervention and outcome measures. Therefore the authors completed a narrative synthesis of the data.

Results

Results of the search

A total of 505 articles were obtained from the electronic searches (after de-duplication). The titles and abstracts were screened from the initial pool and 46 citations met the initial inclusion criteria and underwent a full text review. Reference lists from similar systematic reviews and the retrieved articles were hand searched to identify a further six studies. The inclusion and exclusion criteria were applied to the 52 full text articles subsequently 37 studies were excluded during the full text analysis. The texts were excluded due to participants not meeting the criteria for chronic pain, the interventions been non-psychological, interventions were not delivered within a self-help format and the articles were review papers. After this systematic procure of gathering literature only 15 studies met all the inclusion criteria and were included in the review.

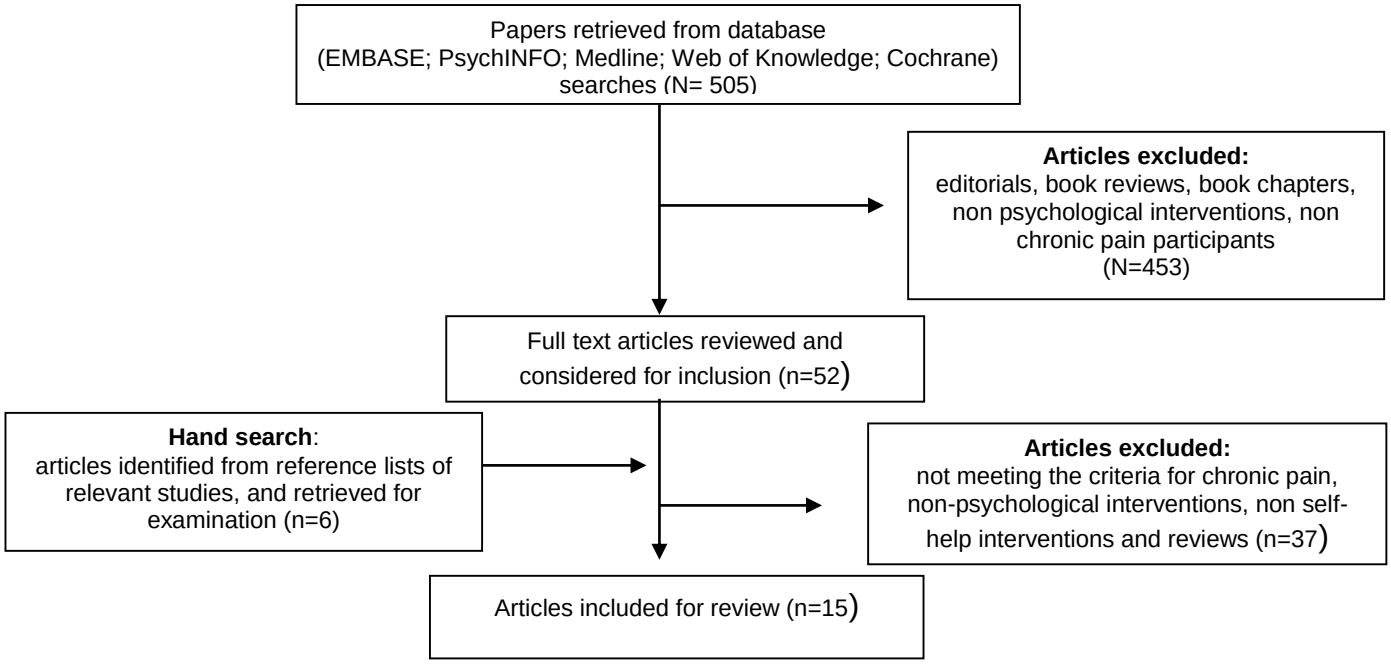

Figure 1: Quorum diagram outlining the selection process

Overview of included studies

Table 1 summarises the characteristics of the 15 studies included in the current review. The number of participants per study at the end of treatment ranged from 24[32] (Johnston et al. 2010) to 855[33] (Lorig et al., 2008) and all of the studies had a female gender bias (ranging from 58-100%). The studies were predominately conducted in Sweden (n=7) or the USA (n=7), with one study being conducted in New Zealand. Four studies examined interventions for chronic pain in general [20,32,36,44.] with others more specifically targeting back pain (n=4)[37-40], fibromyalgia (n=4)[33,35,42,,45], headaches (n=3) [34, 41, 43] and arthritis (n=1)[43].

The psychological intervention that was implemented was CBT (n=9) or had a CBT component (n=2), ACT (n=3), Emotional Freedom Techniques, (n=1) and Applied Relaxation (n=1) self-help interventions. The majority of these interventions were delivered in an online format (n= 12), with two using self-help manual and one study using audiotapes. Six studies also provided the participants with telephone support, whereas the remaining nine did not include this as part of the intervention package.

Methodological Quality

All 15 studies were rated for their quality. The overall quality of the studies ranged from 22[43] to 31[45]. The design quality score ranged from 16[38,43] to 24[45] and all the treatment scores were either six or seven. Seven was the maximum score that

could be achieved on this subscale, with nine of the studies achieving this[33-36,38-40,44-45].

All of the studies in the review had clearly specified and provided evidence that they had adhered to the inclusion/exclusion criteria of their study and provided a description of the study sample, with evidence that the groups had broadly equivalent participants. In addition the outcome measures used in the studies were justified, valid and reliable. However, due to the high attrition rates a large proportion of the studies did not make it explicit whether this had impacted on the results nor did they comment on whether there were significant differences in attrition between treatment and control conditions. A large proportion of studies also failed to minimise bias by checking for equivalence in treatment expectations. Appendix D contains a full breakdown of these scores.

The studies were also assessed using the Cochrane Collaboration quality of reporting criteria[29] . Only five studies met all of the criteria[32,37-38,42,45]. None of the studies included in the review were deemed to have performance or reporting bias. Appendix E contains the full scoring of the studies.

Table 1: Summary of included studies

Study	Population, setting	Intervention	Conditions/ assessments	Outcomes
Anderrson et al. (2003)[34]	Population: Headache, for over 6 months Mean age (years): 40.3 % female: 82 Country: Sweden	CBT with telephone support	T: Online CBT with therapist-initiated telephone support (n=24) C: Online CBT- pure self-help (n=20) Duration: 6 weeks Ax: pre, post	Attrition: 29% (treatment); 35% (control) Pain Intensity: significant decrease in duration for treatment group. Mood: Both treatment and control had significant decrease in depression
Brattberg (2008)[35]	Population: Fibromyalgia Mean age (years): 43.8 % female: 100 Country: Sweden	Emotional Freedom Techniques (EFT)	T: online EFT (n=43) C: WLC (n=43) Duration: 1 day for 8 weeks Ax: pre, post	Attrition: 40% (treatment), 16% (condition) Pain Intensity: Treatment significant reduction compared to condition Mood: significant reduction in self reported stress, anxiety and depression in treatment compared to control group Management: Treatment group significant improvement in pain activity engagement, but the two groups the same in pain willingness Self Efficacy: no significant difference
Buhrman et al. (2013)[36]	Population: Chronic Pain Mean age (in years): 49.1 % female: 59.2 Country: Sweden	ACT	T: Online ACT with two phone calls (n=38) C: waiting list invited to online discussion forum (n=38) Duration: 7 weeks Ax: pre, post, six month follow up	Attrition: 24% (treatment), 16% (condition) Pain Intensity: no significant difference Mood: treatment significant improvement in both anxiety and depression compared to control Quality of Life: no difference Pain Acceptance: Significant improvement in treatment group compared to controls
Burhman et al. (2011)[37]	Population: Chronic Back Pain Mean age (years): 43.2 % females: 68.5 Country: Sweden	CBT	T: Online CBT with one telephone call and weekly email correspondence (n=26) C: WLC (n=28) Duration: 9 weeks Ax: pre, post	Attrition: 12% (treatment), 4% (condition) Pain Intensity: no difference Mood: no significant difference on anxiety and depression
Burhman et al. (2004)[38]	Population: Chronic Back Pain Mean age (years): 44.6	CBT Online with telephone support	T: Online CBT with telephone support (n=22) C: WLC (n=29) Duration: 6 weeks	Attrition: 9% Pain intensity: no significant difference Mood: no significant difference in anxiety and depression

	% female: 62.5 Country: Sweden	7 weeks	Ax: pre, post, 3 month follow up	Management: treatment group significant increase in control over pain and ability to decrease pain. Treatment group significant reduction in catastrophising compared to control
Carpenter et al. (2012)[39]	Population: Chronic Lower Back Pain Mean age (years): 42.5 % women: 83 Country: USA	CBT	T: online CBT (n=70) C: WLC (n=71) Duration: 6 weeks Ax: pre, week 3, post	Attrition: 10% (treatment), 22.5% (control) Pain Intensity: no significant difference Mood: Treatment group significantly better mood regulation, lower ratings of helplessness Management: Treatment significantly stronger beliefs they could control pain, less strongly believed that they were disabled by pain Self efficacy: Treatment significant improvement compared to control
Chauzzi et al. (2010)[40]	Population: Chronic Back pain Mean age (years): 46.1 % female: 78 Country: USA	CBT	T: Online CBT(n=104) C: placebo, text material (n=105) Duration: two weekly sessions across four weeks (8 modules) Ax: pre, post, three month follow up, six month follow up	Attrition: 15% (treatment) 1% (condition) Pain Intensity: Treatment lower scores on 'worst' and 'average' pain ratings Mood: significant improvement on reducing stress, coping statements, no difference on depression, anxiety, stress Self efficacy: no significant differences
Devineini & Blanchard (2005)[41]	Population: Chronic Headache Mean age (years): T= 43.6, C= 41.0 % female: T= 88, C= 79 Country: USA	CBT	T: Online CBT (n=39) C: WLC (n=47) Duration: 4 weeks Ax: pre, post two month follow up	Attrition: 38.1% post; 64.8% follow up Pain Intensity: reduction in headache number, headache symptoms, headache disability Mood: no changes in depression and anxiety
Johnston et al.(2010)[32]	Population: Chronic Pain Mean age (years): 43 % female: 58% Country: New Zealand	ACT	T: ACT self-help book (n=12) with telephone support C: WLC (n=12) Duration: 6 weeks Ax: pre, post	Attrition: 50% (treatment), 33% (condition) Pain Intensity: no differences Mood: significant improvement in anxiety, satisfaction with life in treatment group Management: significant improvement in acceptance
Lorig et al. (2008)[33]	Population: Arthrtis and fibromyalgia Mean age (years): 52.4	Arthritis self management programme	T: internet Arthritis Self-Management programme and peer moderated online workshop (n=433) C: TAU (n=422)	Attrition: post- 28% (treatment), 22% (condition) Pain Intensity: significant improvement between treatment and control groups

	% female: 89.8 Country: USA	(CBT main component)	Duration: 6 weeks Ax: pre, post, one year follow up	Mood: Treatment group significant decrease in health distress Self efficacy: Significant improvement in treatment
Menzies et al. (2006)[42]	Populaiton: Fibromyalgia Mean age (years) :49.6 % female: 97.9% Country: USA	Guided imagery	T: guided imagery plus usual care. Three audiotapes with guided imagery scripts (n=24) C: TAU (n=24) Duration: 6 weeks Ax: pre, post, 10 week follow up	Attrition: not reported Pain Intensity: no significant differences on all scales Self efficacy: significantly improvement in self efficacy for managing pain and managing other symptoms for treatment compared to control conditions Functional Status: significant improvement
Ruehlman et al. (2012)[20]	Population: Chronic Pain Mean age (years): 44.9 % female: 64 Country: USA	CBT	T: online CBT (n=162) C: WLC (n=143) Duration: 7 weeks Ax: pre, post, 14 week follow up	Attrition: 7.6% Pain Intensity: significant improvements on pain severity, interference, perceived disability but not on perceived control Mood: significant improvement in decreasing depression, anxiety, stress, pain induced fear
Strom et al. (2000)[43]	Population: Recurrent Headache Mean age (years): 36.7% % female: 68 Country: Sweden	CBT	T: online CBT (n=20) C: WLC (n=25) Duration: 6 weeks Ax: pre, post	Attrition: 56% Pain intensity: significant decrease in number of headaches, pain intensity Mood: no difference on depression
Thorsell et al. (2011)[44]	Population: Chronic Pain Mean age (years): 46 % female: 64.4 Country: Sweden	ACT & AR	T1: ACT self-help manual with telephone support (n=52) T2: AR self-help manual with telephone support (n=38) Duration: 7 weeks Ax: pre, post, 6 month follow up, 12 month follow up	Attrition: 37% (T1), 18% (T2) Pain Intensity: T1- pre>post pain intensity, level of function; T2- pre=post pain intensity, level of function Mood: T1 - pre>post improvement in anxiety, depression and satisfaction with life T2- pre>post improvement in anxiety, depression, pre=post satisfaction with life
Williams et al (2010)[45]	Population: Fibromyalgia Mean age (years): 50.5 % female: 95 Country: USA	CBT	T: online CBT (n=59) C: TAU (n=59) Duration: 6 months Ax: pre, post	Attrition: 10.2% Pain intensity: significant decrease in pain intensity, increasing physical functioning Mood: no difference in depression, anxiety, fatigue

Notes: T= treatment condition; T2= second treatment condition; C= comparator condition; CBT= cognitive behaviour therapy; ACT= acceptance and commitment therapy; AR= applied relaxation; EFT= emotional freedom techniques; Duration= length of intervention; Ax= timing of assessments; WLC= waiting list control; TAU = treatment as usual

Outcomes

The outcome measures used to assess treatment effectiveness ranged between the studies. The current review focused on measures of pain intensity, with secondary outcomes of mood, management of pain, functional impairment and rate of attrition.

Pain Intensity

Pain intensity was measured in studies using diaries, questionnaires or as part of a subscale on a questionnaire. Eight of the 15 studies reported a reduction in pain intensity upon completion of the self-help intervention, although the extent of this reduction varied. In addition one study demonstrated that self-help with versus without telephone support decreased the duration of reported headaches[34]. Five out of the six interventions that used telephone support did not report a reduction in pain intensity.

Another study reported mixed results on pain intensity reduction for chronic pain[44]. This study compared ACT with applied relaxation (AR), although they found ACT to be effective in reducing pain, AR did not yield significant reduction in pre to post pain intensity. However, the two other ACT studies did not find ACT to reduce pain intensity in their samples. All of the studies investigating chronic headaches reported a reduction in pain intensity, whereas other pain conditions had mixed results.

Mood

All but one of the studies included a measure of mood[42] in their data collection. Mood has been used as an umbrella term for depression, anxiety, stress and fear. Nine of the 14 studies reporting at least one significant difference in a measurement of participant's mood. All three ACT interventions found a statistical significant reduction in distress. AR and EFT intervention also both saw a reduction in anxiety and depression. The five studies that did not find any reductions in emotional distress all used a CBT approach to chronic pain.

Management of Pain

Management of pain refers to the ability of the individual to manage the psychological aspects of the pain, this may be reflective of an increase in coping styles or acceptance of the pain. Different theoretical approaches to pain would aim for chronic pain sufferers to manage their symptomology in different ways. The three

studies that used an ACT approach as the intervention all incorporated outcome measure of 'Acceptance' in their trials. Acceptance was increased for all of the ACT studies. CBT studies used a mixture of coping styles and self efficacy questionnaires. All of the studies that had used a measure reported an improvement in some areas of participants ability to manage pain. CBT studies that used coping style questionnaires consistently reported the subscale of 'Catastrophizing' as being a significant finding of their studies.

Functional Impairment

Nine out of the 15 studies completed a measure that investigated behavioural changes in functioning. The review found that six of these nine studies reported a significant improvement in participant functioning between pre and post interventions. The three studies that reported no significant differences all included chronic back pain participants. Those that did report improvement in functioning were mixed in their locations of pain. In a 12 month follow-up participants continued to report significantly lower activity limitation due to pain compared controls[33]. However, this was only the case for participants diagnosed with arthritis. There were no significant differences between participants with fibromyalgia and the control group at follow-up. The authors concluded that treatment outcomes varied according to pain sub types and that participants with fibromyalgia did not gain benefits from interventions to the same extent than those with arthritis. However, another study found that participants with fibromyalgia gained a statistically significant improvement in physical functioning status compared to standard care only participants[45].

Attrition

Attrition ranged from 7.6%[20] to 56%[43] from pre to post treatment. Attrition was typically higher in the treatment condition compared to treatment as usual and waiting list controls. One study compared self-help interventions with versus without telephone contact and found similar attrition rates across the two conditions[34]. It doesn't appear that telephone support impacted on treatment attrition. The mean attrition for studies in this review that included telephone support was 25.8% and the mean attrition for self-help only interventions was 25.6%.

Discussion

This current systematic review sought to critically appraise the empirical evidence on the effectiveness of self-help interventions for chronic pain. There have been 15 studies that have used randomised control trials to investigate this topic that met the inclusion criteria. The results of the review suggest that are some benefits of chronic pain patients utilising self-help materials. Although, the benefit may not necessarily be a reduction in pain, as the findings regarding pain intensity were inconsistent.

All of the studies included a measure of pain intensity as an outcome measure, which is in accordance with IMMPACT recommendations. However, it is important to note that reduction of pain may not necessarily be a primarily focus of psychological interventions. CBT interventions typically aim to improve symptom management including techniques such as relaxation and develop skills to challenge negative thinking styles. ACT interventions aim at increasing acceptance of pain rather than getting into a struggle to control it. This review provides strong support that self-help interventions improve clients management a pain, something which would have been more in line with the therapeutic aims. Therefore, although the intensity of pain may not always be reduced the ability to manage and cope with the pain is increased. Not all of the studies in this review included a management of pain questionnaire and even fewer included a measure investigating how pain interferes with daily life and function. Future recommendations would be for future studies to investigate the effectiveness of psychological therapies of chronic pain using pain interference and ability to manage symptoms of pain measures. Also a key benefit of using self-help as a format of therapy delivery is to cut costs. It would therefore valuable information could be obtained if studies included a measure of health economy outcomes. Outcome measures of this type were not included in the studies in this review.

The studies in this review provided reasonable support that self-help interventions improve both mood and functioning with chronic pain patients. Although there was inconsistent results on participants improvement in mood in CBT self-help interventions. Whereas there were significant improvements in mood of all of the other therapy modalities. A previous meta-analysis assessing the effectiveness of acceptance based intervention for the treatment of chronic pain, compared ACT to previous CBT studies on improving mood but found comparable results[18]. However, it has also been reported that rheumatoid arthritis patients with recurrent depression benefited more from ACT than they did from CBT, compared to patients that do not have recurrent depression[46]. Key features of depression are experiential avoidance and low levels of meaning in life. ACT interventions primarily focus on improving acceptance (thus decreasing experiential avoidance) and exploring values and

values-based living (increasing meaning in life). Clients with chronic pain have a high co-morbidity with depression[47] and for these people ACT might be a more suitable treatment option.

It was not surprising that clients with chronic headaches had greater improvements in pain intensity than other chronic pain conditions. A previous study chose to exclude headaches from their meta analysis of RCT's of CBT and behaviour therapy for chronic pain[16]. Their rationale for this exclusion was that chronic headaches have a different emphasis in treatment (both in provisions and outcomes) and the pain relief from psychological interventions is much more achievable compared to other chronic pain conditions. These results support this assumptions of the review that pain reduction is more achievable with chronic headache conditions.

Only one study specifically evaluated the impact of including minimal therapist contact in a self-help intervention[34]. This study concluded that the addition of telephone support yielded equivalent results to pure self-help, therefore rendering the telephone calls as inconsequential. It has been widely argued that the therapeutic alliance is the biggest predictor of treatment outcomes in psychological interventions[48]. Therefore it would have been expected that the addition of a therapist, even though the contact is minimal would increase therapeutic outcomes. However, this review found this not to be the case. It was worth noting that the studies in this review classified themselves as investigating self-help therefore the telephone contact would have only been a limited aspect of the intervention, which may have made it difficult for a strong therapeutic relationship to be achieved. Previous reviews with different population have however, found that therapist contact leads to lower attrition rates and better outcomes[21,49]. Further studies are required to confirm whether telephone support does offer benefits to self-help treatments for chronic pain. Given that self-help interventions are becoming more widely implemented in an effort to reduce cost then the cost-benefit of telephone could be important in saving additional money and resources. Although one study did not have a telephone support condition they did assess the cost effectiveness of self-help interventions[43]. The study reported that pure self-help interventions were twice as cost effective as minimal therapist interventions and 12 times as cost effective as clinic based interventions.

The current review has several limitations. Firstly only adult interventions were included in the review, this was due to the interventions for children were likely to differ to that of adults. To the authors knowledge there has not been a review exploring the effectiveness of self-help intervention for chronic pain with children and adolescents, which could be an area of future research. Secondary the ability to

apply these results to the general population of chronic pain is difficult due to the gender bias in the studies included. There was a higher prevalence of females in all of the studies. Furthermore there were high attrition rates in these studies; this was something that was highlighted in the quality assessment of the studies.

There were no studies in this review that scored on all aspects on the measure of quality; therefore there is a need for more quality studies in this area. However, a limitation of the quality assessment completed was that it was made on the basis of one researcher's findings on the study. To improve the reliability of this assessment another researcher should have also completed this and the results cross referenced for inter-rater reliability.

An aim of this review was to investigate differences between therapeutic modularity's. Unfortunately there is a limited amount of studies that have investigated the effectiveness of self-help in a non CBT format. Additional studies would be needed to make any comparisons between interventions. Due to a lot of the studies in this review not meeting sufficient power of analysis due to small sample sizes further explorations using a meta-analysis of the data could also be beneficial. This review failed to achieve this.

In summary, the current review provides support to the growing body of evidence that self-help interventions are an effective treatment. This is especially pertinent to a client group that may have difficulty physically accessing services.

Word Count: 5261

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Appendix A: Search Terms (example psychinfo search strategy)

1. exp Pain
2. "diabetic neuropath$".mp.
3. "failed back syndrome".mp.
4. "reflex sympathetic dystrophy".mp.
5. neuralgi$.mp.
6. causalgi$.mp.
7. "chronic pain".mp.
8. "neuropathic pain".mp.
9. or/1-8
10. (self-help or "self help").mp.
11. (self-change or "self change").mp.
12. (self-directed or "self directed").mp.
13. (self-administered or "self administered").mp.
14. bibliotherapy.mp.
15. or/ 10-14
16. therap$
17. intervention$
18. treatment$
19. psychol$
20. psychotherap$
21. or/ 16-20
22. 9 and 15 and 21
23. Limit to 22 to English language, humans and adults

Appendix B: Yates et al. (2005) scoring sheet

Quality Rating Scale – Coding Notes

Treatment Quality

The aim of this section is to ensure that in the report a clear account of the treatment is given and that there is evidence that the investigators took steps to ensure that the treatment was delivered as intended by trained and competent personnel. Each item is therefore a judgement about whether this has been achieved.

Item	Question and Items	Score & Coding Notes
1	**Has a clear rationale for the treatment been given and an adequate description of its content?**	
1 part	**Treatment Content / Setting** The aim of this item is to make a judgment of the quality of the treatment in the trial by ascertaining whether a coherent rationale is given e.g. reference to the relevant evidence base for the treatment. Another consideration is whether an adequate description of the treatment content is given such that there may be sufficient information to stratify studies for example.	**2 - Adequate:** A clear rationale for the treatment has been reported along with an adequate description of its content. **1 - Partial:** Either a clear rationale or a description of the content of the treatment is reported. **0 - Inadequate:** Neither the rationale for treatment or the treatment content are adequately reported
2	**Has the total treatment duration been reported?**	
1 part	**Treatment duration** Total treatment duration includes both number of treatment sessions and duration of each session. Issues relating to the actual number of sessions attended i.e. attrition is dealt with in a later section.	**Reviewer decides.** **1 - Reported** **0 - Unknown**
3	**Is there a treatment manual that describes the active components of treatment?**	
2 parts	**Manualisation** Treatment manuals should clearly prescribe the active components of the treatment and ideally proscribe activities that should not be included within the treatment. Trials with more than one treatment arm should demonstrate that manuals were utilised for each of the treatments where	**2 - Adequate:** there is reference to use of a manual that describes the active components of the treatment of study. If more than one treatment arm, manuals were used for all the appropriate treatments. **1 - Partial:** In trials with more than one treatment arm, the use of a manual is described but not for all the treatments that would be expected to be manualised.

	appropriate, e.g. for relaxation training and coping skills training but not for treatment as usual	**0 - Inadequate:** no evidence that a manual has been used, but reference is made to various principles.
	Adherence to the manual Treatment manuals are also considered essential as they provide a benchmark for various checks of validity e.g. whether therapists are adhering to the treatment under study and whether patients are doing what is required of them.	**1 - Adequate:** there is evidence that the investigators have checked adherence to the manual during the period of study via direct observations, tape recording or supervisory processes that explicitly state adherence to the manual. **0 - Inadequate:** no evidence of adherence checks reported.
4 1 part	**Have the therapists been appropriately trained in the relevant procedures for this trial?**	
	Therapist training The important issue here is not just whether the therapists have the appropriate qualifications and experience *per se,* as a multidisciplinary team may implement the treatment. Of importance is whether the therapists involved have been trained appropriately to conduct the particular treatment of the trial.	**2 - Adequate:** there is documentation of explicit training for the treatment of the trial. **1 - Partial:** the general level of therapist training is reported and is adequate (professionally qualified) but there is no mention of explicit training for the trial. **0 - Inadequate:** there is no convincing evidence that the therapists have an adequate level of training (e.g. graduate level) or explicit training for the trial.
5 1 part	**Is there any evidence that the patients have actively engaged in the treatment?**	
	Client Engagement This item assesses whether the investigators took steps to check that the patients actively engaged in the therapy and complied with the instructions of the treatment e.g. checks for evidence of skills practice, reviews of homework.	**1 - Adequate:** documented that evidence of engagement was sought e.g. checks on homework were made, skills practice in sessions. **0 - Inadequate:** no evidence that checks were made on level of engagement.

Quality of study design and methods

The aim of this section is to ensure that investigators made attempts to ensure that the design of the study was appropriate for its aims and that rigorous methodological effort were made to reduce the potential for bias. Each item is a judgement about whether this has been achieved.

Item #	Question and Items	Score & Coding Notes
1	**Are the inclusion and exclusion criteria clearly specified?**	
2 parts	**Sample criteria** This item explores the context of the patient selection and allows the generalisability of the trial to be examined. Detailed information of the sample can also be used for stratifying in meta-analyses.	**1 - Adequate:** the inclusion and exclusion criteria are clearly specified and there is evidence of adherence to the criteria. **0 - Inadequate:** criteria not clearly specified.
	Evidence that the criteria have been met It is equally important to check for evidence that the inclusion and exclusion criteria have been met.	**1 - Adequate:** clear evidence is reported that the criteria have been met. **0 - Inadequate:** no evidence that any criteria have been met.
2	**Is there evidence that the CONSORT guidelines for reporting attrition have been followed?**	
2 parts	**Attrition** It is considered essential that good quality trials follow the CONSORT guidelines for reporting attrition i.e. “For each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons”. It should be noted that this criteria automatically biases against pre-CONSORT trials i.e. prior to and during 1996	**2 - Adequate:** documented evidence that the CONSORT guidelines have been followed. **1 - Partial:** a reasonable account of how attrition was dealt with is given, but without reference to CONSORT. **0 - Inadequate:** there is no documented evidence or insufficient evidence reported of how attrition was dealt with.
	Rates of attrition It is also important to ascertain whether final sample could be biased due to differential dropout rates between the treatment groups.	**1 - Adequate:** there is evidence that any differential rates of attrition were **not** statistically significant. **0 - Inadequate:** there is insufficient evidence that differential rates of attrition have not resulted in significant bias.
3	**Is there a good description of the sample?**	
2 parts	**Sample characteristics** This criterion is concerned with there being an adequate description of the actual sample obtained in terms of	**1 - Adequate:** there is a good description of the sample in the trial detailing areas such as demographic details, treatment history etc.

	demographic information, concurrent treatments, treatment history, gender, diagnosis, site of pain and chronicity.	**0 - Inadequate:** insufficient information is reported to allow adequate comparisons to be made.
	Group equivalence Good descriptions of the sample characteristics and testing are essential for ascertaining whether there is equivalence between the treatment groups.	**1 - Adequate:** there is evidence that the groups are broadly equivalent shown by testing or examination of reported data. **0 - Inadequate:** either equivalence of groups is not reported or there is evidence of non-equivalence.
4 4 parts	**Have adequate steps been taken to minimise biases?**	
	Randomisation This item examines the steps taken to ensure that each participant of the trial has an equal chance of being allocated to the different treatment arms. In particular, it asks for evidence that an adequate method of randomisation has been used e.g. random number table or computerised random number generator (CONSORT, 1996).	**2 - Adequate:** a convincing method for generating a random allocation sequence is reported that used an independent person not involved in enrolment or allocation of participants. **1 - Partial:** a convincing method of randomisation is reported but this did not involve an independent person. **0 - Inadequate:** randomisation is mentioned but there is not an adequate description of the methods used.
	Allocation bias Were steps taken to ensure that the allocation sequence of patients to the treatment arms was concealed so that investigators could not have biased it? Ideally, an independent person should make assignment; alternatively, assignment can be enclosed in sequentially numbered, opaque sealed envelopes (CONSORT, 1996).	**1 - Adequate:** an adequate method is reported that removes the potential biases of investigators e.g. use of an independent person or sequentially numbered opaque sealed envelopes. **0 - Inadequate:** there is not an adequate description of attempts to deal with potential allocation bias.
	Measurement bias In order to reduce the risk of measurement bias a third party who is blind to the patient's study group should be responsible for the collection of data.	**1 - Adequate:** a convincing effort to reduce bias in outcome measurement is reported e.g. 3rd party blind data collection. **0 - Inadequate:** efforts to reduce measurement bias are not reported or are insufficient e.g. outcomes collected by therapist.
	Treatment expectations It is impossible for participants to be blind to the treatment they are receiving therefore it is imperative that steps are taken to check for equivalence in treatment expectations.	**1 - Adequate:** credible checks for equivalence in treatment expectations are reported. **0 - Inadequate:** checks have not been reported or are insufficient.
5 3 parts	**Are the outcomes that have been chosen justified, valid and reliable?**	
	Justification of outcomes This item is concerned with whether the outcomes measures that have been chosen encompass the aims of the treatment and are therefore justified with regard to those aims.	**2 - Adequate:** all of the outcome measures are justified. **1 - Partial:** most of the outcome measures are justified. **0 - Inadequate:** most or all of the measures used are not justified.

	Validity of outcomes for context A report stating that measures with known validity were used is not sufficient as measures cannot be said to be valid *per se*, only that they have validity in a particular context. This item therefore requires an informed judgement as to whether the measures chosen are valid given the context of the study population and the treatments implemented.	**2 - Adequate:** all of the outcome measures are valid given the context of the study. **1 - Partial:** most of the measures are valid. **0 - Inadequate:** most or all of the measures are not valid given the context of the particular study.
	Reliability and sensitivity to change It is important that the outcome measures chosen have both good reliability (generally defined as $r \geq 0.8$) and sensitivity to change.	**2 - Adequate:** all the outcome measures chosen were shown to be reliable and sensitive to change. **1 - Partial:** most of the measures were reliable and sensitive to change. **0 - Inadequate:** most of the measures were not reliable or sensitive to change.
6 1 part	**Has there been a measure of any sustainable change between the treatment and control groups?**	
	Follow up This item examines whether attempts have been made to measure sustainable changes between the treatment and control groups e.g. over a period of at least 6 months.	**1 - Adequate:** follow up measurements for at least 6 months are reported. **0 - Inadequate:** the follow up period was inadequate to measure sustainable change e.g. less than 6 months.
7 5 parts	**Are the statistical analyses adequate for the trial?**	
	Has a power calculation been used? The report must state that power calculations were calculated a priori.	**Reviewer decides.** **1 - Yes** **0 – No**
	Has a sufficient sample size, based on the power calculation been obtained?	**Reviewer decides.** **1 - Yes** **0 – No**
	Has the data analysis been adequately planned to assess the hypothesis and aims of the trial?	**Reviewer decides.** **1 - Yes** **0 – No**
	Is there adequate reporting of summary statistics? The means, standard deviations and numbers should be reported for the variables. The proportions or frequencies should be reported for dichotomous variables.	**Reviewer decides.** **1 - Yes** **0 – No**

	Did the analysis include an intention to treat analysis? It is important to account for any potential biases in rates of attrition by performing an intention to treat analysis as well as an analysis per protocol.	**Reviewer decides.** **1 - Yes** **0 – No**
8 1 part	**Has a good, well-matched alternative treatment group been used?**	
	Control group This item is concerned with the quality of the control condition in the trial and the efforts made to ensure that as many features as possible have been controlled for	**2 - Adequate:** an active alternative treatment group has been used that is well matched in terms of structural features of the treatment and its meaningfulness. **1 - Partial:** an active alternative treatment group has been used but it is not matched for structural features e.g. bibliotherapy. **0 - Inadequate:** a poor control group has been used that merely controls for the duration of time e.g. waiting list control.

Appendix C Criteria for judging risk of bias in the 'Risk of bias' assessment tool

RANDOM SEQUENCE GENERATION **Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.**	
Criteria for a judgement of 'Low risk' of bias.	The investigators describe a random component in the sequence generation process such as: • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; • Minimization*. *Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
Criteria for the judgement of 'High risk' of bias.	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example: • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.

Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.
ALLOCATION CONCEALMENT **Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.**	
Criteria for a judgement of 'Low risk' of bias.	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: • Central allocation (including telephone, web-based and pharmacy-controlled randomization); • Sequentially numbered drug containers of identical appearance; • Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgement of 'High risk' of bias.	Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.
BLINDING OF PARTICIPANTS AND PERSONNEL **Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.**	

Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; • Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; • Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgement of 'Low risk' or 'High risk'; • The study did not address this outcome.
BLINDING OF OUTCOME ASSESSMENT **Detection bias due to knowledge of the allocated interventions by outcome assessors.**	
Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; • Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; • Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgement of 'Low risk' or 'High risk';

	• The study did not address this outcome.
INCOMPLETE OUTCOME DATA **Attrition bias due to amount, nature or handling of incomplete outcome data.**	
Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No missing outcome data; • Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); • Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; • Missing data have been imputed using appropriate methods.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; • 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; • Potentially inappropriate application of simple imputation.

Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided); • The study did not address this outcome.
SELECTIVE REPORTING **Reporting bias due to selective outcome reporting.**	
Criteria for a judgement of 'Low risk' of bias.	Any of the following: • The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; • The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • Not all of the study's pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; • One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); • One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; • The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. It is likely that the majority of studies will fall into this category.

Appendix D: Quality of Research Design for all of the Studies in the Review

Treatment Scale

Study	Treatment content/ setting (0-2)	Treatment duration (0-1)	Manualisation (0-3)	Patient Engagement (0-1)	Treatment scale score (0-7)
Andersson (2003)	2	1	3	1	7
Brettberg (2008)	2	1	3	1	7
Buhrman (2013)	2	1	3	1	7
Buhrman (2011)	2	1	3	0	6
Buhrman (2004)	2	1	3	1	7
Carpenter (2012)	2	1	3	1	7
Chauzzi (2010)	2	1	3	1	7
Devineini (2005)	2	1	2	1	6
Johnston (2010)	2	1	3	0	6
Lorig (2008)	2	1	3	1	7
Menzies (2006)	2	1	2	1	6
Ruehlman (2012)	2	1	3	0	6
Strom (2000)	2	1	3	0	6
Thorsell (2011)	2	1	3	1	7
Williams (2010)	2	1	3	1	7

Design & Methods scale

Study	1. Inclusion / Exclusion		2. Attrition		3. Sample description		4. Minimise Bias				5. Outcome measures			6. F/up	7. Statstical Analysis					8. Control Group *	Total: methods (0-26)
	A	B	A *	B	A	B	A *	B	C	D	A *	B*	C *		A	B	C	D	E		
Andersson (2003)	1	1	1	1	1	1	1	0	0	0	2	2	2	0	0	0	1	1	0	2	17
Brettberg (2008)	1	1	1	0	1	1	1	1	0	0	2	2	2	0	0	0	1	1	1	2	18
Buhrman (2013)	1	1	1	1	1	1	2	1	0	1	2	2	2	1	0	1	1	1	1	2	23
Buhrman (2011)	1	1	1	1	1	1	2	1	0	0	2	2	2	0	1	0	1	1	1	2	21
Buhrman (2004)	1	1	1	0	1	1	1	0	0	0	2	2	2	0	0	0	1	1	0	2	16
Carpenter (2012)	1	1	1	0	1	1	1	0	0	0	2	2	2	0	0	1	1	1	0	2	17
Chauzzi (2010)	1	1	1	0	1	1	1	0	0	0	2	2	2	1	1	1	1	1	1	2	20
Devineini (2005)	1	1	1	0	1	1	1	1	1	0	2	2	2	0	1	0	1	1	0	2	19
Johnston (2010)	1	1	2	0	1	1	1	1	0	0	2	2	2	0	0	0	1	1	1	2	19
Lorig (2008)	1	1	1	1	1	1	1	0	0	0	2	2	2	1	1	1	1	1	0	2	20
Menzies (2006)	1	1	0	0	1	1	2	1	0	0	2	2	2	0	0	1	1	1	0	2	18
Ruehlman (2012)	1	1	2	0	1	1	2	1	0	0	2	2	2	0	0	1	1	1	1	1	20
Strom (2000)	1	1	1	0	1	1	1	0	0	0	2	2	2	0	0	0	1	1	0	2	16
Thorsell (2011)	1	1	1	0	1	1	1	0	0	1	2	2	2	1	1	1	1	1	0	2	20
Williams (2010)	1	1	1	1	1	1	2	1	1	1	2	2	2	1	1	1	1	1	1	1	24

* this is scored from 0-

Appendix E: Risk of Bias for all the Studies included in the Review

Study	Selection Bias		Performance Bias	Detection Bias	Attrition Bias	Reporting Bias
	Random sequence generation	Allocation Concealment	Blinding of participants & personnel	Blinding of outcome assessment	Incomplete outcome data	Selective Reporting
Andersson (2003)	-	+	+	+	-	+
Brettberg (2008)	+	+	+	-	+	-
Buhrman (2013)	+	+	+	+	+	+
Buhrman (2011)	+	+	+	+	+	+
Buhrman (2004)	-	+	+	+	-	+
Carpenter (2012)	+	+	+	+	-	+
Chauzzi (2010)	-	-	+	+	+	+
Devineini (2005)	-	-	+	+	-	+
Johnstone (2010)	+	+	+	+	+	+
Lorig (2008)	-	-	+	+	+	+
Menzies (2006)	+	+	+	+	+	+
Ruehlman (2012)	-	-	+	+	+	+
Strom (2000)	-	-	+	+	-	+
Thorsell (2011)	+	+	+	-	-	+
Williams (2010)	+	+	+	+	+	+

JOURNAL PAPER

A feasibility randomised control trial of acceptance and commitment therapy for spinal cord stimulation patients

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Abstract

The aim of this study was to assess the feasibility of conducting a randomised control trial (RCT) investigating the efficacy of an Acceptance and Commitment Therapy (ACT) intervention for a chronic pain sample of Spinal Cord Stimulation (SCS) surgery patients. This study used a mixed-between-within participants design. A total of 14 patients that were undergoing SCS were randomised to an ACT self-help intervention or treatment as usual. A third arm included participants that were assessed for SCS but the surgery was not deemed suitable, this group only received the ACT intervention (n=5). The study found a lower than anticipated recruitment rate and 77% of the participants in the ACT arms did not complete the self-help manual. Outcome measures on self-efficacy, pain, mood and health related quality of life was completed at pre and post intervention. All the participants that had SCS and ACT had reliable improvement on pain interference. The qualitative component of the study demonstrated varying degrees of acceptance of pain with this population and identified potential explanations for the high attrition rates. We concluded that a full RCT is not yet feasible and that further adjustments to the study design and self-help manual need to be investigated in a further feasibility study.

Key words: Spinal Cord Stimulation, Acceptance and Commitment Therapy, Chronic Neuropathic Pain, Feasibility study

Introduction

It has been proposed that the prevalence of chronic pain is one of the most under-reported health care challenges in the world (World Health Organization, 2004). Not only is the prevalence rate for chronic pain thought to be underreported but the longevity of the condition is also debilitating, with reports that 60% of sufferers live with the pain for up to 15 years (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006). Therefore chronic pain can be costly to health-care systems, disability compensations and work productivity (Gatchel & Okifuji, 2006). It also has a large impact on the individual (and their carers/family) and is associated with psychological distress (Breivik et al., 2006).

Chronic neuropathic pain (CNP) is more severe than other forms of chronic pain and is thought to be one of the most difficult conditions to treat, due to being less responsive to analgesic drugs (Dworkin *et al*., 2003). Therefore CNP sufferers often undergo a multitude of pharmacological and non-pharmacological interventions in a bid to alleviate their symptoms. The NICE guidelines (NICE, 2008) recommend Spinal Cord Stimulation (SCS) surgery for CNP as a last treatment option due to it being an evasive and costly procedure (Beltrutti *et al*., 2004).

SCS surgery involves surgically implanting a small battery-powered stimulator into the individual. This stimulator delivers electricity to the spinal cord that changes the pain messages that are sent to the brain. The individual has a remote control and is able to adjust the amount of stimulation they receive for the pain relief. The aim of neurostimulation is not to eliminate pain but to reduce its intensity, duration and frequency (Falowski, Celii, & Sharan, 2008). Prior to SCS, individuals are required to have a trial electronic stimulation under local anaesthetic, to determine whether the full operation would provide effective pain relief of at least 50% (NICE, 2008). It is only if pain relief reaches above this threshold that the patient is able to have the full implantation.

A number of RCTs have found SCS to be effective in reducing pain when compared to baseline measures and control groups at six and 12 month post-surgery (e.g., Kemler *et al*., 2004; Kemler, de Vet, Barendse, van den Wildenberg, & van Kleef, 2008). However it should be noted that there are potential biases in these results as some of these RCT's were funded by companies who manufacture the stimulators (e.g., Kemler *et al*., 2008). Other authors have expressed uncertainty about the efficacy of SCS due to it not being effective for everyone (Racz, McCarron, & Talboys, 1989).

Psychological factors may account for these differences and why some individuals experience a loss of analgesia after the surgery (Doleys, 2006). In the chronic pain literature it has been widely established that medical interventions can be affected by the patient's beliefs about the symptoms, the ability to control the pain and the impact this has on their life (Tota-Faucette, Gil, Williams, Keefe, & Goli, 1993). Turner, das Nair, Macniven and Basu's (submitted) study suggested that psychological intervention post-SCS would be valuable to SCS patients. The study explored how patients made sense of their life prior to and following SCS. They found that out of the seven participants interviewed all but one were disappointed with certain aspects of their surgery, which was predominately related to adapting to the process of acceptance of their current pain relief and capabilities. As such, Turner *et al*. (submitted) recommended that some SCS patients may benefit from Acceptance and Commitment Therapy (ACT) to assist with the associated emotions and behaviours during this acceptance process.

Acceptance and Commitment Therapy focuses on accepting rather than controlling pain, and views experiential avoidance as a core pathogenic process (Dahl, Wilson & Nilsson, 2004). The therapy has been used to treat individuals with chronic pain and states that while pain hurts it is the struggle with pain and trying to control it that causes the real suffering (Dahl & Lundgren, 2006a). Pain itself is critical in survival and is an unconditioned reflex that has the function of alerting us to danger or tissue damage, preventing further injury. It is the extent to which an individual fuses thoughts and feelings associated with pain that impacts the intensity of their suffering. The aim of ACT is to increase psychological flexibility in the presence of

these negative thoughts and feelings and to increase engagement in valued activities.

There is a growing evidence base for the efficacy of ACT with chronic pain populations (Ost, 2014). Veehof, Oskam, Schreurs and Bohlmeijer (2011) conducted a meta-analysis of acceptance-based interventions for the treatment of chronic pain. The meta-analysis found that acceptance-based therapies had small to medium effects on physical and mental health in chronic pain patients that were comparable to CBT. However, the authors noted that given the important role acceptance and mindfulness play in adaptation to chronic pain (McCraken, MacKichan & Eccleston, 2007), the development of more effective therapies was warranted. Since this meta-analysis was conducted there has been studies investigating the effectiveness of ACT in a self-help format for chronic pain sufferers (Johnston, Foster, Shennan, Starkey, & Johnson, 2010; Thorsell et al., 2011). These studies have yielded promising findings, with ACT participants showing improved outcomes from pre to post intervention. However, the studies did not specify the severity of the participant's chronic pain. Chronic pain is often adopted as an umbrella term for a multitude of different diagnosis, ranging from arthritis, fibromyalgia to chronic fatigue syndrome. The term 'chronic' means that the pain must have been experienced for a minimum of six months or beyond the time expected for normal tissue repair (Turk, & Okifuji, 2001). However, people can have chronic pain for many years and exhausted all of the available treatment options available to them or they may have experienced chronic pain for six months and a psychological intervention is one of the first treatment options they have explored. As already discussed patients undergoing SCS surgery are in the latter part of their pain treatment journey. To the author's knowledge, the efficacy of an ACT self-help, or any other psychological therapy for the SCS population has yet to be investigated.

When developing a complex intervention, as in the current study, the Medical Research Council (MRC, 2008) guidelines stipulate that piloting work is of great importance. According to these guidelines, the feasibility and piloting stages include: testing procedures for their acceptability, estimating the likely rates of recruitment and retention of participants, and calculation of appropriate sample sizes.

Consequently, the MRC guidelines on developing complex interventions have informed the aims and design of the current study. Therefore the primary objective of this feasibility study was to address issues with recruitment and the acceptability of the intervention in the SCS treatment pathways. The secondary objectives were to assess how the self-help manual could be improved and the effectiveness of an ACT self-help intervention with SCS patients.

Method

Participants

Participants were recruited from one Neuromodulation clinic over a twelve month period. During this time fourteen participants who were due to have SCS surgery consented to participation and were randomised to either the SCS and ACT intervention (SCS-ACT) or SCS and the treatment as usual (SCS-TAU) intervention. A third arm of the study included participants that had the trail SCS but did not have the full SCS surgery, they were recruited via a letter from the clinic inviting them to the study. All the participants that consented to the study in this arm received the ACT self-help manual (ACT-only). The third arm of the study was included to gather additional information on the ACT self-help manual, it is not anticipated that this group would feature in a future full RCT.

Procedure

Potential participants were identified during a routine clinic appointment prior to the SCS surgery. Participants were given a study information sheet, signed a consent form and completed the baseline measures. They were then randomised to either the SCS-ACT or SCS-TAU conditions using the Sequentially Numbered, Opaque Sealed Envelopes (SNOSE) method.

As per the department's standard protocol, one week after consenting to the study participants had SCS surgery. At this stage participants randomised to the SCS-ACT arm were given the self-help book and completed a section of the self-help manual each week for six consecutive weeks. All participants completed the

measures again seven weeks after the baseline assessment. These measures had been sent in the post to the participants.

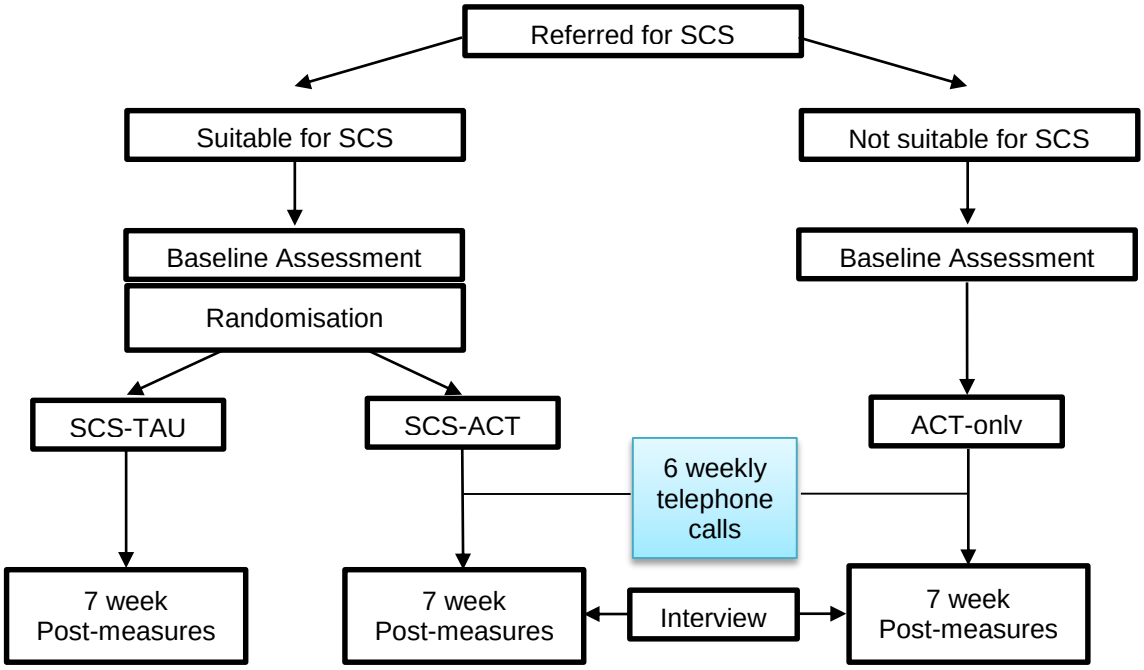

Figure 1. Flow chart representing study procedure

The procedure for the ACT-only group slightly differed from the other study arms. Potential participants in the ACT-only arm attended an assessment appointment for SCS surgery however, they were not deemed to be suitable for the surgery. The clinic sent these participants an information pack on behalf of the researchers. This information pack included a covering letter outlining the study, a consent form and the baseline measures. To opt into the study participants signed a consent form and completed the baseline measures. They were also sent the self-help manual in the post (Figure 1 is a diagrammatical representation of the study procedure).

Intervention

Participants in the two ACT intervention conditions were provided with a copy of the *Living Beyond Your Pain* (Dahl & Lundgren, 2006a) manual. The book comprises of eight chapters, in addition to introduction and conclusion sections. The chapters and

topics covered each week is summarised in Table 1. The manual was chosen due its use in similar trials that reported positive results (Johnston *et al*., 2010; Thorsell *et al*., 2010). Although the participants worked independently on the materials, they received weekly telephone support from the first author throughout the six weeks. Telephone sessions aimed at providing participants with the opportunity to discuss any difficulties they may have been having with the book and to discuss the main points of each of the chapter and its applicability to their daily lives. Participants were also asked three standardised questions: (i) Did you do all, some or none of the exercises? (ii) Did you find the reading level easy, medium or hard? (iii) Did you find this chapter useful?

Table1

Chapters in Living Beyond Your Pain (Dahl & Lundgren, 2006a) Covered Each Week and a Summary of Content

Week	Chapters	Summary of Content
1	Introduction Chapter 1 & 2	Changing ideas about pain, an explanation of ACT, the pain avoidance-suffering cycle, the impact of limited participation in valued activities due to experiences of pain
2	Chapter 3	Identifying values, introduction to "values illness"
3	Chapter 4	Getting distance from thoughts, the problems with cognitive fusion, introducing defusion and the idea of thoughts, observation without judgements
4	Chapter 5	Mindfulness, the aspects of self, practising mindful activities
5	Chapter 6 & up to page 136 Chapter 7	Introduces acceptance to engage with pain, looking at participants values to make behavioural changes
6	From 136 of Chapter 7 & Chapter 8	Committed actions, identifying potential obstacles, developing committed action plans for these obstacles

Measures

For the selection of outcome measures, the recommendations of the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT; Dworkin *et al*., 2008) were considered. Assessments included measures of self-efficacy, pain intensity, depression, anxiety, and health related quality of life.

Self-Efficacy

The Pain Self Efficacy Questionnaire (PSEQ; Nicholas, 1989) is a 10-item questionnaire that assesses the confidence people with ongoing pain have in performing activities whilst in pain. The questionnaire asks participants to rate how confidently they can perform a wide range of activities including completing household chores, socialising, and work despite being experiencing pain. Higher scores reflect higher self-efficacy beliefs. The PSEQ has high internal consistency (α=0.92) and test-retest reliability is high over a three month period (Asghari & Nicholas, 2001).

Pain Intensity

Participants' pain intensity was measured using the Brief Pain Inventory (BPI; Cleeland, 1991). The BPI was originally developed for use with cancer patients, but has increasingly been used with patients with chronic non-malignant pain. The BPI produces two subscales: pain severity and pain interference. The pain severity scale asks respondents to rate their current pain intensity and the pain they had experienced in the past 24 hours at its worst, least and average using a scale of 0 to 10, with “0=no pain” and “10=pain as bad as you can imagine”.

The BPI interference subscale measures the extent to which pain interferes with daily functioning. A higher score represents greater pain interference. Internal consistently of the BPI for non-cancer patients with chronic pain has been found to be 0.85 for the intensity items and 0.88 for the inference items (Tan, Jensen, Thornby & Shanti, 2004).

Depression and Anxiety

Participants' mood was measured using the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). This tool is recommended by NICE (2011) to inform assessment and to support evaluation of any interventions with common mental disorders. The HADS contains two subscales; anxiety and depression. High scores indicate reflect high level of depression and anxiety symptoms. The internal consistency for the anxiety scale is between 0.80-0.93 and the depression scale is between 0.81-0.90 (Lisspers, Nygren & Söderman, 1994).

Health Related Quality of Life

The EQ-5D is a widely applied, valid, and reliable measure of health related quality of life (HRQoL), which has five items related to mobility, common activities, self-care, anxiety/depression and pain/discomfort, in addition to a visual analogue scale (VAS) concerning health state (Rabin, & de Charro, 2001). The EQ-5D has been used to measure HRQoL of patients with specific neuropathic pain diagnoses (Doth, Hansson, Jensen & Taylor, 2010). Higher scores indicate greater health related quality of life.

Interviews

The two ACT groups (SCS-ACT and ACT-only) additionally received a telephone interview at the six week period, after they had finished the self-help intervention. Thirteen participants were interviewed by the first author. The interview was intended to find out the helpful and unhelpful aspects of the intervention, the practicalities of completing the manual within the time frame and ways in which that it could be improved in the future. A semi-structured interview schedule was used to guide the interview. This provided flexibility through the use of prompts allowing exploration of interesting claims or concerns that arose.

Data analysis

The study is a mixed-methods RCT design so included quantitative and qualitative data. The quantitative data were collected from the psychometric measures, taken at the two points in the study.

Quantitative Data

The Reliable Change Index (RCI) was used to "determine whether the magnitude of change for a patient (was) statistically reliable" (Jacobson, & Truax, 1991). That is, to ascertain whether the change falls beyond that of what would be likely based on the measurement variability of the outcome measures. Clinically Significant Change (CSC) criteria was used to explore whether the participants that demonstrated reliable change would also be viewed to be "recovered" following the intervention. The combination of the RCI and CSC criteria enables participants to be classified into one of five possible outcomes at post-intervention (Davies, & Sheldon, 2011):

1. Clinically significant improvement – improvement that meets both RCI and CSC criteria
2. Reliable improvement – improvement that meets RCI criterion but not criterion for CSC
3. No change- the magnitude of any change is within the expected range due to measurement error
4. Reliable deterioration – deterioration that meets RCI but not CSC criteria
5. Clinically significant deterioration – deterioration that meets both RCI and CSC criteria.

Qualitative Data

The semi-structured interviews were included to provide more nuanced data about how those in the ACT conditions experienced the self-help manual and telephone support. The interviews were recorded on the telephone and transcribed verbatim. A thematic analysis was used to identify, analyse and report themes within the data (based on Braun & Clarke, 2006).

Results

Recruitment to the trial

Figure 2. demonstrates the flow of participants through the trial. Over the 12 months trial recruitment period, 30 patients had SCS surgery at the Neuromodulation clinic. Twelve of these patients were already assigned to another study, leaving a potential participant pool of 18, of which 14 consented to participate (consent rate of 78%). These participants were randomised into the study; eight to SCS-ACT and six to SCS-TAU.

Twenty-four participants that had the SCS trial but not the full SCS surgery were invited to the study. Five (21%) participants consented to the study. Therefore there was a total of 21 participants across the three treatment arms. Demographic details for the patients and whether they met the criteria for the reliable and clinically significant change from pre-treatment to post-treatment is provided in Table 2.

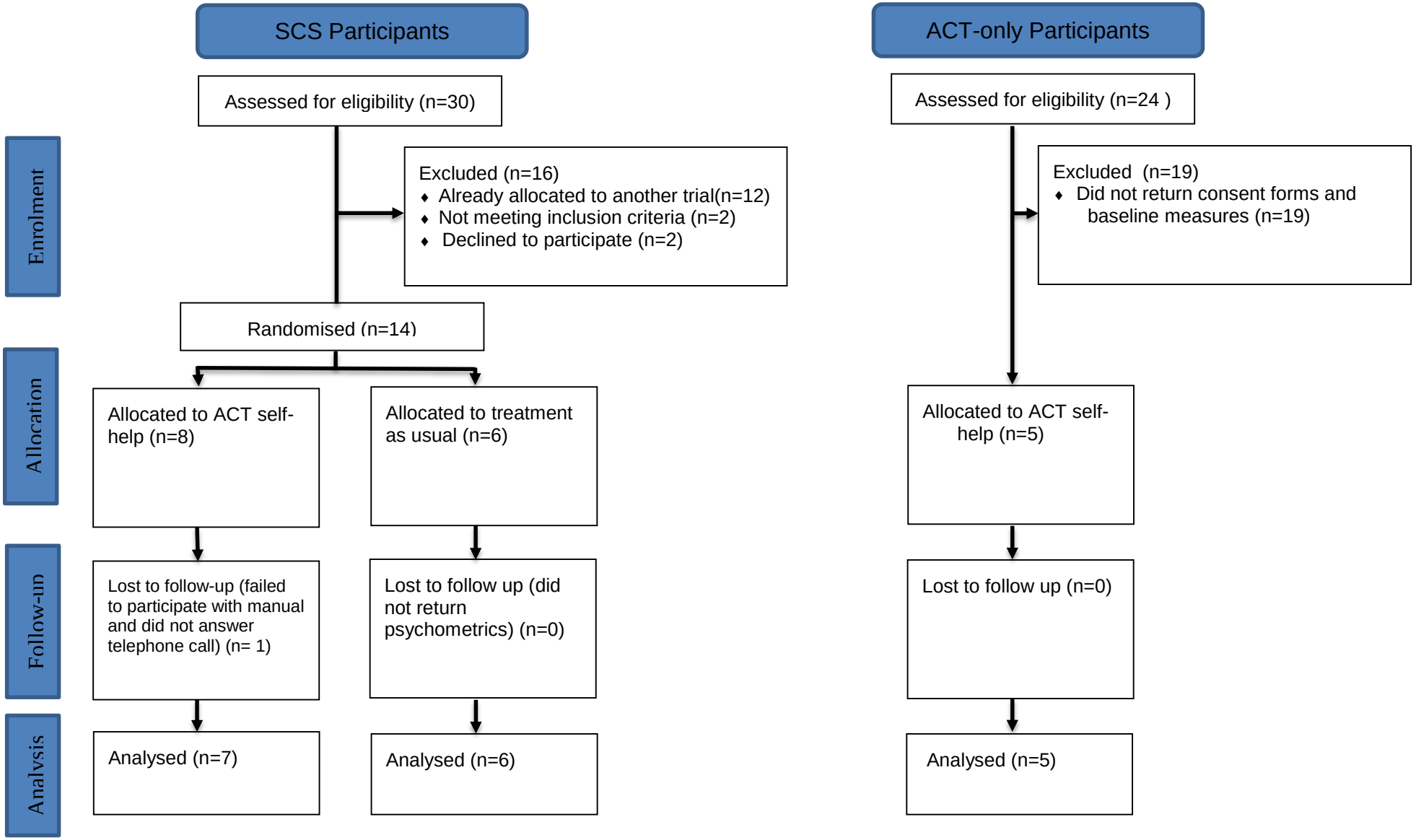

Figure 2. Participants' flow diagram

Table 2

Summary of demographic information and RCI and CSC results for each individual participant

Participant	Study arm	Age	Gender	Duration of pain (years)	No of weeks completed	PSEQ	HADS Depression	HADS Anxiety	BPI Pain Severity	BPI Pain Interference	EQ-5D Values Index	EQ-5D VAS
Laura	SCS-ACT	43	Female	4	3				✓	✓		✓✓
Emma		30	Female	17	3	✓	✓✓		✓	✓✓		✓✓
Stuart		42	Male	17	3	✓✓	✓	✓✓		✓		✓✓
Simon		44	Male	12	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Amy		49	Female	20	6	×			✓	✓	✓	
Jack		32	Male	15	4	✓✓	✓		✓	✓		
Anthony		43	Male	10	3				✓	✓		
Shaun		30	Male	9	2	✓✓				✓		
Jessica	SCS-TAU	43	Female	18					✓	✓		
Charlie		45	Male	15		✓✓	✓✓			✓✓		
Dave		36	Male	8								
Louie		38	Male	12			✓✓	✓✓				
Heather		41	Female	10		✓✓	✓		✓	✓		✓✓
Ann		50	Female	20					✓			
Phyllis	ACT-only	75	Female	7	2							
Joshua		49	Male	7	4	✓✓	✓	✓✓				
Suzie		64	Female	22	6	✓✓						
Brian		56	Male	20	6					✓		
Michael		75	Male	5	3							

Abbreviations: ✓ indicates reliable improvement, ✓✓ indicates CSC, × indicates reliable deterioration

Attrition

Out of the 13 participants that were randomised to the ACT conditions (8 SCS-ACT and 5 ACT only) only three (23%) participants completed the full intervention. The remaining ten participants dropped out at various stages of the six week intervention, however nine of these participants completed the post-treatment questionnaires and interview. All of the SCS-TAU participants completed the post-intervention measures. Overall, 95% of the post-intervention measures were completed.

Outcome Measures

Means and standard deviations for all measures and the two assessment points are presented in Table 3. Initial one-way ANOVAs showed that there were no significant pre-treatment group differences on any of the assessments.

Table 3

Means and Standard Deviations across time and condition

Measure	Conditions					
	ACT-SCS		SCS-TAU		ACT-only	
	Pre Mean(SD)	Post Mean(SD)	Pre Mean(SD)	Post Mean(SD)	Pre Mean(SD)	Post Mean(SD)
PSEQ	17.4 (9.8)	33.3(11.2)	16.7 (5.7)	26.5 (9.6)	22.6(14.9)	29.2(12.4)
HADS Depression Anxiety	 11.9 (3.4) 9.1 (3.8)	 6.6 (3.9) 6.2 (2.8)	 10.5 (4.6) 8.2 (3.5)	 5.2 (1.9) 5.8 (3.3)	 11.1 (4.4) 9.4 (4.9)	 10.8 (5.2) 6.2 (2.8)
BPI Severity Interference	 7.8 (1.1) 8.3 (1.5)	 5 (1.4) 5.0 (1.6)	 7.2 (0.8) 7.3 (2.3)	 5.7 (0.9) 5.0 (2.2)	 6.6 (2.5) 6.6 (2.2)	 6.2 (2.7) 5.7 (2.1)
EQ-5D Index Values VAS	 0.2 (0.2) 37.1 (16.5)	 0.6 (0.1) 65.3 (19.8)	 0.3 (0.1) 38.3 (16)	 0.5 (0.1) 62.5 (12.1)	 0.3 (0.1) 53 (27.2)	 0.5 (0.2) 63.4 (23.5)

Abbreviations: BPI. Brief Pain Inventory; HADS, Hospital Anxiety and Depression Scale; PSEQ, Pain Self Efficacy Questionnaire; VAS, visual analogue scale.

The study found a between group effect size of d= 0.41. A power analysis for future studies was conducted in order to ascertain the feasibility of achieving power. The traditional level of significance for social science research was adopted (α = 0.05;

Field, 2013). This determined that a minimum sample size of 43 participants for each group would be sufficiently powered to detect relevant differences.

Reliable change on outcome measures

The percentage of participants in the three study arms that met RCI and CSC for each outcome measure is shown in Table 4. All of the participants in the ACT-SCS met RCI on at least one outcome measure. For instance, all of the participants randomised to SCS-ACT demonstrated reliable improvement in pain interference. However, for some of the other measures changes could not be distinguished from measurement error. One SCS-ACT participant showed reliable deterioration on the PSEQ, however, no participants in the study showed clinically significant deterioration on any of the outcome measures.

Table 4.

Percentage of the number of participants in each of the three groups achieving RCI and CSC on the outcome measures.

Measure	Participant Group	RCI % (n)	CSC % (n)	No reliable change % (n)	Reliable deterioration % (n)
PSEQ	SCS-ACT SCS-TAU ACT only	57% (4) 33% (2) 40% (2)	43% (3) 33% (2) 40% (2)	29% (2) 67% (4) 60% (3)	14.% (1) 0% (0) 0% (0)
HADS Depression	SCS-ACT SCS-TAU ACT only	43% (3) 50% (3) 20% (1)	14% (1) 29% (2) 0% (0)	57% (4) 50% (3) 80% (4)	0% (0) 0% (0) 0% (0)
HADS Anxiety	SCS-ACT SCS-TAU ACT only	14% (1) 17% (1) 20% (1)	14% (1) 17% (1) 20% (1)	86% (6) 83% (5) 80% (4)	0% (0) 0% (0) 0% (0)
BPI Pain Severity	SCS-ACT SCS-TAU ACT only	71% (5) 50% (3) 0% (0)	0% (0) 0% (0) 0% (0)	29% (2) 50% (3) 100% (5)	0% (0) 0% (0) 0% (0)
BPI Pain Interference	SCS-ACT SCS-TAU ACT only	100% (7) 50% (3) 20% (1)	14% (1) 17% (1) 0% (0)	0% (0) 50% (3) 80% (4)	0% (0) 0% (0) 0% (0)
EQ-5D Index Values	SCS-ACT SCS-TAU ACT only	14% (1) 0% (0) 0% (0)	0% (0) 0% (0) 0% (0)	86% (6) 100% (6) 100% (5)	0% (0) 0% (0) 0% (0)
EQ-5D VAS	SCS-ACT SCS-TAU ACT only	43% (3) 17% (1) 0 %(0)	43% (3) 17% (1) 0% (0)	57% (4) 83% (5) 100% (5)	0% (0) 0% (0) 0% (0)

Abbreviations: BPI. Brief Pain Inventory; CSC, Clinical significant change; HADS, Hospital Anxiety and Depression Scale; PSEQ, Pain Self Efficacy Questionnaire; RCI, Reliable change index VAS, Visual analogue scale.

Thematic Analysis

Following the process of coding, searching for and reviewing themes (as outlined in the Extended Method) four main themes emerged: battle with pain, benefit of the manual, obstacles, and suitability. These themes were categorised by a further ten sub-themes as illustrated in Table 5.

Theme 1: Battle with Pain

This theme encapsulates the "fight" participants experienced in trying to control their CNP and where they currently feel they are in this battle. Two subthemes were identified.

Table 5

Themes and Subthemes

Battle with Pain	Journey of Acceptance
	Continued Fight
Benefits of the Manual	Hope
	Prompting Activity
Obstacles	Language
	Length of the manual
	Relatability to the content
Suitability	Time after surgery
	Format of the intervention
	Too late

For clarity, each extract states whether the participant was in the SCS-ACT or ACT-only groups.

Journey of Acceptance

This subtheme reflects participants' perspective that the pain is always going to be present, which they accept and still try to live a full life rather be dominated by the pain.

"The dawning on me that my pain is here to stay and I accept it. I still get on with most of the things that I want to do. I do not sit in a chair on the pretext of giving up." – Michael, ACT-only

All of the participants had had CNP for many years and for some this battle with the pain appeared to be on a continuum. There were a few participants that claimed they had already accepted the pain prior to the ACT intervention and others suggested that since completing the self-help manual they were beginning to accept the permanency of their pain. It was noted that this theme was more dominant in those that had the ACT-only group.

Continued Fight

At the other end of the spectrum to acceptance were those who continued to fight against their pain. This sub-theme encapsulates the experience of participants who discussed their continued pursuit to manage their pain. They reported dissatisfaction that they were not pain free and typically viewed their pain within a biological/medical framework. They, therefore, reported seeking further medical interventions to aid them in their 'battle with pain':

"I still have quite a lot of pain, more than I thought I would. It's really difficult, I need to speak to my consultant and see what he can do…. I can't accept this all they can do and I am always going to be in pain." Shaun, ACT-only.

Shaun then discussed how the pain and the continued pursuit of a pain-free life had impacted on his mood:

"It really gets you down, trying one thing after another and nothing working."

Theme 2: Benefits of the Manual

This theme reflects participants' reports of positive changes that they had attributed to the intervention.

Hope

Some participants expressed that reading the manual had given them a sense of hope for their future. We noted that the participants who expressed hope were typically those that had also vocalised a more accepting stance of their CNP. Thus it appeared that hope and accepting may somehow be linked, and therefore there is some overlap between the two sub-themes:

"It's(the self-help manual) *made me realise that I have a valued life, because sometimes I think what is the point, you know, the point of going on" – Suzie, ACT-only*

In this quote Suzie discusses having a valued life. Within the manual there is a chapter that explores the participant's values and emphasises that these can be achieved in spite of being in pain.

Prompting Activity

There were a few participants that reported that since starting the self-help manual it had encouraged them to be more active. The activities that participants mentioned that the manual had prompted them to do included: participating in yoga classes to aid relaxation, taking the children swimming as they identified valuing being a parent, and joining a cricket club to increase socialisation.

"It's (completing the self-help manual exercises) *already started me doing some things that I wasn't doing. So in that way, it's had a direct impact, it's helped me" – Brian, ACT-only*

Theme 3: Obstacles to Completing the Manual

A large number of participants (77%) that started the self-help manual did not complete the whole intervention. During the interview, several participants discussed the difficulties that they experienced with the manual. These could highlight some of the potential reasons for a high attrition rate.

Language

The majority of the participants described finding the language in the manual as "complex" and "technical". This had an impact on some of the participants' ability to understand and access the material:

"I found it a bit jargon and had to keep referring back on myself." Michael, ACT-only

Some participants reported that they would continue to re-read the chapter and sought support from their partners in addition to utilising the telephone sessions. Eventually they were able to get a better understanding of the content, albeit after taking considerable amount of time and effort. For others, they reported that they were unclear and confused by the manual and this was why they withdrew from the intervention:

"I just couldn't understand some of it. It really confused me. I didn't know what to put in some of the exercises. I said to my husband, I think I must be really thick because it just keeps going over my head." Laura, SCS-ACT

Length of the Manual

A number of the participants commented on the length of the manual and the time it took to complete each section every week. In addition to the complexity of the language each chapter has a number of written exercises that some participants reported as being very time consuming:

"There were a lot of exercises in the chapters, some chapters weren't so bad and I could do them fine. But some others I just didn't have the time to do. Not with the reading as well. I felt bad saying I hadn't done it but I just didn't have the time every week." Antony, SCS-ACT

Relatability

This theme relates to participants' reports that they could not relate to the material in the manual and did not believe it was applicable to themselves. The manual gives exemplars of people in chronic pain that have a negative outlook on their subsequent functional abilities and are consequently avoidant of activities. A number of the participants reported that they could not relate to this as they believed they were active and therefore struggled to connect with the material:

"I think I am pretty positive about my pain, I don't let it beat me. I still work even when I am in pain. Last summer I was in a lot of pain and I had to go off on the sick but usually I try to carry on. So like I said I don't really think that it was for me, if I wasn't already keeping myself busy then maybe it would have helped." Laura, SCS-ACT

The book was originally published in the USA and this is evident in the language used in the manual. This proved to be an issue for some participants:

"I think I've said in the past there's some Americanisms in it, which perhaps does rattle some people." Brian, ACT-only

Theme 4: Suitability

This theme is pertinent to the research question and reflects the participants' experiences and opinions as to whether the current intervention is suitable to those that have CNP and been assessed for SPS surgery.

Time after Surgery

This sub-theme is exclusive to the participants that had the SCS surgery. Several participants commented that engaging in the self-help manual after having their surgery had its challenge. Some reported that the intervention may have started too soon after the surgery, because they were experiencing heightened levels of pain and medication, which impacted on their ability to concentrate and read the manual.

"I think it was too soon after the operation to start the book. The first couple of weeks I was on loads of medication but I still couldn't sleep. It was just too uncomfortable. It's hard to understand the book anyway and with being in pain, not sleeping and dozy from the meds it is just so much harder." Shaun, SCS-ACT

Format of the intervention

The majority of the participants voiced that they thought the intervention would have been improved if it had been conducted face-to-face rather than in a self-help and telephone support format. There were participants who felt the current format was "impersonal" and would have preferred to meet with the researcher conducting the telephone calls in person or have a group intervention with others suffering with CNP:

"Personally I need physical contact with people….And I know maybe a group face-to-face with people is not possible." Joshua, ACT-only

Too late

This sub-theme encapsulates participants' beliefs that the intervention would have been more beneficial earlier in their journey of pain treatments. To be assessed for SCS surgery the participants would have been in CNP for a significant amount of time and would have tried less evasive pain interventions. Some participants felt that during the time they had CNP they developed their own strategies to manage symptoms and therefore did not think at this stage a psychological intervention would be beneficial:

"I don't know whether it's because I've had my condition since I was thirteen years old, and so I've got kind of a lot of strategies to cope with my pain already. And I didn't find it added loads on top of that." Emma, SCS-ACT.

Discussion

This randomised controlled feasibility study of ACT for patients assessed for SCS surgery was guided by MRC (2008) guidelines on developing complex interventions. The primary aim of the study was to address issues with recruitment and the acceptability of the intervention in the SCS pathway. The study recruited over a period of 12 months, which was longer than previously anticipated and despite this extended period of recruitment only 14 SCS participants consented to participate in the study. As this was a feasibility study power was not required however, it provided important information regarding the feasibility of gaining power in the full-scale RCT. According to the results 43 participants in each of the two groups (SCS-ACT and SCS-TAU) would need to be recruited, therefore it would take a number of years to obtain enough participants to reach power on this single site. However, it should be noted that the reliability the power calculation is questionable due to the small sample size but provides an estimation for future studies.

In addition, a large number (77%) of the participants that received the ACT intervention did not complete the self-help manual. Adherence was assessed during the weekly telephone calls in which participant's self-reported different levels of completion of the manual. The majority of the participants (95%), did however, complete the post intervention measures and interviews, allowing an insight into their experiences of the ACT intervention. Although, high drop-out rates in bibliotherapy are not uncommon (Banasiak, Paxton, & Hay, 2007), this is a higher attrition than other studies that used the same self-help manual (Johnston *et al*., 2010; Thorsell *et al*., 2011). However, these studies used non-specific chronic pain participants and as has already been discussed CNP tend to have poorer treatment outcomes than nociceptive pain (Dworkin *et al*., 2003).

Due to the difficulties with recruitment and the associated small sample size, it was not possible to conduct inferential statistics to evaluate *statistically* significant treatment signals in outcome measures. However, *clinically* significant changes were investigated. There was a higher prevalence of self-efficacy changes in the two ACT

groups compared to the SCS-TAU groups, although this comparison is difficult due to the small sample sizes and lack of inferential statistics. Interestingly all of the participants in the SCS-ACT group had reliable improvement on the pain interference, compared to 50% of SCS-TAU group. This suggests that a combination of pain reduction from the SCS surgery and an ACT intervention may have prompted the participants to be more active. Within the ACT literature similar studies of increased activity have been reported (Veehof, Oskam, Schreurs, & Bohlmeijer, 2011).

Although, there were increased scores on pain interference within the SCS-ACT group, the pain severity did not appear to differ between SCS-ACT and SCS-TAU groups. Furthermore no participants in the ACT-only group achieved reliable change from pre to post-intervention on the pain severity measure. However, symptom reduction is not a primary goal of ACT. Instead, ACT aims to reduce the distress associated with CNP (Dahl, & Lundgren, 2006b). Although, the results did not indicate that ACT positively impacted on the participant's mood. Veehof and colleagues (2011) meta-analysis of the ACT literature for chronic pain reported medium effect sizes of change before and after treatment for depression and anxiety. However, the current study did not include measures to assess suitability for the study and therefore there were participants with lower levels of depression, leaving less room for improvement. This could be termed as a floor effect (Pradhan *et al*., 2007).

The interviews conducted with participants in the two ACT groups (SCS-ACT and ACT-only) offer a further exploration regarding the feasibility of an RCT and provided potential explanations for the high attrition rate in the study. A key finding in the interviews was that "Journey of Acceptance" theme was largely reported by ACT-only participants. Conversely, the participants that did not accept their pain and were aligned to the "Continued Fight" subtheme were largely SCS-ACT participants. Subsequently the SCS-ACT participants were less positive regarding the benefits of a self-management approach to their CNP. It is proposed that Relational Frame Theory may offer some insight into the differences between the two ACT groups. The theory posits that the ability for an individual to accept their CNP can be attributed to the extent to which they view themselves "as their pain". Within an ACT

approach it is through the process of cognitive defusion which enables the individual to detach themselves from the notion that they are the pain, thus allowing the process of acceptance to engender an openness to redefine them and reengage with valued life despite their pain. However, this process would have been compromised for the SCS-ACT group by the fact they have recently invested a lot of their physical and emotional resources into having an intrusive medical operation related to their CNP and were recovering from surgery. Due to ACT intervention occurring so shortly after the SCS operations this may not have been an optimal time for an individual to be able to defuse themselves from their pain.

In addition, the literature states that a person's beliefs about the cause of their pain and the anticipated effects of treatment will influence the likely treatment outcomes (Walsh & Radcliff, 2002). Chronic pain sufferers are also likely to be sceptical towards an approach that is incompatible with their beliefs about their pain (Pincus & Morley, 2002). SCS-ACT participants appeared to believe that the cause of their pain was solely biological and could only be cured by a medical intervention, hence why they have undergone an evasive surgery. Whereas an ACT approach to chronic pain focuses on achieving value-driven goals and acceptance as opposed to controlling or eliminating the pain (Hayes, & Duckworth, 2006). Therefore, this tension between a continued fight to find a cure for pain and an ACT approach is likely to have not only impeded acceptance but also on their willingness to complete the self-help manual.

The participants that appeared to have developed acceptance towards their pain during the course of the self-help manual appeared to benefit the most from the intervention. This is consistent with the extant literature that reports that psychological acceptance has a mediating effect on treatment change in ACT (Cederberg, Cernvall, Dahl, von Essen, & Ljungman, 2015), as well as CBT (Åkerblom, Perrin, Fischer, & McCracken, 2015). One of the reported benefits of the self-help intervention was that it instilled a new sense of hope that the participant had towards their future. In the context of their CNP hope could be conceptualised as the process of "redefining normal" (Hayes, & Smith, 2005). It has been postulated that the process of acceptance involves establishing a new life in the context of a new reality. The theory states that to be able to "redefine normal", the person must

be willing to have some acceptance of the pain. This therefore could explain why those that were more accepting of the pain may have also felt more hopeful.

In addition to hope, another benefit of the manual was that it encouraged some participants to engage in meaningful and valued activities. The fear-avoidance model (Letham, Slade, Troup, & Bentley, 1983) proposes that if a person has a non-threatening view of their pain they will consequently be more likely to continue with normal activities. Conversely, chronic pain sufferers that interpret pain as threatening are more inclined to have "pain catastphrohsing" thoughts. Catastrophising thoughts are hypothesised to lead to a fear of experiencing pain and avoidance behaviours in anticipation of experiencing pain. In applying this theory to ACT, it would be the person having an acceptance of their pain are more likely to engage in activities rather than those that have pain catrostrophising thoughts and fight the physical sensations.

Despite the self-help manual providing benefits for some participants it was often noted that the language adopted within the text was complex. Johnston *et al*'s (2010) study reported similar difficulties with comprehension due to the level of complexity, therefore the manual may require some refinements to increase its accessibility. The length of the manual also impacted on participant's ability to complete the intervention as did their ability to relate to the content of the material. It is likely an accumulation of these factors impacted on the high attrition rates and could provide an insight into ways in which the manual could be improved.

There are additional issues in the suitability of the format of the intervention. Participants reported they felt a self-help intervention was not appropriate and suggested alternative formats of delivery, including group work. ACT groups for chronic pain have yielded positive results (McCraken, Sato, & Taylor, 2013). The benefit of a group intervention is that it provides socially supportive elements that have been shown to encourage feelings of belonging and reducing social isolation (Martensson, & Dahlvin-Ivanhoff, 2006). However, there is a dearth of literature assessing the differences in effectiveness between different formats of interventions

to be able to confidently state whether a group intervention would be superior to a self-help manual with telephone support.

Limitations and Future Research

There are a few key limitations to this present study. In addition to acting as the lead researcher the author also completed the telephone support sessions and conducted the interviews. This would have increased the risk of response bias and participants may not have felt able to give a true reflection of the self-help manual due to fear of upsetting or offending the author. In addition, the small sample size resulted in the study not facilitating the use of inferential statistics to explore treatment signals in the outcome measures. Therefore, larger sample sizes are required in future studies in order to obtain more conclusive outcomes on the appropriateness of an ACT self-help intervention in the SCS treatment pathway. The current study recruited over a period of 12 months therefore it is unlikely that a larger sample size would be achieved using the current recruitment criteria. It is recommended that future feasibility trials include more than one research site to optimise the participant pool.

In addition to a larger sample size a future study would benefit from a follow-up assessment as a limitation of the current feasibility study was that it did not include a long-term follow-up assessment period which would have allowed for the exploration of delayed therapeutic effects. The current study also found that the timing of the ACT intervention may not have been optimal for those that had undergone SCS surgery. Therefore a future feasibility trial may benefit from being completed pre SCS surgery, when patients are first assessed in the clinical and before they have the trial implantation. Another amendment to the recruitment procedure could be that assessment measures are completed prior to recruitment to ascertain whether a clinical needed for psychological intervention for CNP is warranted. In the current study, a number of the participants did not require psychological input as they had already developed adaptive strategies in the management of their pain.

The results of the interviews suggested that participants that reported more benefits of the self-help manual were more accepting of their pain. However, this was not

assessed quantitatively with an ACT specific measure. The rationale for not including such a measure such as the Chronic Pain Acceptance Questionnaire (CPAQ; McCracken, Vowles, & Eccleston, 2004) was that it has been noted that it explores acceptance of pain without taking into account the contribution of other cognitive variables that have been shown to influence adjustment (Nicholas & Asghari, 2006). Further consideration should be given in future research as to whether an acceptance measure would provide useful quantifiable information.

Conclusion

It is recommended by the author that adjustments to the study are implemented and researched prior to completing a large scale RCT. The MRC (2008) guidelines suggest that the feasibility stage of research is an iterative process, and highlights that a number of studies may be required to progressively refine the design, prior to developing a full-scale trial. A key justification for developing a refined-feasibility is the benefits expressed by participants in the intervention during the interviews and the increased self-efficacy and decreased pain interference in both the ACT groups. These future studies should be able to give more conclusive investigations about the efficacy of an ACT self-help intervention when compared to no therapeutic intervention for CNP sufferers.

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EXTENDED PAPER

1. EXTENDED BACKGROUND

The aim of this section is to supplement the journal article by situating the research within a more detailed synopsis of the background literature. Therefore I have reviewed the neuropathic pain literature and its treatment options, in addition to the acceptance and commitment therapy literature.

1.1. Chronic Pain

Pain is a subjective experience that impacts on physical, social and emotional functioning (International Association for the Study of Pain (IASP), 1986). In 1968 McCaffery wrote “Pain is whatever the experiencing person says it is, existing whenever he says it does” (McCaffery & Pasero, 1999, p. 17). This statement has been influential in highlighting the subjective nature of pain.

Due to the subjective and multifaceted experience of pain it can be problematic in identifying a definitive definition. Modern definitions of pain typically refer to both the physical and psychological features. The IASP defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (Merskey & Bogduk, 1994, p. 210-211).

Pain can be identified within two broad categories; acute and chronic. Acute pain may temporarily interrupt activities and can usually be linked to an identifiable cause (Renn & Dorsey, 2005). Whereas, pain is deemed chronic when it has been experienced for six months or beyond the expected healing phase after trauma or surgery (NICE, 2013a). However, the research does not always differentiate between chronic nociceptive (pain in response to activation of primary nociceptive afferents by actually or potentially tissue-damaging stimuli) and chronic neuropathic pain (CNP). Therefore, the paper will need to draw upon relevant research from the broader chronic pain (CP) literature which will include the CNP population. However, when referring specifically to CNP research it will be explicitly stated.

1.2. Neuropathic Pain

1.2.1 Etiology

The IASP define neuropathic pain as initiated or caused by a primary lesion or dysfunction in the nervous system (Merskey & Bogduk 1994). This definition was more recently refined as the direct result of a lesion or dysfunction of the nervous system (Treede et al., 2008). CNP comprises of a complex combination of negative symptoms or sensory deficits, and positive symptoms that include pain, paranesthesia (abnormal perception of a non-painful nature) and dysesthesias (abnormal pain perception) (Mortimer, Steedman, McMillan, Martin & Ravey 2002). NP is usually maladaptive and chronic and is less responsive to conventional analgesic drugs than nociceptive pain (Dworkin et al., 2003; Finnerup, Otto, McQuay, Jensen & Sindrup 2005; McQuay, 2002). Therefore different treatment options for the symptoms are often sought, dependent on the pain condition.

A number of pain conditions could be classified as CNP but the most common types are Complex Regional Pain Syndrome I & II (CRPS I & II) and Failed Back Surgery Syndrome (FBSS). The development of CNP after surgery is not uncommon, with estimates ranging from 10% to 50% after many common operations (Shipton, 2008).

1.2.2 Prevalence rates of CNP

The majority of epidemiological studies of pain have tended to focus on CP more broadly rather than specifically targeting CNP. A large scale survey in Europe concluded that 19% of the adult European population has CP (Breivik, Collett, Ventafridda, Cohen & Gallacher, 2006). However, this survey failed to discriminate between chronic nociceptive and CNP. It has been suggested that there is currently no accurate estimate of CNP in the United Kingdom (UK) population (Smith & Torrance, 2012). Although, in a UK primary care survey, it was reported that the prevalence of pain that had neuropathic origin was thought to be 8% in this general population (Torrance, Smith, Bennett & Lee, 2006). Similar prevalence rates were reported in a French survey (Bouhassira, Lanteri-Minet, Attal, Laurent & Touboul, 2008). However, the prevalence of CNP is felt to be under-diagnosed and under

treated (Taylor, 2006) and therefore likely to be more common in the general population than previously suggested (Torrance et al., 2006).

1.2.3. Impact of CNP

The experience of CNP varies widely and is often dependent on its etiology, specific sensations, location and the extent it impacts on everyday functioning. There is extensive empirical evidence that highlights the impact CNP has in general on daily life (Niv & Kreitler, 2001; Katz, 2002). Jensen, Chodroff and Dworkin's (2007) systematic literature review of health related quality of life (HR-QoL) concluded that the presence of CNP was consistently associated with reduced emotional and physical functioning.

The daily functioning of those with CNP is impacted by difficulties with sleeping, concentrating, lack of energy and drowsiness, these then impact on their ability to integrate socially (McDermott, Toelle, Rowbotham, Schaefer, Dukes, 2006; Smith, Torrance, Bennett & Lee, 2007). It is therefore reported that CNP patients have difficulties in maintaining a range of relationships (Closs, Staples, Reid, Bennett & Briggs, 2008) and that there is increased levels of stress within families due to the expression of negative emotions such as irritability, frustration and anger from the CNP patients (Henwood & Ellis, 2004).

The link between CNP and mood disorders is well established in both epidemiological surveys and studies of mental health problems in clinical pain samples (Bair, Robinson, Katon, & Kroenke, 2003). It has been estimated that between 40-50% of patients experience significant depressive symptoms (Tunks, Crook, & Weir, 2008) and 35% experience anxiety (McWilliams, Cox, & Enns, 2003). However, it is difficult to establish the direction of causality with prospective studies arguing that pain is a significant predictor of affective symptoms and vice versa (Gatchel, Peng, Peters, Fuchs, & Turk, 2007). Rudy, Kerns, and Turk (1988) suggested that a bidirectional relationship exists in which pain and mental health difficulties are mutually maintaining. Another argument is that CNP and mood

disorders may share a vulnerability, potentially due to genetics or early life experiences, which can lead to the manifestation of both conditions under certain environmental influences (Asmundson & Katz, 2009). Regardless of the direction of causality it has been noted that a pertinent feature of this relationship is that patients with comorbid depression and CNP tend to have poorer outcomes with regards to pain severity and disability than patients without depression (Bair, et al., 2003).

1.3. Treatment for Chronic Neuropathic Pain

1.3.1 Conventional medical management

The general treatment for CNP is predominately pharmacological (Gallagher, 2006). However, a difficulty in the pharmacological approach to treating CNP is identifying what specific neuropathic mechanisms are involved so that the most effective drug for that mechanism can be identified (Nicholson & Verma, 2004). This often results in a trial and error approach with different medications. The Special Interest Group on Neuropathic Pain of the IASP (NeuPSIG) guidelines propose that tricyclic antidepressants (TCA), antiepileptic drugs (AEDs) and topical lidocaine should be potential first-line treatment options for CNP (Dworkin, et al., 2010). Similarly, the National Institute of Clinical Excellence (NICE; 2013a) recommends that patients with CNP are offered the choice of amitriptyline, duloxetine, gabapentin or pregabalin (the former two are antidepressant medications, the latter two are AEDs) and capsaicin cream for localised CNP for patients that cannot tolerate or wish to avoid oral treatments.

There is mixed results in the efficacy dependent on the condition that is causing the CNP. Furthermore the primarily problem with the use of medications is their adverse-effect profile. These side effects include heart rhythm problems, such as

palpitations or tachycardia, constipation, drowsiness, weight gain, excessive perspiration, dry mouth and dizziness.

Following pharmacological interventions, the next most common option offered to CNP patients is corrective surgery (Turk & Burwinkle, 2005). However, a CNP sufferer will undergo a variety of interventions in their journey for pain relief. Table 6 is based on the recommendations by NICE of the treatments that patients should undergo prior to Spinal Cord Stimulation (SCS) surgery. The NICE guidelines (NICE, 2008) also recommend SCS surgery for CNP as a last treatment option due to it being an evasive and costly procedure (Beltrutti et al., 2004). Prior to SCS, patients have typically undergone a number of different treatment options; these are highlighted in Table 4.

1.3.2 Spinal Cord Stimulation Surgery

Spinal cord stimulation has been implemented in the treatment of various pain conditions, including FBSS (Taylor & Taylor, 2005; Turner, Loeser, Deyo & Sanders, 2004), CRPS (Taylor, Van Buyten & Buscher, 2006; Turner et al., 2004), peripheral vascular disease (PVD; Erdek & Staats, 2003), refractory angina, and visceral pain (Khan, Raza & Khan, 2005). It remains unknown what the exact mechanisms of pain relief by SCS are but the basic scientific background was initially based on Melzack and Wall's (1965) Gate Control Theory.

SCS surgery involves surgically implanting a small battery-powered stimulator into the individual. This stimulator delivers electricity to the spinal cord that changes the pain messages that are sent to the brain. The SCS patient has a remote control and is able to adjust the amount of stimulation they receive for the pain relief. Another attractive feature of SCS is unlike other surgical procedures for pain relief where patient's anatomy is changed or rupture pain pathways SCS can be reversed (North & Shipley, 2007).

Table 6

The different treatment options for chronic neuropathic pain.

Treatment Option	Description
Tricyclic Antidepressants (TCA)	TCAs were not originally designed to be painkillers but there is evidence to suggest they are effective in treating CNP in some patients (Dworkin et al., 2010; Finnerup, Sindrup & Jensen, 2010). However, they typically have significant side effects. Types of TCA's include: • Amitriptyline • Imipramine • Clomipramine
Antiepileptic Drugs (AED)	Experts do not know exactly how AED's work to reduce CNP symptoms. It has bene suggested that they may block the flow of pain signals from the central nervous system. Types of AED's include: • Carbamazepine • Gabopentin • Pregabalin A recent Cochrane review assessed the evidence around efficacy and safety for 10 anticonvulsant drugs used to treat neuropathic pain and found evidence of efficacy for only two — gabapentin and pregabalin (Wiffen, et al., 2013).
Analgesics	Analgesics are drugs that alleviate pain without causing anesthesia Types of analgesics include: • Paracetamol • Aspirin • Ibuprofen Simple analgesics are often ineffective in neuropathic pain.

Opioid analgesics	Opioid analgesics are the most powerful analgesics. They are used routinely and effectively for the treatment of acute severe pain following trauma, extensive burns or surgery. They are also used for patients with painful terminal diseases such as cancer. In these time-limited situations the efficacy of opiates is extensively documented and broadly accepted. They are increasingly being used in CNP but are liable to cause abuse and addiction. Types of opioid analgesics include: • Codeine • Tramadol • Morphine • Methadone A recent Cochrane Review reported that the use of opioids for CNP is controversial (McNicol, Midbari, & Eisenberg, 2013). This is due to studies being small, having yielded equivocal results, and have not established the long-term profile of benefits and risks for people with CNP.
Nerve Block	A nerve block is an injection of an anaesthetic directly in the area of the affected nerve. The purpose of this intervention for treating CNP is to interrupt transmissions of the pain signal to the brain. Agents that may be injected include opioids, local anaesthetics, and steroids. • Steroid injections may decrease the inflammation and irritation to that nerve and may decrease pain • Local anaesthetics may also break the cycle of pain and provide some relief of the patient's CNP • Opioids injections can also provide powerful, short-term pain relief Evidence regarding the effectiveness of nerve block in treating neuropathic pain is scarce. However, it is reported in actual clinical situations, nerve block has been used as a treatment in combination with other methods, such as pharmacotherapy, psychotherapy, and physiotherapy (Nishiyama, & Ohseto, 2012).
Physiotherapy	Physiotherapy helps restore movement and function when someone is affected by injury, illness or disability. There is limited published trials on the efficacy of physiotherapy on the treatment of CNP.

Acupuncture	Acupuncture is a system of healing which involves the insertion of fine needles into specific points/energy channels on the body. It is believed that this stimulates the body's own healing response and helps restore a natural balance. A recent meta-analysis on the effects of acupuncture on CNP found that the majority of trials demonstrate a positive effect over control conditions (Dimitrova, Murchinson, & Oken, 2015).
Transcutaneous electrical nerve stimulation (TENS)	TENS is a non-invasive self-administered technique that delivers pulsed electrical currents through the intact surface of the skin to activate peripheral nerves. Celik, Erhan, Gunduz, and Lakse (2013) reported that TENS provided a significant reduction in pain when compared with placebo TENS in people with spinal cord injury. However, Johnson and Bjordal (2011) report that there are too few randomized control trials on TENS for CNP to judge effectiveness.
Psychological therapies	Despite modern definitions and understanding of pain being biopsychosocial, the majority of SCS patients may not have had psychological interventions prior to surgery, See Section 1.6 for further information on this approach to CNP.
Corrective Surgery	The NICE (2008) guidelines suggests that for some CP conditions there may also be condition-specific treatments; for example, people with failed back surgery syndrome (FBSS) may have a repeat operation. North, Kidd, Shipley, and Taylor's (2007) analysed of cost effectiveness and cost-utility of treating FBSS using SPS versus corrective surgery. The authors concluded that SPS was less expensive and more effective than corrective surgery in FBSS.

The aim of neurostimulation is not to eliminate pain but to reduce its intensity, duration and frequency (Falowski, Celii, & Sharan, 2008). Prior to SCS, individuals are required to have a trial electronic stimulation under local anesthetic, to determine whether the full operation would provide effective pain relief of at least 50% (NICE, 2008). It is only if pain relief reaches above this threshold that the patient is able to have the full implantation.

1.3.3. Empirical Evidence for SCS

There is an extensive evidence base for the efficacy of SCS in the treatment of CNP. However, to the knowledge of this paper there have only been two robust randomised control trials (RCTs) that have investigated SCS for CNP, one with CPRS patients (Kemler, & de Vet, 2000; Kemler, de Vet, Barendse, an den Wildenberg, van Kleef, 2004, 2008), and one with FBSS patients (Kumar et al., 2007; 2008). In both CNP conditions SCS was found to be effective at reducing pain compared to control groups and baseline results. Participants with CRPS showed improvements in pain relief and health related quality of life (HRQoL) at six and 24 month follow-ups, however, these improvements were not sustained at the 60 month follow-up (Kemler at al., 2004; 2008). Whereas, participants in the FBSS studies showed improvements in functional capacity, HRQoL, greater patient satisfaction and reduction in medication use at six and 12 month follow-up (Kumar et al., 2007; 2008).

There has been further empirical support for the application of SCS for CNP in retrospective evaluations. North, Kidd, Farrokhi, and Piantadosi (2005) found in a mean follow-up of three years SCS that in terms of pain control SCS was significantly more successful than reoperation with patients that had FBSS. They reported that 47% of SCS patients reported 50% or greater pain relief compared to 12% of reoperation patients. Furthermore SCS patients used significantly less narcotic analgesics. There were no reported differences between SCS and reoperation on work status and activities of daily living.

It is important to note that despite there being some promising empirical support for SCS, some of these trials are funded by companies that manufactures the stimulators so there is the potential for biases in the results (e.g. Kelmer et al., 2008). Furthermore, other authors have expressed uncertainty about the efficacy of SCS due to it not being effective for everyone (Racz, McCarron, & Talboys, 1989). Additionally it has been reported that 25-50% of patients report loss of analgesia within 12-24 months of SCS surgery (Cameron, 2004). There have been studies that have examined why this loss of angelasia occurs but this has focused primarily on operational factors (Sparkes, Raphael, Duarte, LeMarchand, Jackson, & Ashford, 2010). However, due to pain being established as multidimensional there has more recently been an increase investigation into the psychological characteristics that could impact the efficacy of the implantation.

1.4. Psychological Factors in Pain

There is growing recognition that pain is a complex perceptual experience, influenced by a wide range of psychosocial factors, including expectations and beliefs, social and environmental context, in addition to biological factors (Turk & Okifuji, 2002). It has also been suggested that psychosocial factors play a crucial role in the efficacy of SCS (see Doley, 2006; Sparkes et al., 2010). Research has highlighted the importance of patients being prepared for having SCS as this can impact on treatment outcomes. The patient's expectations regarding treatment and psychological stability has been emphasised as factors that can impact on treatment outcomes (Doley, 2006). Consequently, the NICE (2008) recommendations and IASP guidelines for the use of neuromodulation for pain relief (Gybels et al., 1998) specify that during screening for SCS a thorough psychological assessment should be conducted. However, currently there is not sufficient evidence to establish whether psychological screening has an impact on SCS outcomes (Celestin, Edwards, & Jamison, 2009). Furthermore the guidelines fail to recommend any specific tests for assessment and it is reported that in the UK only 61% of pain management services report implementing a psychological assessment in selecting patients for SCS (Ackroyd, Bush, Graves, McVey, & Horton, 2005).

Although, there is limited evidence of the impact of psychological screening for SCS there has been several reviews that have attempted to outline the psychological risk factors for SCS. It has been reported that psychosocial risk factors are a better predictor of disability and pain compared to discography and MRI (Carragee, Alamin, Miller & Carragee, 2005). Furthermore, Sparkes, Duarte, Raphael, Denny and Ashford's (2012) review of the SCS literature highlighted that coping with pain and the emotional impact on coping was a major determinant of outcomes for SCS patients. On the basis of these results the authors recommended improved education/preparation alongside a psychological intervention for patients prior to undergoing SCS surgery as they believed this could serve to minimise the impact of negative effect during the treatment period.

The literature on the impact of psychological factors on treatment outcomes in SCS is growing, however, is not as well established as the literature in CP. Within the CP literature is widely recognised that understanding of the experience and response to pain can be enhanced by consideration of psychological constructs such as the concepts of beliefs, self-efficacy, locus of control, perceived control of pain, adjustment and readiness to change. It is argued that the factors identified in the CP literature are also important predictors for treatment outcomes in implantable devices (Campbell, Jamieson & Edwards, 2013). Therefore, these concepts are considered below.

1.4.1 Beliefs

It has become increasingly accepted that patient's beliefs in CP are important to recovery (Jensen & Karoly, 2001). Beliefs about the patient's ability to control the pain, the impact pain has on their life, the meaning of the symptoms, and concerns for the future, have been shown to play a central role in CP, and psychological functioning and response to treatment (Tota-Faucette, Gil, Williams, Keefe, & Goli, 1993).

It has been suggested that in CP, pain-related anxiety and fear may accentuate the pain experience (Crombez, Vlaeyen, Heuts, & Lysens, 1999). Fearful patients are more inclined to attend more to the signals of threat and are less able to ignore pain-related information (Crombez, Vervaet, Lysens, Baeyens, & Eelen, 1998). This has been extended by Mayer and Gatchel (1998) who suggested that CP patients often demonstrate prolonged protectiveness and passivity, which is largely the result of fear. Consequently, it is likely that the patients decrease mobility, muscle strength and cardiovascular fitness and ultimately increase their disability.

1.4.2. Self-efficacy

Based on the theory of social learning, self-efficacy describes the confidence the person has on their ability to achieve a desired outcome (Bandura, 1977). With regards to CP sufferers, self-efficacy not only includes the expectation that a person could perform a particular behavior or task, but also their confidence in being able to perform a task despite the pain. This is coined as pain self-efficacy (Nicholas, 2007).

Pain self-efficacy affects the performance of actions necessary for managing pain itself. For example, people with low self-efficacy may avoid activities that are accompanied by pain (Jackson, Wang, Wang, & Fan, 2014). Furthermore, Costal, Maher, McAuley, Hancock, and Smeets (2011) investigated whether pain self-efficacy and/or fear of movement mediated the relationship between pain intensity and disability in patients with early onset chronic low back pain. The study found that when measured at the same time, both self-efficacy and fear of movement beliefs partially mediated the effects of pain intensity on disability at the onset of chronic low back pain. However, in the longitudinal analysis it was only improvements in self-efficacy that mediated the relationships between pain and disability over a 12 month period. Not only is higher levels of self-efficacy with CP sufferers associated with lower levels of pain and disability (Denison, Åsenlöf, Lindberg, 2004; Reid, Williams, & Gil, 2003), but it is also a protective mediating role between stress and depression (Maciejewski, Prigerson, & Mazure, 2000).

1.4.3. Locus of Control

Jensen, Turner, Romano, and Karoly (1991) defined locus of control as a cognitive style characterised by a generalised expectancy about the relationship between behavior and the subsequent occurrence of reinforcement in the form of reward or punishment. Individuals with internal locus of control will anticipate reinforcements to be the consequence of own efforts, conversely individuals with external locus of control view reinforcements by chance, fate, luck or the actions of powerful others (Colman, 2003). The literature proposes that pain sufferers who manifest an internal local of control are more inclined to use active coping strategies and less likely to be depressed compared to those with an external local of control (Crisson, & Keefe, 1988).

1.4.4. Perceived Control over Pain

The literature has found an association between perceived control over pain and mood, psychological functioning and activity levels (Jensen & Karoly, 1991). It is believed this is due to the fact that those that believe they can control pain feel better due to their persistence with utilising adaptive coping strategies. Another explanation is that this perceived control over pain has an impact on well-being. Learned helplessness is connected to this sense of control and occurs when people learn that their experiences and outcomes are independent of each other (Alloy, Abramson, Peterson, & Seligmann, 1984). The consequence of this learning is that individuals expect their responses will be futile, and therefore interfering with new situations and further learning (Alloy et al., 1984). Jensen et al.'s (1991) literature review found that pain control beliefs were consistently related to adjustment, even when controlling for pain severity.

1.4.5. Adjustment

The concept of adjustment is idiosyncratic and multi-dimensional that includes an effective individual learning process to mental functioning and the ability to perform "normal" physical and psychosocial activities (Jensen, et al., 1991). Gatchel and colleagues (2007) have highlighted differences in CP adjustment. Some CP

sufferers function adaptively whereas others do not. For many that have CP this can lead to inactivity, emotional suffering and depression, whereas for others this is not the case (Gatchel et al., 2007). The dimensions of adjustment that are relevant to CP are: activity level, pain severity, medication use, physical strength and mobility, employment status, health service utilisation and depression.

1.4.6. Readiness to change

Prochaska and DiClemente (1998) transtheoretical model of behaviour change hypothesises that patients vary in their stage of readiness to change bahviours (e.g. to quit smoking and start exercising). There has been debate regarding the appropriateness of applying the transtheroetical model to CP (Jensen, Nielson, Romano, Hill, & Turner, 2000). Kerns, Rosenberg, Jamison, Caudill, and Haythornthwaite (1997) adapted the model and developed the Pain Stages of Change Questionnaire (PSOCQ) to assess patients' readiness to adopt a self-management approach to their CP condition. In the development of the questionnaire, confirmatory factor analysis supported a four-factor measure corresponding to Prochaska and DiClemente's (1988) 'Precontemplation', 'Contemplation', 'Action' and 'Maintenance' stages of change (Kerns et al., 1997). 'Precontemplation' denotes the belief patients hold that the pain is solely medical, and therefore self-management is unlikely to be helpful. 'Contemplation' is indicative of appraisals regarding the potential value of a self-management approach, but a hesitation to cease the pursuit of a medical solution. 'Action' is characterised by an acceptance of a self-management approach to CP and attempts to improve self-management skills, while 'Maintenance' represents consolidation of a self-management approach and a continuation of development of self-management skills.

This adaption of the stages of change model to CP has been empirically supported. Studies have found that as precontemplation scores decreased and action and maintenance stages increased, desired outcomes such as reduced pain severity, disability and depression, and increased goal achievement tended to improve (Gersh, Arnold, & Gibson, 2011; Jensen, Nieslon & Kerns, 2003).

1.5. Psychological Models of Chronic Pain

There is no single unifying model of CP, many have been proposed (Jensen et al., 1999; Novy, Nelson, Francis, & Turk, 1995). The most prominent psychological models of CP in the literature include the operant behavioural and fear avoidance model. More recently the psychological flexibility model, more commonly known as the Hexaflex model has bene introduced, this is discussed in section 1.8 and depicted in Figure 4.

1.5.1 Behavioural Model

In the 1970s and 1980s, behavioural theories were a prominent psychological model of CP. The model focused on how principles of classical conditioning and operant conditioning could explain “pain behaviours” such as avoiding certain activities, taking analgesic medication, limping and verbal expressions of pain. From a classical conditioning perspective, pain behaviour is an unconditioned response to a pain stimulus. Through this learning, responding can become conditioned so that it replicates or is similar to the response when the injury occurred (Turk, & Fernandez, 1991). According to this theory, memories of pain and the fear of pain can reproduce the sensation (Main, Keefe, & Rollman, 2002). As pain becomes chronic, an increasing number of circumstances can be conditioned to elicit pain which can add to further physical de-conditioning and maintenance of avoidant behaviour (Turk, & Fernandez, 1991).

Operant conditioning theory hypothesises that all behaviour is sensitive to the effects of environmental responses to that behaviour. Fordyce (1973) noted that pain behaviours are no different than any other behaviours with respect to their sensitivity to environmental influences. Pain behaviours followed by reinforcing events, such as sympathetic responses from medical staff and family members and sanctioned time out from social responsibilities, will increase in frequency (Fordyce, Fowler, Lehmann, Delateur, Sand, & Trieschmann, 1973). This was thought to lead patients to exhibit pain behaviours as social cues to others that they were in pain, irrespective as to whether or not pain was present. Some behaviourists believe that pain

behaviours, which can be protective in the short run following acute injury, are no longer useful in the context of CP. In fact, once healing has occurred the continuous engagement in these behaviours often become maladaptive in that they can contribute to disability (e.g. ongoing resting cause muscle atrophy) and maintain pain.

The theoretical underpinnings of the behavioural model have been criticised. Turk (1996) argued that the concept of pain behaviours are poorly defined and that the assumption that these behaviours are maladaptive may not be accurate. It is also criticised for there being a high rate of relapse to behaviour interventions, suggesting that the underlying factors maintaining the pain, and perhaps the emotional difficulties associated with them, have not been addressed (Turk, & Rudy, 1991).

1.5.2. Cognitive Behavioural Models

The criticisms of the Behavioural model coupled with the broader shift of incorporating cognitive theories led to the development of cognitive behavioural models of CP (Asmundson, Norton & Vlaeyen, 2004; Turk & Okifuji, 2002; Vlaeyen & Linton, 2000). Whilst these models acknowledge the role of operant conditioning principles in maintaining CP they place greater importance on the cognitions regarding the pain and the secondary appraisals made about the meaning of having pain, including their interpretation of environmental influences. A full review of cognitive behavioural models for CP would be beyond the scope of this paper, therefore the most cited cognitive-behavioural model, the fear avoidance model (Letham, Slade, Troup, & Bentley, 1983) will only be discussed.

Letham and collegues (1983) introduced the Fear-Avoidance Model which proposed that fear of pain was the central cause of disability associated with pain. The model suggests that long term pain, led to safety behaviours such as escape and avoidance (Vlaeyen & Linton, 2006). Vlaeyen, Kole-Snidjers, Rotteveel, and Ruensink (1995) postulated that avoidance and confrontation can be viewed as two bipolar opposite approaches to managing the fear, with the former maintaining CP

and the latter leading to recovery. This hypothesis has since been extended by Vlaeyen and Linton (2000) and is represented diagrammatically in Figure 3.

Figure 3: Fear-avoidance model of CP

According to the model, pain can be interpreted as either threatening or non-threatening and the extent to which it is disabling, both physically and emotionally is dependent on this interpretation. It is postulated that the perceived threat associated with pain stems from individual differences in vulnerability to anxiety and previous experiences that have led to beliefs about personal resources or self-efficacy (Mineka, & Zinbarg, 2006).

If an individual does have a non-threatening view of their pain and are less fearful of the sensory experience they will consequently be more likely to continue with normal activities, eventually leading to some form of recovery. Conversely, CP sufferers that interpret pain as threatening are more inclined to have “pain catastphrohsing” thoughts. Catastrophising thoughts are hypothesised to lead to a fear of experiencing pain and avoidance behaviours in anticipation of experiencing pain.

Continued avoidance is negatively reinforced as pain is not experienced, however, there is reduced opportunities to disconfirm the belief that engaging in a specific activity will cause damage. Avoidance may be generalised to further activities and according to the model, if certain bodily movements are feared and avoided, increased pain can arise from lack of movement in that area of the body (Lohnberg, 2007).

1.6. Psychological Treatment of Chronic Pain

1.6.1. Cognitive Behaviour Therapy

Cognitive Behaviour Therapy (CBT) focuses on identifying and modifying unhelpful thoughts and beliefs about pain whilst incorporating behavioural techniques such as activity scheduling, pacing and relaxation strategies (Morley, Williams, & Hussain, 2008). Changes in catastrophic thinking, self-efficacy and pain beliefs have been linked to improvements in patients' physical functioning following intervention (Turner, Holtzman & Mancl, 2007; Vowles, McCracken, & Eccleston, 2007) thus emphasising the significance of cognitive techniques.

Three meta-analyses have indicated good outcomes of the CBT approach to pain (Hoffman, Papas, Chatkoff & Kerns, 2007; Morley, Eccleston, & Williams, 1999; Ostelo, van Tulder, Vlaeyen, Linton, Morley, & Assendelft, 2008). However, a Cochrane review of CBT for CP reported only a weak treatment effect for pain, disability and psychological distress at follow-up when compared to control groups (Eccleston, Williams, & Morley, 2009). This report, as well as others in the field have highlighted the poor treatment quality of some of the studies and the possibility that the fundamental elements of CBT have been diluted which may reduce the possible gains (Morley, 2011). In addition, a large scale study of a CBT-informed pain management programme found that only one in four experienced clinically significant change in their level of pain and one in three experienced clinically significant changes in measures of depression and anxiety (Morley et al., 2008). Not only does this research highlight that a significant number of participants did not benefit from

the treatment but it also brings into question why CBT is effective for some but not others (Vlaeyen, & Morley, 2005).

A key tenet of CBT is that specific cognitive change techniques are essential to the achievement of adaptive behaviour (Clark, 1995). However, this hypothesis has not been supported within recent pain literature. Vowles and colleagues (2007) found that achieving cognitive change was not necessary to achieve positive treatment outcomes in CP. Additionally, a number of studies have indicated that CBT coping strategies such as activity pacing, distraction and cognitive restructuring are only weakly related to emotional and physical functioning (see Vowles & McCracken, 2010 for review).

1.6.2. Acceptance and Commitment Therapy

Despite pain being difficult to avoid, traditional approaches such as CBT aim towards eliminating or reducing symptoms of CP (Robinson, Wicksell, & Olsson, 2004). Whereas, from an Acceptance and Commitment Therapy (ACT) perspective, the struggle to reduce pain can be part of the problem (McCracken & Vowles, 2006). The basic premise of ACT as applied to CP is that while pain hurts, it is the struggle with pain that causes suffering (Dahl & Lundgren, 2006). The pain sensation itself is an unconditional reflex that serves a function of alerting individuals to danger or tissue damage, this is critical for survival. Burch (2008) explains that the experience of pain or suffering can be discriminated as two elements: Primary suffering is the actual unpleasant sensation in the body at the time of injury. Secondary suffering is considered as resistance to the physical, emotional and mental experience. It is suggested that the distinction between the two levels of suffering can aid CP patients to identify the resistance that may cause secondary suffering and ultimately their relationship with their pain. This is an assumption of an ACT based approach to pain management (Dahl, Wilson, Luciano & Hayes, 2005).

1.7. Conceptual and theoretical underpinnings of ACT

In contrast to other theoretical approaches, such as CBT, ACT is somewhat unique in that it is built on a complex philosophical and theoretical foundation. These philosophical and theoretical underpinnings will now be discussed.

1.7.2. Functional Contextualism

At a philosophical level, ACT is grounded in functional contextualism (Hayes, Brownstein, Zettle, Rosenfarb, & Korn, 1986), which at its core views psychological events as on-going interactions in and within historically defined and situational contexts (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). It is a contemporary update of radical behaviourism that assumes that behaviour is shaped in an ongoing way by an individual's social and physical environments. In this way, an individual's historical and situational contexts give meaning to everything that a person does, and studying any behaviour outside of its context is thought to miss the nature of the problem and avenues for its solution. Therefore from a functional contextualist perspective no thought, feeling, memory or behaviour can be viewed as inherently pathological or problematic, rather it depends on the context.

Distressing thoughts and feelings will function differently in contexts where they are held to be objectively true and thus be avoided, compared to contexts in which they are 'accepted' (Hayes et al., 2006). In the latter context, the thoughts and feelings might still be painful but it is argued that it is not as harmful and does not prevent the individual having a valued life compared to the former context (Harris, 2009).

1.7.3. Relational Frame Theory

Functional Contextualism serves as a philosophical basis for Relational Frame Theory (RFT), which is the theoretical basis of ACT (Fletcher & Hayes, 2005). RFT is a contextual behaviour approach to language and cognition that attempts to explain how humans infer relationships between arbitrary objects (Fox, 2006). A detailed discussion of RFT is beyond the scope of this thesis (see Hayes et al, 1999,

for a comprehensive explanation of both Functional Contextualism and RFT) however, a premise of RFT is that humans form relationships between stimuli via language and cognition and that individuals respond to stimuli based on these relationships.

The theory states that once the "relational frame" around two stimuli has been created it acts as a cue for how the stimuli will respond in the future. Once this frame has been established it is very difficult to break (Hayes, & Wilson, 1996) and relational rules means that the way individuals relate events is dependent on both history and contextual factors (Hayes, Barnes-Holmes, & Roche, 2001). Verbal relations are strong, difficult to interrupt and are evident in the form of psychological rigidity and use of self-rules (Hayes, Masuda, & Dey Mey, 2003). Furthermore, Hayes, Strosahl and Wilson (2003) suggest that verbal behaviour is a key to psychopathology and culturally derived change efforts are a system that can perpetuate human suffering.

1.7.4. Experiential Avoidance

Experiential avoidance has been broadly defined as the attempt to avoid or escape thoughts, feelings, physical sensations and other internal experiences (Hayes, 2004). Experiential avoidance strategies can include either suppression, which involves attempts to control and/or eliminate the experience of negative private events; or situational avoidance, which constitutes the avoidance of or escape from contextual factors which are associated with the emergence of unwanted private experiences. Therefore in CP suppression will be trying to eliminate the pain and associate feelings. Situational avoidance will be avoiding situations they believe may trigger pain. The literature has demonstrated that experiential avoidance does not reduce pain; conversely it may actually serve to increase pain (Gutierrez, Luciano, Rodriguez, & Fink, 2004). The avoidance of the feared or painful situation has been shown to strengthen the underlying relational frames in CP sufferers leading to psychological rigidity (Hayes at al., 1999). An ACT intervention focuses on aiding patients to break the cycle of experiential avoidance in order to be more psychologically flexible and therefore able to adjust living their lives despite pain.

1.8. The model of change underlying ACT

1.8.1 Psychological Flexibility

Hayes, and colleagues (2006) state that the primary goal of ACT is “psychological flexibility”. The intervention aims to enable CP sufferers to flexibly respond to pain, distress and related experiences in a particular way, such that struggling with these experiences decreases with frequency, options for living well with them are maximised, and, ultimately, that one’s behaviour is in accord with their goals and values. There are six core processes in the ACT model of change that promote psychological flexibility, these are illustrated in the ACT hexagonal model of change (see Figure 4). Each point in the diamond shape model is occupied by a core process that represents a healthy psychological skill (Hayes et al., 2006). The six core processes in the ACT hexagonal model of change are briefly outlined below.

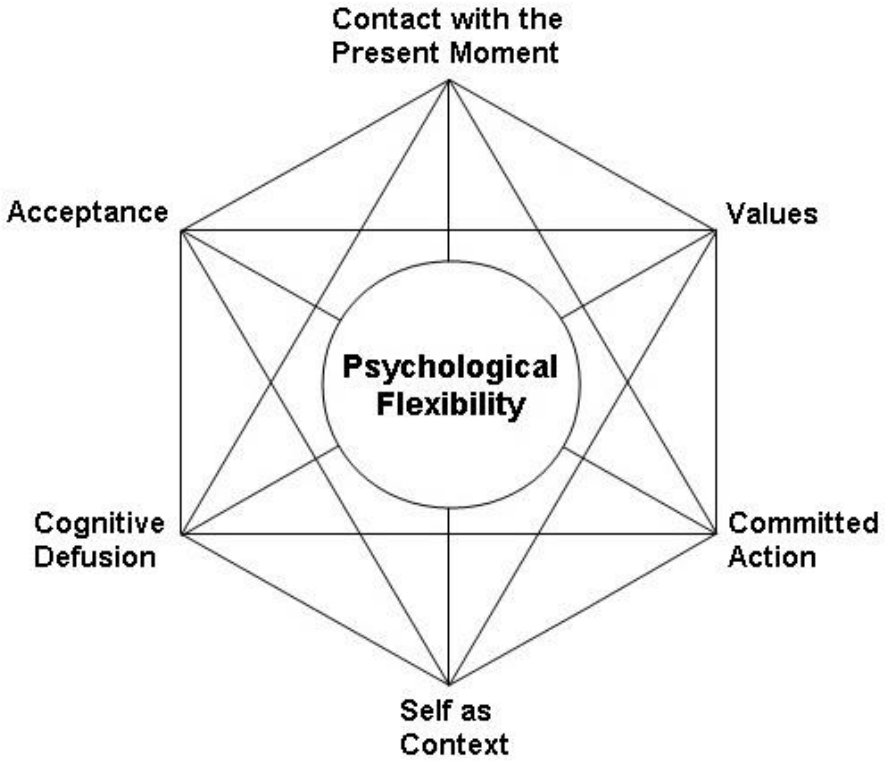

Figure 4: The hexagonal model of change (Hayes et al., 2006).

1.8.2. Acceptance

Acceptance is a core construct and process within ACT, which refers to the willingness to experience pain sensations and emotions without judgement, control or resistance (Hayes & Strosahl, 2010). It is proposed that acceptance can be thought of as a process of disengagement from struggling with pain, where the sufferer learns how to experience and accept intense feelings about their suffering and somatic sensations of pain without judgement or fear or harm (Robinson et al., 2004). This is antithetical to the inflexible approach of experiential avoidance (Hayes, Wilson, Gifford, Folette, & Strosahl, 1996). Engaging in this avoidance may result in symptom relief in the short-term. However, it inhibits CP sufferers from participating in activities that lead to longer term life satisfaction (Wicksell, Lekander, Sorjonen, & Olsson, 2010).

1.8.3. Cognitive Defusion

Cognitive fusion is defined as "fusing with or attaching to the literal content of private experiences whereby we respond to a thought or feeling not just as a thought or feeling but as the actual event it describes" (Eifert & Forsyth, 2005, p.88). According to the ACT model, the struggle with pain is viewed as a form of non-acceptance and the extent of the suffering is reliant on the extent of the patients fusion with thoughts and feelings associated with pain (Hayes, & Strosahl, 2010). Individuals are described as "fused" with their thoughts if they have a strong belief cognition (e.g. "I have to get rid of my pain before I can do anything I value in life") and then behave in accordance with this thought, even if this is incongruent with their values.

The aim of ACT is to aid the patient in developing greater psychological flexibility in the presence of thoughts, feelings and behaviours associated with pain. Thus the process of cognitive defusion involves an individual distancing themselves from the content of the thought (Ciarrochi & Bailey, 2008). Cognitive defusion is an acquired skill in which the individual observes the thoughts without judgement or giving attention to them (Dahl & Lundgren, 2006). In other words, it involves looking at the thoughts rather than from them (Hayes et al., 2003).

1.8.4. Self as Context

This is where individuals are encouraged to observe themselves as independent from the thoughts and feelings that arise, thus enabling them to defuse from or not identify with harmful thoughts or feelings (Dahl & Lundgren, 2006). Self as a context is fostered in ACT by mindfulness, metaphors and experiential processes.

1.8.5. Values

Values can be considered as a stated direction in which a person wants to go in their life and what is meaningful to them. Arch and Craske (2008) contend that the ultimate goal of an ACT intervention is for the client to achieve valued living (via values-driven behaviours), and that this is one of the major ways in which ACT differs from CBT, for which symptom reduction is the primary therapeutic objective.

Values are distinct from goals in that they cannot necessarily be achieved, but are rather guiding principles what give meaning to individuals lives (Hayes & Smith, 2005). CP sufferers are encouraged to identify what they value most in life. Values aim to empower CP sufferers to have a meaningful life and not to allow pain to occupy all their attention (Dahl & Lundgren, 2006).

1.8.6. Committed Action

Committed action refers to the practical application of moving towards chosen values, in a way that brings about tangible changes in behaviour. CP sufferers are encouraged to follow the goals in the presence of pain. The goal is to increase the extent to which behaviour is consistent with the person's values, and part of the goal of this phase of treatment is to show the individual how to gradually build patterns of sustainable, committed, value-driven behaviour (Strosahl, Hayes, Wilson & Gifford, 2004).

1.8.7. Contact with the Present Moment

Contact with the present moment involves attending to both internal and external stimuli in the 'here and now' (Harris, 2009). ACT encourages the individual to see the self as a process, observing events in a non-judgmental way and without making appraisals of themselves or their thoughts. Mindfulness training is used as a strategy to help sufferers achieve this neutral awareness of the present moment.

1.9. Empirical Support for ACT

There is growing evidence base for ACT generally (Hayes, Masuda, Bisset, Luoma, & Guerro, 2005) and specifically for CP (Veehof, Oskam, Schreurs, & Bohlmeijer, 2011). A recent systematic review of the effectiveness of ACT identified 60 RCTs on psychiatric disorders, somatic disorders and stress at work (Ost, 2014). The author found that the mean effect size across all comparisons was small (0.42) and concluded that ACT is not yet a well-established for any disorder. Although, they reported that it was probably efficacious in CP.

A search of the literature identified eleven studies that assessed the effectiveness of ACT in the treatment of CP. Table 7 provides a summary of the results from these RCTs. As the table highlights the majority of the studies compared ACT to various forms of TAU and WLC. In all but one of the studies (Dahl, Wilson & Nilsson, 2004) it was reported that ACT had significant improvements compared to the treatment as usual and waiting list control conditions on at least one outcome measure.

A further two studies have compared ACT to other psychological therapies in CP (Thorsell et al., 2011; Wetherall et al., 2011). These studies reported slightly different outcomes. When ACT was compared to CBT, there were no reported significant differences between the two interventions (Wetherell et al., 2011). Although, the study reported that both ACT and CBT improved pain interference, depression and pain related anxiety in patients with CP. Whereas, when compared to applied relaxation (AR) ACT participants were found to have significantly more

Table 7

Evidence of the effectiveness of ACT with chronic pain conditions

Study	Population	Intervention Format	Comparison	Duration	Outcomes
Buhrman et al. (2013)	CP Mean age (in years): 49.1 % female: 59.2	Online ACT with two phone calls (n=38)	WLC (n=38)	7 weeks	Attrition: 24% (treatment), 16% (condition) Significant improvement in acceptance compared to control group. Also ACT group had reductions of pain-related distress, anxiety and depressive symptoms. Authors concluded that an acceptance based internet-delivered treatment can be effective for persons with CP.
Dahl et al. (2004)	CP Mean age (years): 40 % female: 79.5%	Individual sessions (n=11)	MTAU (n=8)	4 weeks	Attrition: 0% No significant differences between medical TAU and ACT were found in levels of pain, stress, or quality of life.
Johnston, Foster, Shennan, Starkey, & Johnston (2010)	CP Mean age (years): 43 % female: 58%	Self-help manual (n=12)	WLC (n=12)	6 weeks	Attrition: 50% (treatment), 33% (condition) Compared to controls, participants in the ACT condition showed improved quality of life and decreased anxiety. The authors concluded that the study's findings support the hypothesis that using the self-help book, with minimal therapist contact adds value to the lives of people who experience CP.
Luciano et al., (2014).	FM Mean age (years): 48 % female: 50	Group ACT (n=51)	RPT (n=52)	8 weeks	Attrition: 9% Overall ACT was reported to be statistically superior to both RPT and WL immediately after treatment, and improvements were maintained at six months with medium effect sizes in most cases.

McCraken, Sato & Taylor (2013).	CP n in General Practice. Mean age (years): 58 % female: 68.5	Group ACT (n=37)	TAU (n=36)	4 sessions in 2 weeks	Attrition: 24.3% did not complete posttreatment data. Immediately post treatment, relative to TAU, participants in ACT demonstrated lower depression and higher ratings of overall improvement. At a 3-month follow-up, again relative to TAU, those in ACT demonstrated lower disability, less depression, and significantly higher pain acceptance
Thorsell et al. (2011)	CP Mean age (years): 46 % female: 64.4	Self-help manual with telephone support (n=52)	Applied Relaxation self-help manual (n=38)	7 weeks	Attrition: 37% (T1), 18% (T2) ACT condition increased their level of acceptance significantly compared with the AR condition. Significant interaction regarding satisfaction with life in which the ACT condition had improved in comparison to the AR condition. ACT condition reported a higher level of function and decreased pain intensity compared with the AR condition. Both conditions improved significantly regarding depression and anxiety
Trompetter, Bohlmeijer, Veeholf, & Schreurs (2014)	CP Mean age (years): 52.9 % female: 76.8	Online ACT (n=82)	C1: Online expressive writing (n=79) C2: WLC (n=77)	8 weeks	Attrition: 28% (T), 37% (C1). At follow-up, ACT participants had improved pain interference in daily life compared to participants compared to expressive writing group but not WLC.
Wetherall, et al., (2011	CP Mean age (years): 54.9 % female: 50.9	ACT group (n=57)	CBT group (n=57)	8 weeks	Attrition: 14.1% No significant differences found between CBT and ACT
Wicksell, Ahlqvist, Bring, Melin	Whiplash associated disorders	Individual ACT sessions (n=11)	TAU (n=9)	8 weeks	Attrition: 4.8% After treatment, significant differences in favour of the treatment group were seen in pain disability, life satisfaction,

& Olsson (2008).	Mean age (years): 48.2 % females: 61.5				fear of movements, depression, and psychological inflexibility. No change for any of the groups was seen in pain intensity. Improvements in the treatment group were maintained at 7-month follow-up.
Wickell, Melin, Lekander, & Olsson (2009)	Chronic paediatric pain Mean Age (years): 14.8 % females: 78	Individual ACT (n=16)	Multidisciplinary treatment (n=16)	10 weeks	Attrition: 9.5% At follow-up, ACT group performed significantly better than MDT on perceived functional ability in relation to pain, pain intensity and pain-related discomfort. Results support the effectiveness of Act orientated intervention for paediatric longstanding pain.
Wicksell et al., (2013)	FM Mean age (years): 45.1 % females: 100	ACT group (n=23)	WLC (n=17)	12 weeks	Attrition: 10% Significant differences in favour of ACT were seen in pain-related functioning, FM impact, mental-health related quality of life, self-efficacy, depression, anxiety and psychological inflexibility.

Abbreviations: ACT, Acceptance and Commitment Therapy; CBT, cognitive behaviour therapy; CP, chronic pain; FM, fibromyalgia; MTAU, medical treatment as usual; RPT, recommended pharmacological treatment; TAU, treatment as usual; WLC, waiting list control

improvements on level of functioning and decreased pain intensity (Thorsell et al., 2011).

Despite the empirical support for ACT this review also identified a number of shortcomings in the published studies. This includes small sample sizes, non-manualised treatment components and a lack of medical and psychiatric diagnostic evaluations. In addition, there has been dispute over the ability of traditional psychological self-report measures to capture changes ascribed to acceptance (Ruiz, 2010). One of the challenges in the literature is that there are no clear outcome measures to determine success in the treatment of CP (Connor-Smith, Compas, Wadsworth, Thomsen, & Saltzen, 2000). Consequently, Levine and Hayes (2009) have postulated that all future studies of ACT must fully integrate quantitative and qualitative data as the exclusive use of self-report inventories may expose trials to significant response bias. However, to the author's knowledge no studies have explored qualitatively, the experience of completing an ACT self-help intervention for CP.

1.10. Self-help interventions

Self-help materials, such as books, videos and computer programmes, are increasingly being adopted as a cost-effective way to increase the availability of psychological therapies, with a surge in use and research over the past decade. These self-help interventions are designed to provide patients with skills and confidence to manage symptoms or challenging situations without significant input from professionals (Gellatly, Bower, Henessey, Richards, Gilbody, & Lovell, 2007). There has been encouraging evidence from review studies which suggest that such methods are effective in reducing the distress and interference associated with CP (see systematic literature review). Gellately and colleagues (2007) proposed that self-help materials are more effective when they are accompanied by support from professionals or paraprofessionals (practitioners without specialised training in formal psychological therapy). However, despite studies demonstrating effectiveness of self-help interventions, patients have reported ambivalence towards this format of psychological intervention (Khan, Bower, & Rodgers, 2007).

Bower and Gilbody (2005) suggested that the acceptability of minimal interventions such as guided self-help is crucial for effective implementation. Scogin, Hanson and Welsh (2003) warned that patients may view guided self-help as inappropriate or inadequate. Consequently, Waller and Gilbody's (2009) review found there was a low uptake of such interventions. Similarly, poor adherence and high attrition have been observed in numerous studies on guided self-help; for example, Banasiak, Paxton and Hay (2007) outline a number of studies relating to eating disorders, some with attrition rates as high as 70%.

1.11 Aims and Research Questions

This was a feasibility study in which the primary objective was to address issues with recruitment and the acceptability of the intervention SCS treatment pathway. To date, literature has focused on the treatment as CP, with little or no distinction between those that have chronic nociceptive pain and CNP. As already discussed CNP is typically more difficult to treat, therefore it would be beneficial to explore if ACT is effective with this participant group. Based on Medical Research Council guidelines (MRC; Craig, Dieppe, Macintyre, Michie, Nazareth, & Petticrew, 2008) due to limited psychological research in the CNP field and more specifically SCS it was pertinent to initially complete a feasibility trial.

The secondary objective of this research was to assess how the self-help manual could be improved and whether it was applicable to participants with CNP having SCS surgery. Furthermore the study explored the effectiveness of ACT self-help interventions with patients that had SCS surgery, albeit this was with a small sample size.

Encompassed within these aims were the following questions:

1. Is it feasible to complete a full RCT with this population?
2. What would the sample size need to be to reach statistical power?
3. How could the manual be improved?
4. Does it appear that ACT is effective with participants that undergo SCS surgery?

2.0 EXTENDED METHODS

The following information is an extension of the method section in the journal paper.

2.1. Epistemological position

The researchers ontological (nature of reality) and epistemological (what can be known) positions inform the methodology adopted. At one end of the spectrum, there is the naïve realist ontology. This is a belief that we can objectively see reality without bias. The naive realist ontology informs a positivist epistemological position.

Auguste Comte (1930) was a 19th century philosopher that articulated the doctrine of positivism, this has since been elaborated on by succeeding scholars. It has been argued that these elaborations have lacked consistency with each other or with Comte's original formulation, thereby making it difficult to define precisely what is meant by positivism (see Bryman, 1988). However, central to the philosophy remain these main tenants: (i) that scientific observation should be restricted to observable facts. Whereas, inferred constructs, such as motives or beliefs do not have a place in science. (ii) Science is objective and value free.

The positivist doctrine was incorporated into psychology in the form of methodological behaviourism. Behaviourists such as Watson viewed psychology as 'science of behaviour' and eschewed consideration of 'inner variables' e.g. affects and cognitions. The self-help intervention adopted in the research is a third wave behaviourism based on relational frame theory. However, ACT's epistemological orientation is functional contextualism (Vilardaga, Hayes & Schelin, 2007).

At the other end of the ontological spectrum to positivism is the relativist position, which argues that there are multiple, constructed realities that are influenced by social, historical and cultural factors. A range of interpretative and constructionist epistemologies are informed by the relativist ontology. These epistemologies acknowledge the dynamic relationship between the participant and researcher

(Ponterotto, 2005). The qualitative approach from this position would explore the participant's perspective and understanding phenomenon in given situations (Yardley, 2000).

The ontologies and epistemologies that have been discussed are from two ends of the spectrum and there are many others that fall between these two positions. The position that I have adopted for this research is that of positivism. The aim of the paper is to give direct observations regarding the feasibility of the RCT; this includes documenting the difficulties with recruitment, attrition rates and the feedback of the self-help manual. A secondary aim of the study was to explore the effectiveness of the ACT intervention using quantitative measures, which is compliant with the positivist framework.

2.2. Feasibility study

Randomised controlled designs are considered the gold-standard by which to evaluate psychosocial interventions (Schulz, Atman, Moher & the CONSORT Group, 2010). A predominant strength of this design is the randomised allocation of participants under controlled conditions which protects against the threat of internal validity of the researcher (Clark-Carter & Marks, 2004). However, as with all research designs there are potential limitations of RCTs. In many clinical trials, retention and recruitment of participants is a significant problem (Howard, de Salis, Tomlin, Thornicroft & Donovan, 2009). McDonald and colleagues (2006) review found that less than one third (31%) of the trials funded by the UK Medical Research Council and the Health Technology Assessment programme achieved their original recruitment target within the allocated time period. These shortfalls could lead to costly extensions or failure of a trial. Furthermore this could delay effective interventions being introduced into clinical practice (Patterson, Mairs, & Borshmann, 2011). A possible solution to this problem is to conduct a feasibility or pilot study to ascertain how participants will respond to the trial design and intervention (Rojavin, 2009).

The MRC guidance for designing and evaluating complex interventions recommends that sufficient piloting and feasibility work should precede a full RCT (Medical Research Council, 2008). Feasibility studies can estimate the likely rates of recruitment and retention of participants and the calculation of the appropriate sample size. The MRC also suggest that a mixture of qualitative and quantitative methods are likely to be required in a feasibility study to understand the barriers to participation and to estimate response rates.

There has yet to be any research conducted on applying ACT self-help interventions with patients that have had SCS surgery. Therefore in accordance with the MRC a feasibility study is utilised to assess the potential barriers to this research. A mixed method approach was utilised to extrapolate the optimum data for future RCTs and to adhere to the guidance on evaluating complex interventions.

The inclusion of participants that had been assessed for SCS surgery (including having the trial surgery) but not had the implant was to gather additional information on the self-help intervention and suggestions of how this could be improved for future studies. It is not anticipated that this participant group would be included in a full RCT.

2.3. Mixed Method Approach

Johnson and Onwuegbuzie (2004) define mixed methods research as the combination of qualitative and quantitative research techniques, methods, concepts or language within a single study. This combination of methodologies is often referred to as “triangulation” (Hussein, 2009). Hussein (2009) argues that this combination of multiple methods and theories using a triangulation method can increase the depth of understanding of the phenomena under question. In addition, Hussein suggests that this method is particularly beneficial to adding deeper understanding to less explored or unexplored research topics. The purpose of this current research is to assess the feasibility of conducting a RCT to assess of ACT with SCS patients. A feasibility study is required due to this being an unexplored

area, therefore it was pertinent to gather as much information for the potential future RCT. Consequently, it is argued that a mixed method approach is the most suitable method to gather as much data as possible regarding the study design and intervention.

2.4. Participants

2.4.1. Inclusion and Exclusion Criteria

The study concerned participants that had been assessed for SCS surgery at one Neuromodulation clinic. Participants in the two SCS arms (SCS-ACT and SCS-TAU) they were due to have SCS surgery a week after they were recruited to the study. These participants had the SCS implant still fitted throughout the duration of the study.

The inclusion criteria for the ACT-only arm was that they had been assessed for SCS surgery and had the trial implantation, however had not undergone the full SCS.

All participants were required to be able to give informed consent to participate in the study and must be literate in English. Participants that were already engaging in psychological therapy or involved in another clinical trial were excluded from the study.

2.4.2 Sample Size

It was originally proposed that a total of 50 participants would be recruited for this study. This sample size was determined on professional clinical advice on the projected number of clients in the surgery and the expected percentage that would be likely to agree to participate in the study. It was envisaged that there would be 30 participants that have had the SCS surgery and they would be randomly allocated to

either ACT (SCS-ACT) or treatment as usual (SCS-TAU), with 15 participants in each condition and 20 participants that have had not SCS surgery (ACT-only).

The study did not recruit this number of participants and it was found that the original proposal over-estimated the number of potential participants that could be approached for the study, a common pitfall in many RCT's. Due to the study being a feasibility RCT a power calculation was never calculated nor was it intended that the study would reach power. The NIHR guidance states:

"If a feasibility study is a small randomised controlled trial, it need not have a primary outcome and the usual sort of power calculation is not normally undertaken. Instead the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision."

2.4.3 Recruitment Procedure

Following gaining single-site ethical approval (see Appendix B) and NHS R&D approval (see Appendix C), I commenced the recruitment process in June 2014. Participants were recruited from one Neuromodulation department. All the participants had a clinical diagnosis of CNP and having exhausted other less evasive pain management options were assessed for SCS.

SCS participants

The participants in the two SCS groups (SCS-ACT and SCS-TAU) were recruited in clinic during a routine appointment. The clinicians at the department were fully briefed on the study and initially approach potential participants regarding the study during a routine appointment. If the participants expressed an interest in the study they were then approached by the researcher who gave further information (including an information sheet) and recruited into the study.

ACT-only participants

With regards to the participant group that have not been deemed suitable for the SCS intervention, they were recruited through a different route as they were discharged from the neuromodulation service. To introduce the study to these potential participants, information packs were sent out by the Department of Neurosurgery on my behalf. Therefore, no personal information was accessed prior to participants' contacting myself and consenting to participate in the study. The pack included a covering letter (see Appendix D), a participant information sheet (see Appendix E) and the baseline measures. The covering letter consisted of an overview of the research and details of what they were required to do if they wanted to participate in the study. The patient information sheet provided an explanation of the study objectives, further details of the participant's role, an overview of the self-help intervention, and a description of participant's ethical rights. To opt into the study participants completed the baseline measures and consent form and returned them to the researcher.

Further information regarding the recruitment process and a participant flow diagram consistent with the Consolidation Standards of Reporting Trials (CONSORT) statement (Begg et al., 1996) is available in the Journal Method.

2.4.4 Randomisation

The two groups that have had the SCS were randomised into the SCS-ACT or SCS-TAU conditions. In accordance with CONSORT guidelines (Moher, Schulz & Arltman, 2001) randomisation occurred after the participants had completed the baseline measures and consented to the study. Participants were randomised using the sequentially numbered, opaque sealed envelopes (SNOSE) method. This is a recognised method of randomisation, particularly when the random allocation happens as part of a clinical consultation.

The allocation of the conditions was with sequentially numbered, otherwise identical, sealed envelopes, each containing paper with a written code designating intervention or control. These papers were placed in a folded sheet of aluminium foil fitted inside the envelope. There were no detectable differences in size or weight between intervention and control envelopes. Envelopes were opaque and lined inside with carbon paper. The envelopes were opened sequentially only after writing the subject's tracking information on the envelope so that the carbon paper served as a trail. Therefore allocation of groups was not influenced by baseline measures or how well the clinicians think participants would respond to psychological intervention.

2.4.5. Sample of participants information

Certain demographic information for the 19 participants who were recruited for the study were collated and presented in Table 8. Information is also included regarding the number of weeks that each of the SCS-ACT and ACT-only participants completed the self-help manual and telephone support sessions. For the purposes of anonymity and confidentiality, alias names were used to protect the identity of the participants.

2.5. Intervention

2.5.1. ACT manual

The *Living Beyond Your Pain* (Dahl & Lungen, 2006) book was given to the participants in the two ACT intervention conditions. This ACT manual was selected as it had previously been used in the Johnston et al. (2010) and Wetherall et al. (2011) studies and is a key text in ACT and chronic pain. The author of the book JoAnne Dahl was emailed prior to the study to gain her permission for the book to be photocopied and given to participants. Dahl was aware that the study was part of clinical qualification and there was a possibility that results would be published in a peer reviewed journal.

Table 8

Table of Participant Information

Name	Study Arm	Age	Gender	Work status	Site of pain	Duration of pain	No. of weeks completed
Laura	SCS-ACT	43	Female	Part-time	Lower back, one leg	4 years	3
Emma	SCS-ACT	30	Female	Full-time	Lower back, one leg	17 years	3
Stuart	SCS-ACT	42	Male	Part-time	Lower back, both legs	17 years	3
Simon	SCS-ACT	44	Male	Do not work, due to CP	Lower back, one leg	12 years	1
Amy	SCS-ACT	49	Female	Do not work, choice	One Leg	20+ years	6
Jack	SCS-ACT	32	Male	Full-time	Back, both legs	15 years	4
Anthony	SCS-ACT	43	Male	Do not work, due to CP	Back, one leg, buttock	10 years	3
Shaun	SCS-ACT	30	Male	Do not work, due to CP	Lower back, both legs	9+ years	2
Jessica	SCS-TAU	43	Female	Part-time	Lower back, both legs	18 years	
Charlie	SCS-TAU	45	Male	Full-time	Both legs	15 years	
Dave	SCS-TAU	36	Male	Do not work, due to CP	Lower bag, one leg	8 years	
Louie	SCS-TAU	38	Male	Do not work, due to CP	Back, both legs	12 years	
Heather	SCS-TAU	41	Female	Part-time	Lower back, one leg	10 years	
Ann	SCS-TAU	50	Female	Part-time	Back, buttocks, one leg	20 years	
Phyllis	ACT-only	75	Female	Do not work, choice	Back, both legs	7 years	2
Joshua	ACT-only	49	Male	Do not work, due to CP	Back, neck, arm	7 years	4
Suzie	ACT-only	64	Female	Do not work, choice	Back, both legs, buttocks	22 years	6
Brian	ACT-only	56	Male	Do not work, due to CP	Buttocks, both feet	20 years	6
Michael	ACT-only	75	Male	Do not work, choice	One leg, buttocks	5 years	3

The participants were also given a summary of the chapters that would be covered in each of the 6 weeks (See Appendix I).

2.5.2 Telephone Calls

In addition to the participants working independently on the materials, they received weekly telephone support throughout the six weeks. The aim of the telephone support was to provide the participants with the opportunity to discuss any difficulties they had with the manual but also to discuss the main points of each of the chapter and its applicability to their daily life. Furthermore, it was hoped that the telephone support may also encourage the participants to keep to the schedule of completing all the chapters of the manual.

Each phone call was conducted by the primary researcher and started with an open ended question about how they have found the section of the book, followed by a discussion regarding the exercises. At the end of each call the participants were asked three standard questions:

1. Did you do all, some or none of the reading exercises?
2. Did you find the reading level easy, medium or hard?
3. Did you find this chapter useful?

These questions were used to extract more information from the participants, to assess the feasibility of the participants completing the work within the timescale and the effectiveness of the manual. Similar questions were used in Johnston et al's (2010) study, in which the effectiveness of the manual was assessed.

All of the telephone support sessions were recorded. The participants were informed that these sessions were recorded in the consent form and were reminded at the beginning of the support sessions. The data gathered from these calls was analysed using content analysis.

2.6. Measures

The measures used in the study were selected in order to answer the research question and also to adhere as closely as possible to the 'Initiative on methods, measurement and pain assessment in clinical trials (IMMPACT) recommendations for research with chronic pain populations (Dworkin, et al. 2003). The IMMPACT recommendations are that the following six domains should be considered when conducting clinical trials regarding the effectiveness of treatments for chronic pain: (1) pain, (2) physical functioning, (3) emotional functioning, (4) participant rating of improvement and satisfaction with treatment, (5) symptoms and adverse events and (6) participant disposition. However, Dworkin et al (2005) also suggest that there may be circumstances in which the use of some of the core outcome measures will not be appropriate. The measures utilised in the present research covered the domains of pain, physical functioning, emotional functioning, quality of life and self-efficacy are now described.

2.6.1. Pain and Physical Functioning

Participants' rated the severity of their pain and the extent to which pain interferes with their functioning using the Brief Pain Inventory (BPI; Cleeland, 1991). The BPI asks respondents to rate their current pain intensity and the pain they had experienced in the past 24 hours at its worst, least and average using a scale of 0 to 10, with "0 = no pain" and "10= pain as bad as you can imagine". In accordance with other clinical trials the items "worst" and "average" were used to singly represent pain severity. The use of these single items is supported by IMMPACT recommendations for assessing pain in clinical trials (Dworkin et al., 2005; Dworkin et al., 2008).

The BPI also measures the extent to which pain interferes with seven domains of functioning (general activity, walking, mood, sleep, work, relations with others and enjoyment out of life) on 0-10 scale. A mean of these seven items produces a BPI pain interference score.

The IMMPACT recommendations state that physical functioning is one of two outcome domains as core components of health related quality of life (HRQoL) that should be assessed in clinical trials of treatments for chronic pain (Dworkin et al., 2008). Furthermore the guidelines recommend that physical functioning should be assessed using either the Inference Scale of the Multidimensional Pain Inventory (MPI) or the BPI. The BPI was the measure chosen for the present study as it also provides a measure of pain intensity and is a much shorter measure than the MPI.

2.6.2 Emotional Functioning

The second outcome domain that IMMPACT recommends as a core component of HRQoL to assess the effectiveness of treatments for chronic pain is emotional functioning (Dworkin et al., 2008). Emotional functioning was assessed using the Hospital Anxiety and Depression Scale (HADS; Zigmond, & Snaith, 1983).

The HADS is a 14-item questionnaire that measures depression (7 items) and anxiety (7 items) and was designed for use with populations that have somatic symptoms. Participants are asked to rank items according to the frequency or severity of symptoms on a four point Likert scale. Item scores for each subscale is totalled to yield both a depression score and an anxiety score. Participants can score between 0 and 21 for either anxiety or depression (0-7= normal levels, 8-10=mild symptoms, 11-15= moderate symptoms, 16-21 severe symptoms).

Participants are asked to rank items from 0-3 depending on how accurate each statement reflects how they feel, so participants can score between 0 and 21 for either anxiety or depression.

The HADS is considered to be superior to other measures of emotional functioning such as the Becks Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) in health populations as less emphasis is placed on symptoms that may have an underlying physical causes. (Turk et al., 2015).

2.6.3 Health Related Quality of Life (HRQoL)

In addition to HRQoL was assessed using the EQ-5D. The EQ-5D is applicable to a variety of different illnesses and treatments and provides a simple descriptive profile and a single index value for health status. The five dimensions included in the EQ-5D are: mobility; self-care; usual activities; pain/discomfort and anxiety/depression

The EQ-5D tends to be the measure most used in cost-utility analysis and in health technology assessment; for example the use of quality-adjusted life years (QOLYs) is required by the NICE, with the EQ-5D as the preferred measure of utility (NICE, 2013b).

2.6.4 Self-Efficacy

The aim of the ACT intervention is focused on accepting rather than controlling the chronic pain. Therefore the treatment effectiveness assessment needs to be reflective of the intervention strategy. A number of studies assessing the effectiveness of an ACT intervention have used the Chronic Pain Acceptance Questionnaire (CPAQ; McCracken, Vowles, & Eccleston, 2004). However, Nicholas and Asghari (2006) noted that the CPAQ has been used to explore acceptance of pain without taking into account the contribution of other cognitive variables that have been shown to influence adjustment to CP. In their study they measured the role of pain acceptance, as measured by the CPAQ, in accounting for adjustment to pain when controlling the effects of other cognitive variables. They found that not all of the subscales were robust and that the CPAQ was not sufficient to explain the process of acceptance and pain and, hence, adjustment to pain. Alternatively the paper recommends the use of the Pain Self Efficacy Questionnaire (PSEQ; Nicholas, 1989).

The PSEQ is a 10 item questionnaire that assesses the confidence participants with chronic pain have in performing activities whilst in pain. The questionnaire asks participants to rate how confidently they can perform a wide range of activities including completing household chores, socialising and work despite experiencing pain. Scoring is on a 7-point Likert scale of 0 to 6 with "0=not at all confident" and "6=completely confident". Higher scores reflect stronger self-efficacy beliefs. The questionnaire covers a range of functions, including socialisation, work, household

chores, as well as coping with pain without medication. Research has found that higher self-efficacy enhances and maintains the long-term effects of rehabilitation (Keefe, Rumble, Scipio, Giiordano, & Perri, 2004).

The questionnaire has demonstrated high validity with high correlations with the Self Efficacy Scale (Kaivanto, Estlander, Moneta, & Vanharanto, 1995), which is a more activity-specific measure of self-efficacy but does not incorporate the presence of pain as a context (Gibson & Strong, 1996).

2.6.5 Adherence to IMMPACT recommendations

The current research incorporated measures to assess the effectiveness of ACT with SCS participants and to adhere as closely as possible to the IMMPACT recommendations for conducting clinical trials for chronic pain. The criteria advised in the IMMPACT recommendations were met for pain (BPI), physical functioning (BPI) and emotional functioning (HADS), as discussed in the above section. The IMMPACT recommendations include measurement of participant rating of improvement and satisfaction with treatment. Dworkin and colleagues (2008) have suggested the Global Impression of Change measure as an appropriate psychometric but this was not considered appropriate for the present study due to the self-help manual focus on acceptance rather than a change agenda. However, the participants that completed the ACT intervention were asked each week to rate the usefulness of the weekly treatment components. In the interview the participant's satisfaction with treatment was further explored, they were invited to comment on the aspects that they found least and most useful of the intervention.

The criteria recommendation by the IMMPACT consort for 'symptoms and adverse events' was met by the current study design but was not conducted in a psychometric. However, IMMPACT reports that the minimal recommendation is for a passive capture of spontaneously reported events (Dworkin et al., 2005) which was captured in the weekly telephone support sessions. These telephone calls gave participants in the ACT conditions the forum to report any symptoms or adverse events relating to the intervention.

The IMMPACT recommendations also stipulate that inclusion of detailed information about participant disposition and their progress throughout the trial would be beneficial for clinical trials of chronic pain. Participant progress was monitored during a weekly telephone calls and reasons for withdrawal from the study were documented. Assessing attrition rates was one of the primary objective of the present study. Overall, the present study adhered to the IMMPACT recommendations to a sufficient standard as well as including additional measures that were targeted to answer the research question.

2.6.7 Demographic Information

The following demographic information was also collected:

- Age
- Gender
- Ethnicity
- Where the pain is located
- How long they have had the pain
- Employment status (to aid future health economic evaluations)
- The types of treatments to manage their pain they have previously tried

2.7. Semi-structured interview

The aim of the interviews was to assess the practicalities and feasibility of completing the self-help manual. The interview schedule therefore included the following areas:

- The participant's expectations about completing the self-help book and whether these had been met.
- Helpful / unhelpful aspects of the manual.
- Suggestions on what the participants would change, if anything about the manual.

- The practicalities of completing the self-help tasks and exercises.
- Any obstacles to complete the self-help manual.
- The usefulness of the telephone support as an addition to the manual.

2.8. Thematic Analysis

Thematic Analysis (TA) is a method of identifying, analysing and reporting patterns within data (Braun & Clarke, 2006). It is a widely adopted approach to qualitative analysis due to its flexibility in theoretical frameworks whilst also allowing for rich, detailed and complex analysis of data.

The process of TA comprises of searching across an entire data set in order to discriminate repeated patterns of meaning. Themes are then derived from "a specific pattern of meaning found in the data" (Joffe, 2011). These patterns can be located at two levels: the semantic level (directly observable in the information); or latent level (underlying the phenomenon). Latent descriptions are associated with a constructionist epistemology, whereas semantic is in line to a realist epistemology (Burr, 1995; Widdicombe & Wiiffitt, 1995).

In TA themes within the data can be identified in one of two primary ways: in an inductive way or deductive way. An inductive approach means the themes that are identified are related to the data themselves and may bear little relationship to the specific questions that were asked during the interview. In addition, the themes would not be driven by my theoretical interests on the topic. Whereas, a deductive approach is more explicitly analyst-driven as it tends to be guided by the researcher's analytical or theoretical interest in the area. This approach to TA tends to offer less rich description of the data overall, but a more thorough analysis of some aspect of the data.

The two alternative approaches to locating patterns and themes highlights the flexibility of TA but also the need for researchers to be explicit in their epistemology and approach to the data analysis to ensure transparency. TA was considered the

most appropriate approach for the current study due to its systematic and transparent approach. Although the flexibility afforded by the absence of a theoretical framework is often cited as an advantage, it has also been used as the target of criticism with the assumption being that thematic analysis is a process contained within many qualitative methodologies, rather than being a specific method in its own right (Boyatzis, 1998) However, guidelines for conducting TA produced by Braun and Clarke (2006) do go some way to establishing TA as a distinct approach, with its authors affirming that it TA a "method in its own right" (p. 4).

2.9. Different qualitative methods

The aim of this section is to expand on the rationale for choosing thematic analysis as opposed to other qualitative approaches. There are a range of qualitative methods that have divergent, yet "overlapping epistemological underpinnings as well as theoretical and methodological emphases" (Smith, 2004, p. 40). It is beyond the scope of this paper to provide an account of all these approaches so only a selection have been outlined.

2.9.1 Discourse Analysis (DA)

Discourse analysis has been defined as "an examination of language use- the assumptions that structure ways of talking and thinking about the topic of interest and the social functions that the discourse serves" (Powers & Knapp, 1990, p. 40). It has been proposed that discourse is orientated towards particular functions, providing language with both a constructive and constitutive role. There are six traditions of DA: conservation analysis; interactional sociolinguistics; discursive psychology; Foucauldian research and Bakhtinian research (Wetherall, Taylor & Yates, 2001). However, the two dominant approaches in the literature are Foucauldian Discourse Analysis and Discursive Psychology (Jørgensen, & Phillips, 2002).

Foucauldain Discourse Analysis is predominately concerned with the position of discourse in relation to wider social processes of legitimisation and power. Discursive Psychology is more interested in the way language is used to manage and negotiate social interactions to achieve interpersonal objectives (Willig, 2013). Despite these two different strands of DA they tend to be located within a social constructionist epidemiological framework. This is not in line with my epistemological position as it perceives there to be multiple constructed realities whereas I want observerable and measurable results to inform my results.

2.9.2 Grounded Theory (GT)

Influenced by Symbolic Interactionism sociologists Glaser and Strass (1971) developed Grounded Theory (GT). They defined GT as "the discovery of theory from data systematically obtained from social research" (Glaser & Strass, 1971, p. 2). The methodology is ideal for exploring integral social relationships and the behaviour of groups where there has been limited investigation of the contextual factors that affect people's lives (Crooks, 2001). However, the aim of my research was to assess the feasibility of conducting a RCT of ACT with patients that have had SCS surgery. The interview was included to assess the usefulness and practicalities of completing the self-help manual not to develop a theory on this process. Therefore, I did not see GT as an appropriate methodology.

2.9.3 Interpretative Phenomenological Analysis (IPA)

Interpretative Phenomenological Analysis was developed to understand lived experience and with how individuals make sense of these experiences. Therefore its central concern is the meanings which these experiences hold for the participants. The method is phenomenological in that it aims to explore an individual's personal perception of an event opposed to trying to produce an objective record of it. Simultaneously, while attempting to explore the participants personal world, IPA considers that one cannot do this completely and that access is dependent on the researchers own conceptions which are needed to make sense of other personal world through a process of interpretative activity. Therefore, a second important theoretical construct of IPA is hermeneutics.

Although, IPA seeks patterns in behaviours it is theoretically bounded (this is also true for GT). It is attached to a phenomenological epistemology (Smith & Osborn, 2003) which gives experience primacy and is concerned with understanding people's everyday experiences of reality to decipher the phenomenon in question (McLeod, 2011). Conversely, TA is a methodology that is not wed to any pre-existing theoretical framework (Braun & Clarke, 2006). It is a flexible approach that is compatible with both essentialist and constructionist paradigms and therefore more suitable to the current research.

2.10. Data Analysis

2.10.1 Quantitative analysis of the measures

The study utilised ANOVAs to compare differences between the groups and across the two time points. The study did not obtain sufficient data to reliably explore the effectiveness of the intervention via inferential statistics, but this data has been included to estimate effect sizes and to conduct a power analysis for future trials.

Reliable and clinical significant change was addressed for each individual participant on the PSEQ, HADS, BPI and EQ-5D. Jacobson and Truax (1991) report that changes in outcome measures achieve clinical significance if the following two criteria are met:

1. The change in the outcome score was reliable according to the Reliable Change Index (RCI) (RCI <-1.96 or >1.96).
2. Scores transitioned from being above clinical cut-off at baseline to below cut-offs at post baseline.

The Jacobson-Truax method allows for determining whether or not the magnitude of change is statistically reliable by taking into account measurement error. To account for measurement of error the first step of this method included calculation of Standard Error of Measurement. To determine the Standard Error of Measurement for the aforementioned measures calculations were based on estimates of test-retest reliability for the:

- PSEQ obtained by Ashghari and Nicholas (2001) (*r*=0.92)
- HADS obtained by Bjelland, Dahl, Haug and Neckelmann (2002) (*r*=0.80)
- BPI Pain Intensity obtained by Mendoza, Mayne, Rublee and Cleeland (2006) (*r*=0.87).
- BPI Pain Interference obtained by Mendoza et al. (2006) *(r*=0.92)
- EQ-5D obtained by Al-Janabi, Flynn, Peters, Bryan and Coast (2015) (*r*=.61)

Reliable change and clinically significant cut-off points were determined for the PSEQ, HADS, BPI and EQ-5D using the method outlined by Jacobson and Truax (1991). The cut off criteria used to determine whether individual participants who showed reliable change and could be said to have 'recovered' are shown in Table 9.

When assessing whether a participants post intervention scores met the criteria for RCI and/or CSC the scores in this table can be used. For example, normative data for the EQ-5D index values (measurement of HRQoL) produced a critical value for reliable change of 0.62 (i.e. increases or decreases greater than 0.62 would be considered reliable) and a cut-off for CSC at 0.81. Therefore if a participant had a change greater than 0.62 that also crossed the threshold of 0.81 (line between "clinical" and "normative" functioning) they would have said to have achieved clinically significant improvement.

Table 8

Table depicting RCI and CSC Criteria

Measure	**Reliable Change Index value**	**Clinical Significant Change cut-off**
PSEQ	8.23	43.8 and above
HADS Depression	4.77	<8
HADS Anxiety	4.58	<8
BPI Intensity	1.77	<4.74
BPI Interference	1.58	<3.54
EQ-5D VAS	41.54	76.1 and above
EQ-5D Index Value	0.62	0.81 and above

2.10.2. Content Analysis of telephone calls

Content analysis is a research method for "defining, measuring, and analysing both the substance and meaning of texts" (Beck & Manuel, 2008). It is a technique that was adopted for systematically describing the content of the telephone conversations. The methodology provided a quantitative description of this data. This quantification permitted breaking the information down into categories and then to be summarised. Content analysis was the chosen method for these calls as it is less time consuming than other methods and therefore it is able to be used on a large data set. The telephone calls varied in length, with a mean time for each call being 14.10 minutes (*SD*=8.27) and seeing as it was intended that each participant that received the intervention had six telephone calls this accumulated a lot of data. The original research design had not intended to perform an analysis on this data although it was always stated that these telephone calls would be recorded. However, when completed the study it became evident that this provided valuable information regarding the feasibility of completing the intervention and the usefulness of the self-help manual.

2.10.3 Thematic Analysis of Interviews

A deductive and semantic level approach to TA was conducted within Braun and Clarke's guidelines. The authors provide a coherent guidance on the steps involved in identifying emerging themes and their interpretation. They suggest six phrases:

Phase one: Familiarisation with the data

To become immersed in the data I repeatedly read the interviews. The data was read in an active way where even within this first phase I began searching for patterns within the transcripts. At first the transcripts were annotated by hand and any patterns were hand written in the page margins, an example of which can be seen in Appendix K.

Phase two: Generating initial codes

The handwritten notes consisted of initial ideas about the content of the data and any areas of initial interest; these formed the basis of the initial coding stage. These initial ideas taken from the raw data were then organised into a "codebook" (Guest, MacQueen, & Namey, 2012, p. 52). At this stage as many potential themes/patterns

were coded for and the detail around each extract was included to retain the content (Bryman, 2001). This process of coding was systematically carried out with the entire data set and extracts were at times included in multiple codes. Throughout this phase the codebook was developed and refined (see Appendix L for exemplar of the codebook).

Phase three: Searching for themes

Once data extracts had been collated under specific codes, the codes were examined for patterns in the data and this started the process of analyse the data at a broader level of themes (Braun & Clarke, 2006). Codes were brought together with broader themes by the use of a visual "mind map" (Braun & Clarke, 2006). This was depicted in an early thematic map, seen in Appendix M. The relationship between codes, themes and level of themes (main themes and sub-themes) was considered.

Phase four: Reviewing themes

This phase involved two levels of reviewing and refining the themes. Level one involved reviewing at the level of the coded data extracts. All the collated extracts for each theme was read and consideration was paid to whether they appeared to form a coherent pattern. The outcome of this refinement process is illustrated in the thematic map in Appendix N.

Level two involved re-reading the entire data set and considering whether the themes were reflective of the data. Additional data that had been missed in earlier coding was identify and coded into existing themes.

Phase five: Defining and naming the themes

A detailed analysis for each theme was conducted, considered was given to the 'story' each theme tells and how this fits into the broader overall 'story' of the data. A definition of each of the themes and subthemes and of why they were of interest is illustrated in Appendix O.

Phase six: Presentation of analysis

The analysis was written in a way to provide a coherent account of the story told by the data, within and across the themes.

2.11. Ethical Considerations

Ethical approval was sought and granted from the University of Nottingham and Nottingham Research Ethics Committtee 1 (see Appendix B). R&D was sought and approved by a NHS Trust hospital (see Appendix C).

2.11.1 Informed Consent

SCS participants

All SCS participants were recruited face to face and the clinic during a routine appointment. Therefore potential participants were given the opportunity to ask questions about the study. Participants were informed that the decision to participate was voluntary and that they could withdraw from the study at any time, although their data could not be erased, in line with the University research policies. In addition participants were made aware that if they chose not to be involved in the study or withdrew their consent it would have no impact on their future care at the clinic. Participants were given an Information sheet (see Appendix G) and will needed to sign the informed consent form (see Appendix H) prior to participating in the study.

The participants received a copy of the signed and dated forms and the researcher kept the original copy, which was retained in the Trial Master File.

Non SCS participants

Those that had not had SCS were recruited via letter (see Appendix E). The letter provided contact details of the researcher if they had any queries prior to consenting to the study. This group were contacted by the researcher once they had consented and the details of the study including their right to withdraw and their confidentiality were discussed in first telephone call.

The two groups that had the ACT intervention (SCS-ACT and ACT only) also completed an interview. Participants were informed that I would be using direct quotes from this interview in the write up of the study but that pseudonames would

be employed. Participants were told that the thesis would be submitted to the university to be marked and there was a possibility the study would be published.

2.11.2 Confidentiality

The participant's information obtained for the purposes of the study was treated confidentially and not disclosed to third parties. Participant confidentiality was further ensured by using identification code numbers to correspond to treatment data in the computer files.

The clinic did not break the confidentiality of its service users or ex-service users and I only had contact with participants once they had expressed interest or agreed to participate in the study. The clinic posted the letters to those who were not deemed suitable for SCS surgery (arm 3), so not to break confidentiality.

2.11.3 Risk of harm

There had not been identified risks of harm to the participants prior to commencing the study. However, three participants reported finding Chapter 3 difficult and in particular the planning their own funeral exercise. One participant did not continue with the self-help manual and withdrew from the study after this exercise. Whereas, another was unsure whether to continue due to the impact it had on his mood and therefore the participant was supported during the telephone call. The latter participant continued to complete the intervention.

3. EXTENDED RESULTS

3.1. Recruitment

Participants were recruited from one Neuromodulation. This clinic has been regularly delivering SCS surgery since 2005. During this time and up until June 2015 the department had conducted 162 SCS surgeries. All of these surgeries had a successful SCS trial prior to full implantation. However, there were 24 patients for whom such trials had been unsuccessful during this ten-year period and did not go on to have the SCS surgery. The reasons that the trial failed were due to either the surgeons not being able to capture the area of pain, the patients reported not liking the sensations (typically SCS gives a tingling sensation in the area of pain), patients reported the implant made the pain worse or that the new pain from the implant overrode the focal point of pain the trial was targeting. All of the 24 patients that had the unsuccessful trial were sent a letter inviting them to the study. Only five (21%) consented to participate.

The study recruited over a 12 month period, during which time 30 patients had SCS surgery at the Neuromodulation clinic. Twelve of these patients were assigned to a medical clinical trial and therefore could not be recruited so not to contaminate the data for either study. Consequently, this left a sample pool of 18. All potential participants were approached for the study and 14 (78%) consented to participate. Two patients did not participate in the study due to having another psychological therapy at the time of recruitment, and the other two declined to participate.

3.2. Sample Description

Baseline demographic and clinical characteristics for each group are presented in Table 10. Fifty-six percent of the overall sample identified as male and 44% as female. All of the participants identified as White British. The average age of the sample was 46.7 years (SD=13.4; Range 30-75). However, there was variation in the groups regarding age, with those in the ACT-only group having a higher mean

age. A one-way ANOVA found that this was a significant difference between the three groups, *F*(1,17)=27.96. p=.00.

Table 10

Baseline demographics and clinical characteristics for each group

Variable	SCS-ACT (*SD*)	SCS-TAU (*SD*)	ACT-only (*SD*)
N	8	6	5
Age, years	39.1 (7.3)	42.2 (5.0)	63.8 (11.5)
Woman	37.5%	50%	40%
Pain duration, years	13 (5.2)	13.8 (4.7)	12.2 (8.1)
Occupational status:			
Full time work/study	25%	17%	0%
Part time work/study	25%	33%	0%
Unemployed due to pain	37.5%	33%	40%
Retired/homemaker	12.5%	17%	60%

The majority of the participants (85.7%) reported pain in their back and leg(s). The overall mean time since the onset of the CNP was 12 years (SD=5.9; range 4-22 years). The participants reported having tried a number of interventions for their CNP, including acupuncture, nerve injections, medication, physiotherapy, surgery and TENS machines. There was little variation between the three groups on these characteristics.

3.3. Acceptability of the treatment

The study originally started with 19 participants, 13 of which were assigned to one of the ACT intervention groups (SCS-ACT and ACT-only groups). However, the majority of participants (77%) that received the psychological intervention did not complete the self-help manual. Figure 5. depicts the attrition rates from the intervention.

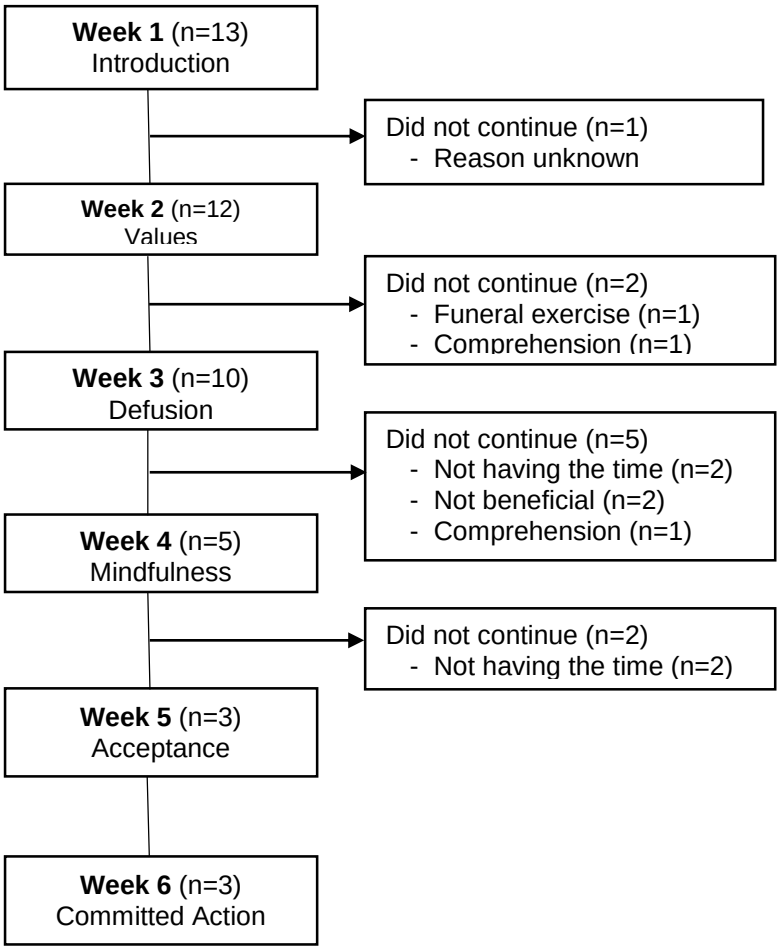

Figure 5: Flow chart of participant drop-out from the ACT intervention

One participant only completed the first week of the chapter, the researcher was unable to contact this participant to collect follow up data so this participant was excluded from the individual level analysis data. Only three participants (23%) completed the full manual. However, nine of the participants that dropped out of the self-help manual still completed the follow-up measures and were interviewed. All of the SCS-TAU participants completed the post-intervention measures. Therefore data was available for 95% of the total participants that consented to the current study. It is worth noting that to achieve this high completion rate the researcher had to send the questionnaires on more than one occasion to 32% of the participants. The researcher also regularly attended the Neuromodulation clinic which some of these post-intervention data was collected.

3.4. Telephone Support Sessions

Thirty-one percent of participants did not answer their telephone on at least one occasion when they were scheduled for a telephone support session and 38% participants cancelled at least one session as they had not completed the chapter. Therefore these sessions were re-arranged. The mean time for each of the telephone calls was 14.10 minutes (SD= 8.27, range 2.05-44.07 minutes).

The participants in the two ACT conditions received weekly telephone support sessions alongside the self-help manual. All these telephone calls were recorded and transcribed. The transcripts were analysed to generate categories for each of the weeks and its corresponding chapter in the manual.

A content analysis for each week are presented in Table 11-Table 16.

3.4.1. Week 1

During the first telephone support sessions all 13 participants reported that they had completed the first two chapters in the manual. The participants discussed a variety of topics during this week but the most commonly reported topic was previously failed treatments. Fifty-four percent of the participants mentioned unsuccessful treatments they had had previously to help manage their pain. Participants often spent some time describing the variety of treatments they had undergone over a long period of time.

Almost half the participants (46%) also commented during the first week telephone call that they tried to keep themselves active in spite of the pain. The first two chapters of the manual highlighted that people in CP often avoid a number of situations, whereas for these participants they did not believe this was applicable to themselves.

In addition, 38% of the participant's discussed the negative impact CNP had on their mood, with a further 30% reporting that they had subsequently experienced mental health difficulties. Other topics that the participants discussed included that they had been in pain for a substantial amount of time (38%), that the manual had provoked some reflections and thoughts about their current situation (30%), and that they felt the book was telling them things they were already aware of and therefore felt it offered nothing new (30%).

Table 11:

Frequency and percentage of categories discussed by participants in Week 1

Category	**Frequency**	**Percentage**
Previous failed treatments	7	54
Still active	6	46
CP impact on mood	5	38
Length of time been in CP	5	38
Mental health	4	30
Provoked thought	4	30
Already knew what book was saying	4	30

3.4.2 Week 2

One participant dropped out after Week 1 meaning that 12 participants had telephone support sessions for Chapter 3. The majority of the participants (75%) discussed the funeral exercise (Hayes et al., 2003) in the Values chapter. This exercise asked participants to imagine their own funeral with the aim to extract some of their values. The majority of these participants had found this a difficult exercise to complete, with three participants stating that completing the exercise had provoked an emotional reaction. This was discussed at length during the phone calls to ensure that participants did not feel very distressed.

Half of the participants reported that the content in Chapter 3 was more difficult than the previous two chapters and a further 25% reported that they found the self-help

manual confusing. Furthermore, 50% reported that they struggled to relate to the material for this week.

Other themes from this week included 42% of participants reported that their pain levels increased after they had done activity. This is related to the manual advocating that people with CP should remain active. Twenty-five percent stated that after reading the chapter it had prompted them to think about their pain differently.

Table 12

Frequency and percentage of categories discussed by participants in Week 2

Category	**Frequency**	**Percentage**
Funeral exercise	9	75
Content more difficult	6	50
Not able to relate to manual	6	50
Increased pain activity	5	42
Provoked emotional reaction	3	25
Confusing	3	25
Prompted thought	3	25

3.4.3 Week 3

A further two participants dropped out of the intervention after Week 2, meaning the following content analysis for Week 3 was from ten telephone contact sessions. All but one of the ten participants reported that the chapter was complex and that they had difficulties with comprehension of the material.

In addition, 40% of the participants felt that the chapter covered in Week 3 was time consuming and one week was not sufficient time to complete all of the exercises. Sixty percent reported that they believed they were already thinking in the way the manual promoted and therefore did not feel this chapter was useful for them.

Reports that participants were already doing what the book suggested, was not unique to this week and was also mentioned in other weeks.

Table 13

Frequency and percentage of categories discussed by participants in Week 3

Category	**Frequency**	**Percentage**
Complex	9	90
Already doing what book says	6	60
Not able to relate to manual	4	40
Time consuming	4	40
One week not sufficient	4	40
Need support	4	40

3.4.4 Week 4

Six participants completed Week 4 of the self-help manual and a content analysis was conducted on these telephone support sessions. The majority of these participants reported that it was difficult to complete the mindfulness exercises in the chapter due to the side-effects of their medications. The medication was reported to have made some of the participants feel “drowsy”. Participants in the SCS-ACT condition were still recovering from surgery and were on a higher dosage of pain relief medication, this impeded their concentration levels. A potential way to aid the difficulties with concentration was suggested by three participants (50%) that felt the exercises would have been easier to complete if there had been an accompanying CD with the chapter. Furthermore, two (33%) participants reported that it was difficult to put some of the exercises into practice in their daily life.

Table 14

Frequency and percentage of categories discussed by participants in Week 4

Category	**Frequency**	**Percentage**
Medication impact	5	83
CD for mindfulness	3	50
Difficult to put into practice	2	33

3.4.5 Week 5

Only three participants remained in the intervention at Week 5, therefore the content analysis on this and Week 6 was based on fewer participants than the earlier weeks. Two of the three participants reported that they were now more active than they were prior to the intervention.

Table 15

Frequency and percentage of categories discussed by participants in Week 5

Category	**Frequency**	**Percentage**
Been more active	2	67%
Confusing	2	67%

However, two participants also reported that they found some of the content in the chapter confusing. During a number of the weeks participants reported finding the content of the self-help manual complex and therefore confusing, therefore this was not unique to this chapter/week.

3.4.6 Week 6

No participants dropped out of the intervention after Week 5; therefore, there remained three participants that completed the final week of the manual. Two participants mentioned that they struggled to relate to the examples given in the manual. They felt that the examples were not age-appropriate for them as they were based on a younger person who was considering returning to education, something these participants were not able to relate to.

In addition, two (67%) participants discussed goals and plans that they had for the future. During the discussions it appeared that these plans were the result of them completing the self-help manual and this had prompted them to give consideration towards their future and what they valued in their life.

Table 16

Frequency and percentage of categories discussed by participants in Week 6

Category	**Frequency**	**Percentage**
Not able to relate to examples	2	67%
Goals for the future	2	67%

3.4.7 Summary

The content analysis explored the content of the telephone calls on a weekly basis rather than examining the data as a whole. It was apparent that there were certain aspects of the manual that the participants reported regularly throughout the intervention and this resulted in some categories being present for a number of the weeks. For instance, the category regarding the content being complex and participants reporting they struggled with comprehension was present for weeks 2, 3 and 5. Participants discussed the content being complex in other week phone calls but this was to a lesser extent. This highlights that difficulties with the complexity of the manual and participants reporting being confused with the content is applicable to a large proportion of the manual rather than just a specific chapter being troublesome. Participants also reported on a few weeks that they had difficulty relating to the material in the manual. Within the content analysis there were also categories that were specific to a given week/chapter; for example, the funeral exercise was very prominent in the telephone calls in the third week of the intervention.

3.5. Treatment Integrity

During each of the telephone support session's participants were routinely asked three questions. These questions were:

1. Did you do all, some or none of the reading exercises?
2. Was the reading level easy, medium or hard?
3. Did you find this chapter useful, yes, no or somewhat useful?

These questions were designed to provide additional details regarding the integrity of the treatment and whether there needed to be amendments to the intervention prior to a full-scale RCT.

3.5.1 Engagement

To evaluate the feasibility of the intervention it was important to ascertain the extent to which the participants completed the exercises on a weekly basis. As already discussed only three participants completed the full intervention with variations in the amount of weekly work participants completed. Figure 7 depicts the percentage of participants for each week according to whether they completed all, some or none of the weekly exercises that are outlined in the manual. This data includes all participants' weekly information up until they completed, therefore if they withdrew during the intervention, their data was included up until that point.

The majority of participants reported that they did all or some of the weekly requirements. There was an increase in the number of participants that did not do any of the exercises in Week 2. Week 2 corresponds with the Values chapter in the self-help book. However, during this week the majority of the participants still reported that they had completed all of the exercises during this week. There was a decline in the reported number of participants that had completed all the exercises in Week 3. Week 3 corresponds with the Cognitive Defusion chapter in the manual.

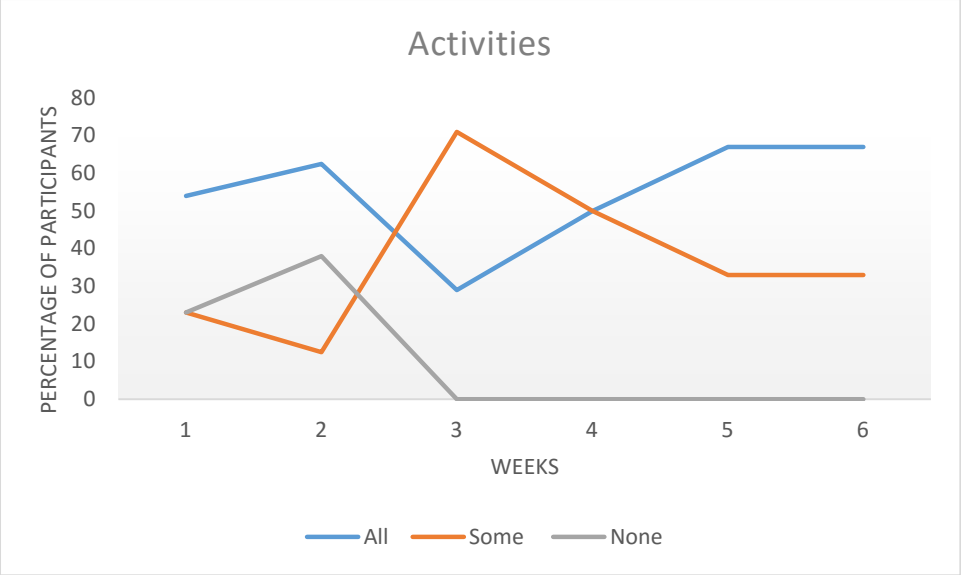

Figure 6: Participants reports of their weekly completion of reading and exercises over the intervention period

3.5.2 Perceived Reading Level

In addition to assessing engagement, participants were asked to rank the reading difficulty, as either easy, medium or hard. This information is presented in Figure 7. As the graph shows there was a lot of variation in the participant's responses to the level of difficulty throughout the six weeks. However, there was a sharp incline in difficulty for week 3 with over 70% of the participants reporting that they found the reading level hard.

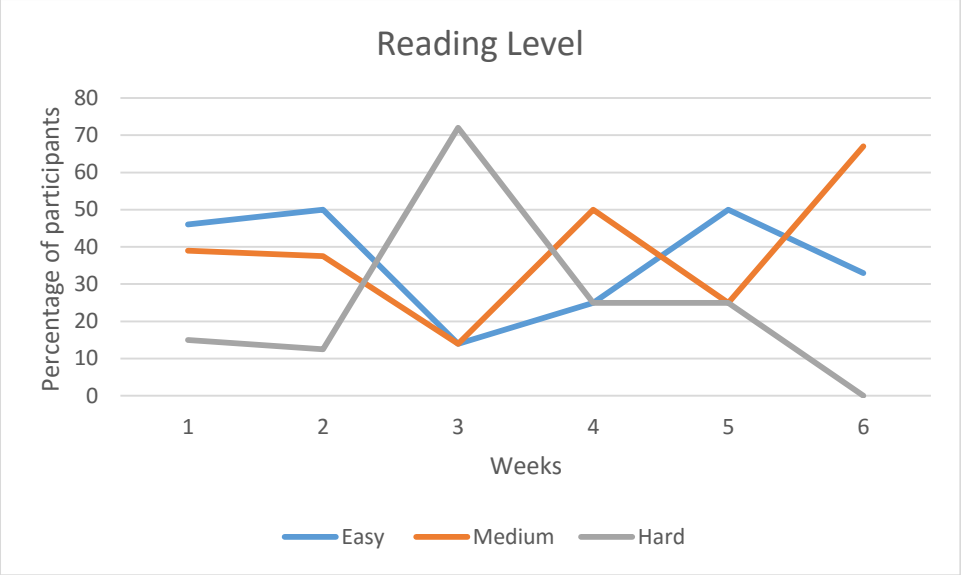

Figure 7: Participants rating for difficulty of reading level per week over the intervention period

3.5.3 Perceived usefulness

The overarching aim of this study is to assess the feasibility of a full-scale RCT with this participant group, however, the study also wanted to assess treatment signals. For a full-scale RCT it would be beneficial to find out what aspects this client group believed to be the most and least helpful and any adjustments to the manual could be made in the future. Therefore during each weekly telephone call, participants were asked to rank the level of usefulness (useful, somewhat useful, or not usual) for the weeks reading and exercises as presented in Figure 8. It can be seen in this graph that Week 2 and 6 were reported to be the most useful by the participants. Week 2 asked participants to explore their values and Week 6 discussed action and potential barriers to this action. The figure also shows that throughout all the six weeks the majority of the participants reported finding the sections useful.

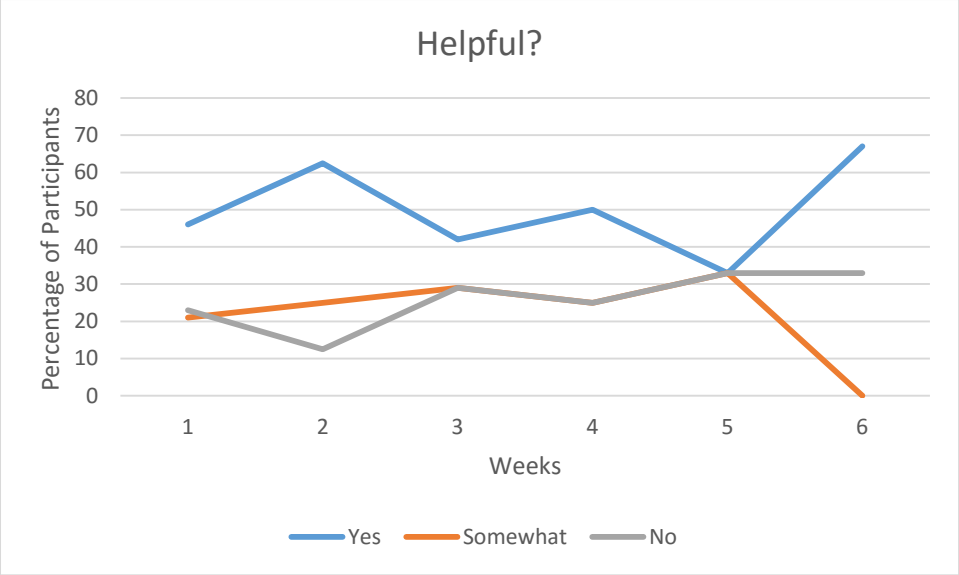

Figure 8: Participants rating of level of use of each week over the intervention period

3.5. Analysis of Pre and Post Treatment Psychometrics

The means and standard deviations for the measures over the two time points across the three groups are described in the Journal Paper.

3.6.1. Analysis of Variance (ANOVA)

The data was analysed using the Statistical Package for the Social Sciences (SPSS) version 18.0. The data was checked to ensure the ANOVA assumptions of normality, homogeneity of variance and sphericity were not violated. The reliability of an ANOVA for the data is questionable due to the small sample size, however, to avoid any further Type 1 error, the alpha level was adjusted to correct for multiple comparisons using the Bonferroni adjustment procedure. A Bonferroni correction suggested a p-value of 0.05/7= 0.007. As the sample size was small, statistical effect sizes were included to give the magnitude of change (from pre to post intervention) on each measure (Dunst, Hamby, & Trivette, 2004). Effect size provides a way to analyse the important change irrespective of sample size (Lakens, 2013). Statistical effect sizes were calculated as part of the ANOVA (partial η2) and were considered small if between .10 to .29; medium if between .30 and .49; and large if greater than

.50 (Cohen, 1988). The results of the ANOVAs and effect sizes are presented in Table 17.

In the table, bolded values represent large effect sizes and italicised values represent medium effect size using the criteria suggested by Cohen (1988). The table highlights that there were large effect sizes on all of the measures apart from anxiety for time. In other words timing between pre and post-intervention appeared to have an impact on participants scoring across the majority of the domains. With regards to the change between the groups across time, only pain severity was shown to have a large effect size.

Table 17

Results of the mixed ANOVA for each of the outcome measures

Measure	*Df*	Time			Time*Group		
		F	*p*	pη2	*F*	*P*	Pn2
PSEQ	1,15	15.47	.00	**.51**	.94	.41	.11
HADS depression	1,15	15.56	.00	**.52**	3.81	.05	*.37*
HADS anxiety	1,15	12.87	.00	*.46*	.19	.91	.01
BPI severity	1,15	47.43	.00	**.76**	8.38	.00	**.53**
BPI interference	1,15	31.00	.00	**.67**	3.59	.05	*.32*
EQ-5D index	1,15	41.13	.00	**.73**	2.23	.15	.23
EQ-5D VAS	1,15	35.09	.00	**.70**	2.19	.15	.23

Abbreviations: *df* = degrees of freedom, *F*= ANOVA statistic; *p* = significance (p< 0.007) i.e. the scores underlined are significant , *P η2*= partial eta squared **(bold** = large, *italics* = medium).

3.6.2. Power Analysis

It is suggested that for a full-scale RCT that the primary outcome measure should be the PSEQ. In this current feasibility study, seven participants in the ACT-SCS group and six participants in the SCS-TAU provided complete data at the pre and post intervention (in future studies it is unlikely that an ACT-only group would be included, therefore not included in the power calculation). The study found a between group effect size of d= 0.41. A power analysis for future studies was conducted in order to ascertain the feasibility of future studies getting enough participants to reach power. The traditional level of significance for social science research was adopted (α = 0.05; Field, 2013). This determined that a minimum sample size of 43 participants for each group would be sufficiently powered to detect relevant differences.

3.7. Reliable and Clinical Significant Change

The reliable change index was used to assess effectiveness of the intervention. As detailed previously, two statistical criteria have been specified that quantify whether the magnitude of change shown by each individual is large enough to be deemed both clinically meaningful and statistically reliable (Jacobson, & Truax, 1991).

3.7.1. Self-Efficacy

The means of the three groups' across pre to post treatment is visually represented in Figure 9. In the SCS-ACT group eight participants completed the baseline and post intervention PSEQ. The pre-treatment mean for these participants was 17.4 (SD=9.8); the post treatment was 33.3 (SD=11.2). In terms of meeting the outcome criteria within the SCS-ACT group one participant (12.5%) showed reliable deterioration; two participants (25%) demonstrated no reliable change (i.e. change could not be distinguished from measurement error), four participants (50%) achieved reliable improvement and three (37.5%) of these participants also made a clinically significant improvement (i.e. improvement that met both RCI and CSC criteria).

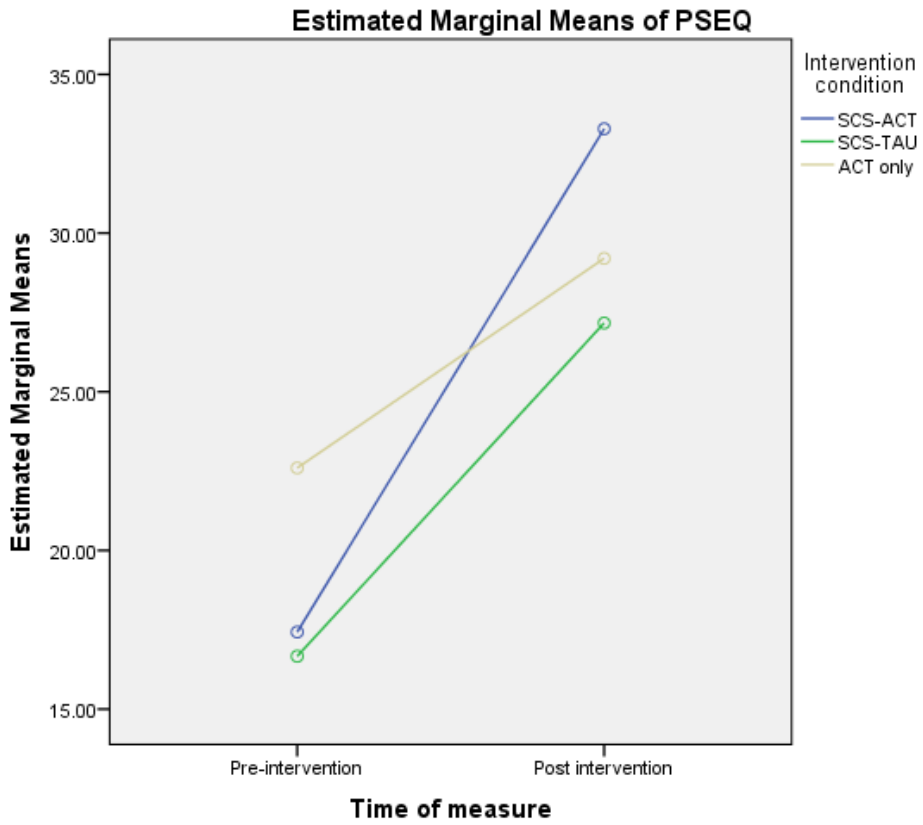

Figure 9: Means of the three groups from pre-to-post intervention on the PSEQ

In comparison, the pre-treatment mean for the six participants in the study that had SCS but had not received the ACT self-help (SCS-TAU group) was 16.7 (SD=5.7), the post treatment was 26.5 (SD=14.9). Within the SCS-TAU group no participants showed reliable deterioration, four participants (67%) demonstrated no reliable change, two participants (33%) achieved reliable and clinically significant improvement.

The final five participants that had not had the surgery but had received the ACT self-help intervention (ACT-only) had a pre-treatment mean of 22.6 (SD=14.9) and a post treatment mean of 29.2 (SD=12.4). In terms of meeting the outcome criteria no participants in the ACT only group showed reliable deterioration on self-efficacy, three participants (60%) demonstrated no reliable change, two (40%) achieved reliable and clinically significant improvement.

3.7.2. Depression

The means of the three groups' across pre to post treatment on the HADS depression scale is visually represented in Figure 10. The SCS-ACT baseline mean on the HADS depression scale was 11.9 (SD=3.4); the post-treatment was 6.6 (SD=3.9).

On HADS Depression scale it is worth noting that one (14%) of the SCS-ACT participants had scores below the cut-off score that would be indicative of depression when assessed at pre-intervention. Therefore, this would have impacted the extent to which participants could achieve CSC. Despite these low scores on the pre-intervention measure three (43%) of the seven SCS-ACT participants had a reliable improvement on HADS depression from pre-to-post intervention. One of these three participants also showed clinically significant improvement at post-intervention. The remaining four (57%) participants in the SCS-ACT had no reliable change from pre-to post-assessment.

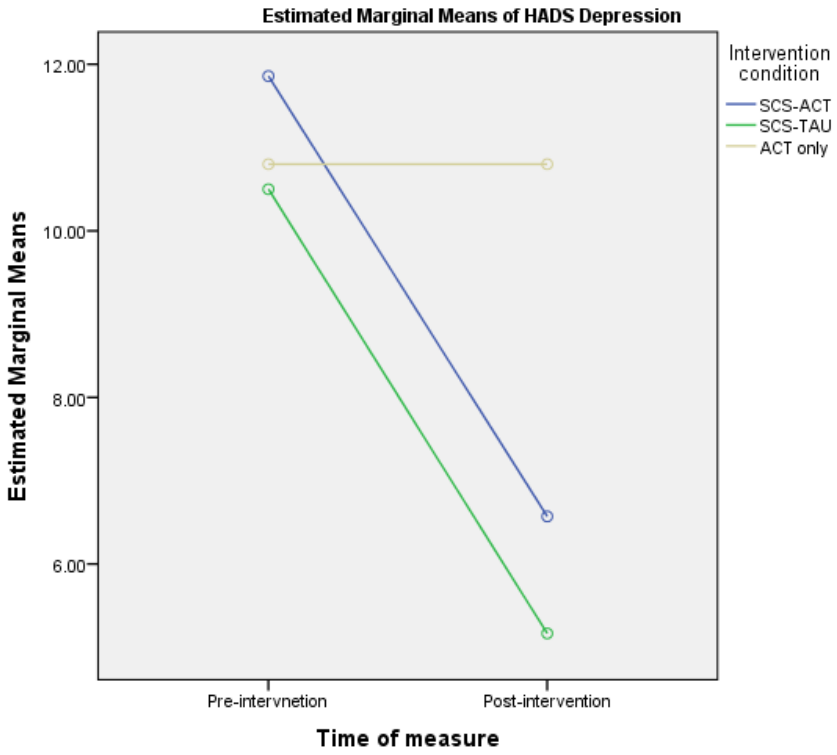

Figure 10: Means of the three groups from pre-to-post intervention on the HADS Depression scale

The mean score on the Depression scale of the HADS for the SCS-TAU group was 10.5 (SD=4.6) at baseline and 5.2 (SD=1.9) at post-intervention. Three (50%) of the six participants had baseline scores below the cut-off for depression. However, three (50%) of the SCS-TAU participants still achieved reliable improvement on the measure of depression and for 33% (n=2) this was also a clinically significant improvement. The other three (50%) SCS-TAU participants had no reliable change.

The participants in the ACT-only condition had a mean baseline score of 11.1 (SD=4.4) and post-treatment 10.8 (SD=5.2) on the HADS depression scale. One (20%) of the ACT-only participant's baseline score was below the clinical cut-off for depression. One participant (20%) achieved reliable improvement however, this was not a CSC. Four (80%) ACT-only participants had no reliable change on this measure.

3.7.3. Anxiety

Anxiety was assessed in the study using the HADS. The means of the three arms on the HADS Anxiety subscale across pre to post treatment is visually represented in Figure 11. The HADS anxiety pre-treatment mean for the SCS-ACT participants was 9.1 (SD=3.8); the post-treatment was 6.2 (SD=2.8). One SCS-ACT participant had a baseline HADS Anxiety score that was below that which would be indicative of anxiety as being a clinic difficulty. In terms of meeting the different outcome criteria six participants (86%) demonstrated no reliable change and one participant (14%) achieved clinically significant improvement on anxiety.

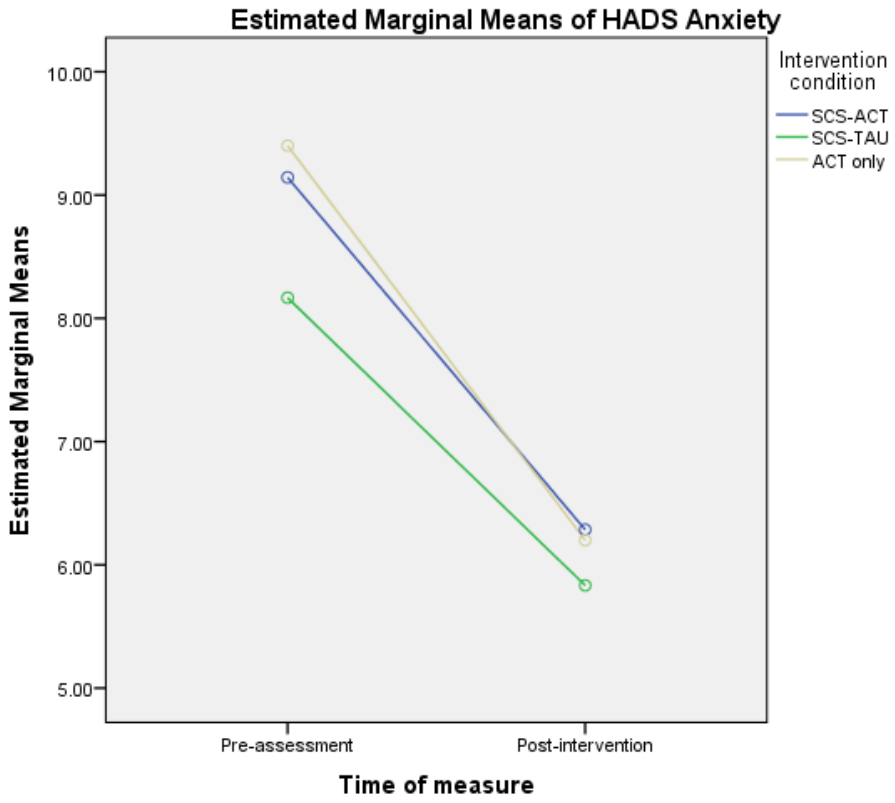

Figure 11: Means of the three groups from pre-to-post intervention on the HADS Anxiety scale

Comparatively, the pre-treatment mean on the HADS anxiety scale for the SCS-TAU group was 8.2 (SD=3.5) and the post-treatment mean was 5.8 (SD=3.3). Half (50%) of the SCS-TAU participants had scores below the clinical cut-off for anxiety at pre-intervention. Only one participant achieved reliable and clinically significant improvement on anxiety. The remaining five SCS-TAU participants demonstrated no reliable change.

With regards to the ACT-only group the mean pre-treatment score on the HADS Anxiety scale was 9.4 (SD=4.9); the post-treatment score was 6.2 (SD=2.8). Again, one participant in this group had a score below the clinic cut-off score for anxiety at pre-treatment. In addition one ACT-only (20%) demonstrated reliable and clinically significant improvement in anxiety. Four ACT-only participants (80%) had no reliable change between pre-to-post intervention on anxiety.

3.7.4. Pain Severity

Pain severity was assessed using the BPI. The means of the three groups' across pre to post treatment on pain severity is visually represented in Figure 12. The pre-treatment mean for the SCS-ACT participants was 7.8 (SD=1.1); the post treatment was 5 (SD=1.4). No participants in the SCS-ACT group achieved clinically significant change, although 71% had reported reliable improvement scores in their pain severity rating and 29% had no reliable change.

The mean score those in the SCS-TAU group reported their pain to be was 7 (SD=0.8) at baseline and 5.7 (SD=0.9) at post-treatment. 50% (n=3) of the participants in this condition achieved reliable improvement from baseline to post-intervention, however, none of these participants demonstrated CSC.

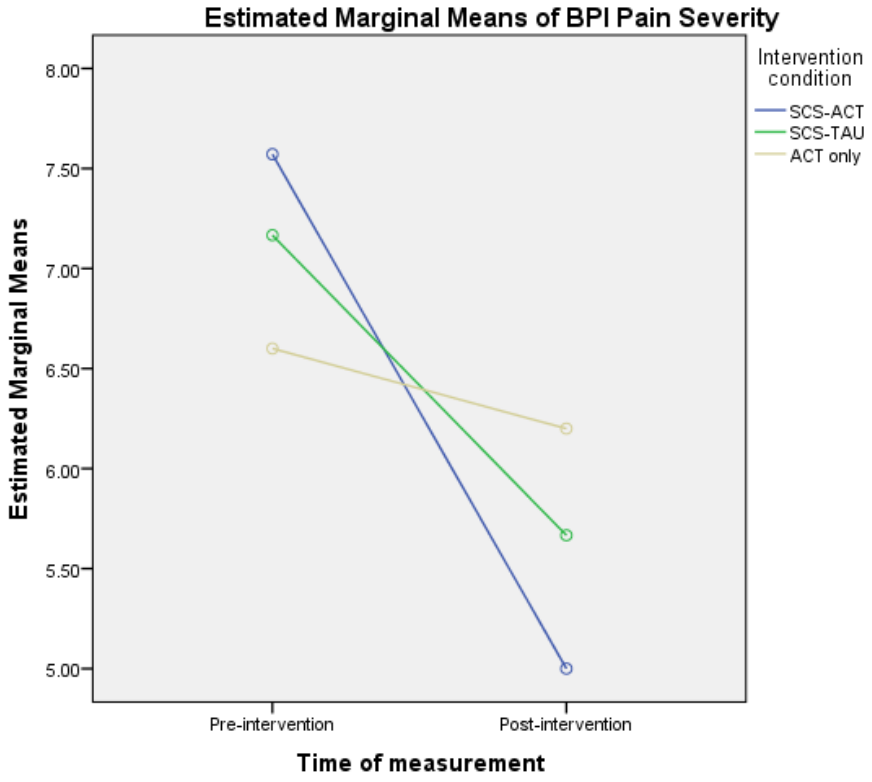

Figure 12: Means of the three groups from pre-to-post intervention on the BPI Pain Severity scale

With regards to those that had ACT only, the mean baseline score was 6.6 (SD=2.7) and the post-treatment score was 6.2 (SD=2.7). All of the ACT-only participants had no reliable change in pain severity between pre and post-intervention.

3.7.5. Pain Interference

The BPI also assessed the extent to which pain interfered in the participant's lives. The higher the score on this subscale, indicates the more pain interferes with daily functioning, therefore the aim of an intervention would be to reduce the reported interference. The means of the three groups' across pre to post treatment on pain interference is visually represented in Figure 13. The pre-treatment mean for SCS-ACT participants was 58.3 (SD= 10.3); the post treatment was 34.9 (SD= 11.2). All the participants in the SCS-TAU demonstrated a reliable improvement in their pain interference and one of these participants (14%) also achieved clinically significant change.

The pre-treatment mean for the SCS-TAU participant group was 50.8 (SD=16.4); the post-treatment mean was 34.7 (SD=15.2). In terms of meeting the pain interference two participants in the SCS-TAU group demonstrated no reliable change (i.e. change could not be distinguished from measurement error), three participants (50%) achieved reliable improvement and one (17%) made a clinically significant improvement (i.e. improvement that met both RCI and CSC criteria).

The ACT-only group had a post-treatment mean of 46.4 (SD=15.5) and a post-treatment mean of 45.3 (SD=11.7). With regards to meeting pain interference one participant (20%) in the ACT only group achieved reliable improvement but this was not a clinically significant change, the remaining four participants (80%) had no reliable change on pain interference.

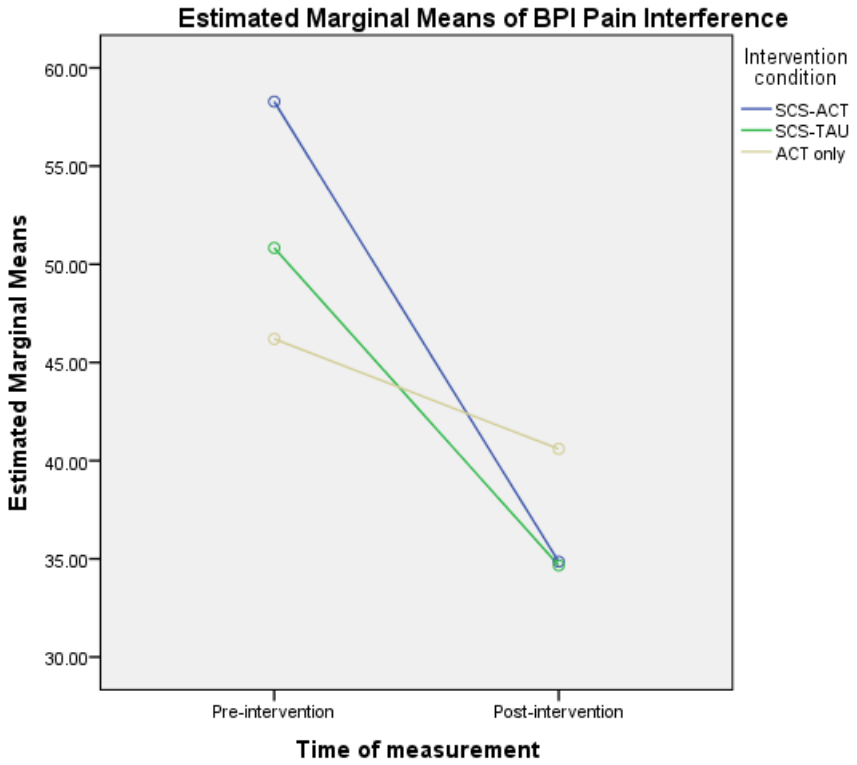

Figure 13: Means of the three groups from pre-to-post intervention on the BPI Pain Interference scale

3.7.6. Health related quality of life

HRQoL was assessed using the index values on the EQ-5D. The means of the three groups across pre to post treatment is visually represented in Figure 14. In the SCS-ACT group eight participants completed the pre and post intervention EQ-5D index values. The pre-treatment mean for SCS-ACT participants was 0.2 (SD=0.2); the post treatment was 0.6 (SD=0.1). In terms of meeting the outcome criteria within the SCS-ACT group one participant (12.5%) achieved reliable improvement and the remaining six participants had no reliable change from pre to post-intervention (i.e. change could not be distinguished from measurement error).

The pre-treatment mean for the SCS-TAU and ACT-only participant groups were both 0.3 (SD=0.1); the post-treatment mean was 0.5 (SD=0.1) and 0.5 (SD-0.1) respectively. All the participants in both SCS-TAU and ACT-only had no reliable change on this measure from pre-to-post intervention.

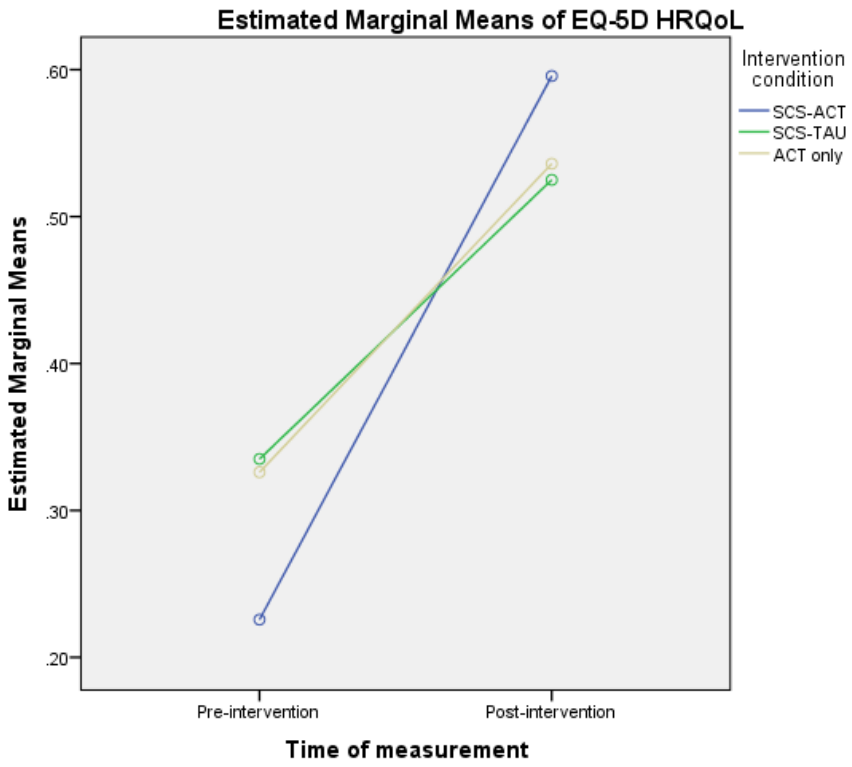

Figure 14: Means of the three groups from pre-to-post intervention on EQ-5D Values Index (HRQoL)

3.7.7. Self-rated health

Participants self-rated their health on the EQ-5D visual analogue scale (VAS). The higher the score denotes a higher self-reported overall health. The means of the three groups' across pre to post treatment on the EQ-5D VAS is visually represented in Figure 15. The pre-treatment mean for SCS-ACT participants on the VAS was 37.1 (SD=16.5); the post treatment was 65.3 (SD=19.8). Three (43%) of the seven SCS-ACT participants demonstrated reliable improvement and a clinically significant change from pre-treatment to post-treatment on the EQ-5D VAS. The remaining four (57%) participants in the SCS-ACT had no reliable change from pre to post-treatment. No participants had reliable deterioration over the time period.

The mean score on the VAS of the EQ-5D for the SCS-TAU group was 38.3 (SD=16) at pre-intervention and 62.5 (SD=12.1) at post-intervention. One participant (17%) of the SCS-TAU participants achieved reliable improvement and clinically

significant improvement on the VAS. The other five (83%) SCS-TAU participants had no reliable change.

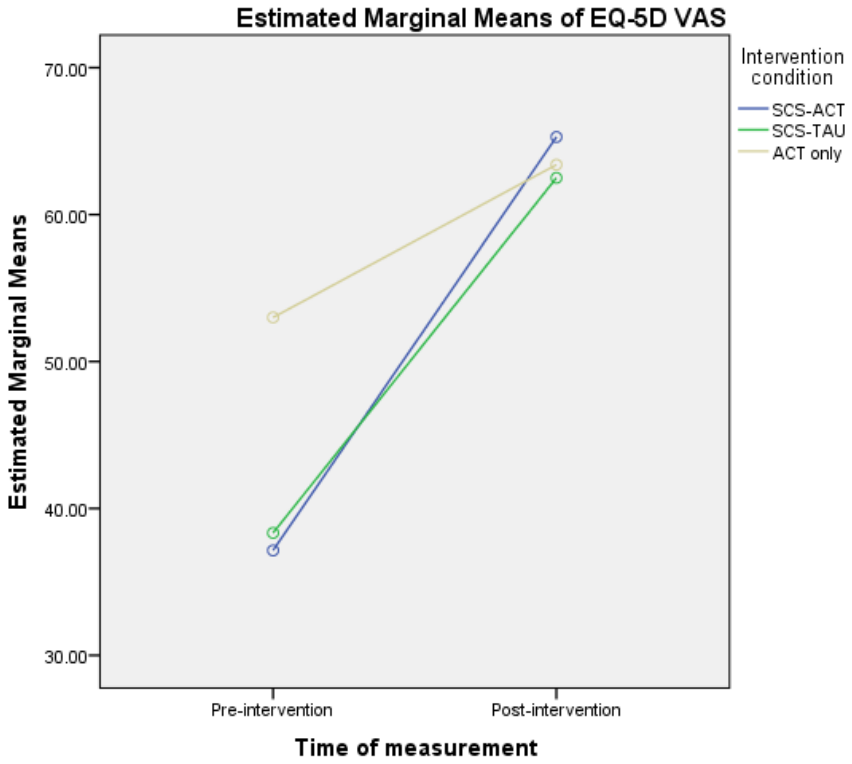

Figure 15: Means of the three groups from pre-to-post intervention on the EQ-5D VAS

The participants in the ACT only condition had a mean baseline score of 53 (SD=27.2) and post-treatment 63.4 (SD=23.5) on the EQ-5D VAS. All of the ACT-only participants had no reliable change on this measure between pre and post intervention.

3.7.8. Summary

Table 18 shows the results for each participant on all of the outcome domains and if they met the criteria for the reliable and clinically significant change from pre-treatment to post-treatment. As the table highlights all of the participants in the SCS-ACT group achieved reliable improvement on at least two of the outcome measures. One SCS-TAU participant had no reliable change on any of the measures, although the remaining SCS-TAU participants achieve reliable improvement on at least two outcome domains. There appears to be fewer reliable improvements in the ACT-

Table 18
Summary of RCI and CSC results for each individual participant

Participant	Treatment arm	PSEQ	HADS Depression	HADS Anxiety	BPI Pain Severity	BPI Pain Interference	EQ-5D Values Index	EQ-5D VAS
Laura					✓	✓		✓✓
Emma		✓	✓✓		✓	✓✓		✓✓
Stuart		✓✓	✓	✓✓		✓		✓✓
Amy	SCS-ACT	×			✓	✓	✓	
Jack		✓✓	✓		✓	✓		
Anthony					✓	✓		
Shaun		✓✓				✓		
Jessica					✓	✓		
Charlie		✓✓	✓✓			✓✓		
Dave	SCS-TAU							
Louie			✓✓	✓✓				
Heather		✓✓	✓		✓	✓		✓✓
Ann					✓			
Phyllis								
Joshua		✓✓	✓	✓✓				
Suzie	ACT-only	✓✓						
Brian						✓		
Michael								

Abbreviations: ✓ indicates reliable improvement, ✓✓ indicates CSC, × indicates reliable deterioration

only group, in which three out of the five participants had reliable improvement on at least one outcome measure.

3.8. Thematic Analysis of Interviews

The following section is an extended version of the themes previously identified in the journal paper. It aims to provide a more comprehensive understanding of the participant's experiences of completing the self-help manual, providing more details of the commonalities and divergences between both groups of participants.

As stated in the journal paper there are four themes; battle with pain, benefits of the manual, obstacles and suitability. In addition to these themes there are ten subthemes. Pictorial representation of these themes can be found in Appendix N.

3.8.1 Theme 1: Battle with Pain

The thematic analysis was completed at a semantic level, however, when completing the analysis it became apparent that there was an overarching theme that appeared to impact on the other themes (e.g. benefits of the manual and obstacles themes). This theme required slightly more interpretation than the other themes presented, however, it has been included due to it offering an insight into why some participants appeared to have benefitted from the self-help intervention and others did not. All participants discussed a long journey of trying to manage their pain and for some they described this as being "battle". Therefore, the theme of "Battle with Pain" encapsulates the fight that the participants report they continue to have with their pain and their ability or wish to accept or fight CNP. The subthemes within this will now be presented.

Journey of Acceptance

A key tenet of the self-help manual was that pain is not always controllable and that a fight against the pain can cause more suffering. Consequently, the intervention

promoted an acceptance stance towards pain. This acceptance that their pain was likely to be present in the future was articulated by a number of the participants. It was noted by some of the participants that they had fought against pain for many years and were coming to the realisation that this battle had been unsuccessful in controlling their symptomology:

"I've been having a fight every day at every moment to try and beat it to win and I actually can't win. All I am doing is giving more time away to an exercise that's pretty futile….I've just found it hard to accept." Joshua, ACT-only

In this quotation it appeared that acceptance was an ongoing process for Joshua, this was vocalised by other participants as well. However, for some other participants this journey had appeared to have started prior to completing the self-help manual:

"Realisation that I have already started to accept the pain but refuse to be dominated by it except in bursts of intense discomfort. I don't give up and sit around all day just because I am in pain" – Michael, ACT-only

As indicated in this quote although Michael has started to accept that his pain is present and rather than try to control this he will remain as active as possible. There were a number of participants that when discussing their various interventions to control the pain had come to the conclusion that CNP may be a feature of their life. However, this was often described as a long journey that was marred with negative emotions prior to feeling able to accept that this was something they could not control. It is worth noting that both the quotes given in this sub-theme were from ACT-only participants.

Continued Fight.

Almost antithetical to the Journey of Acceptance theme emerged the Continued Fight subtheme. Within this sub-theme participants reported that they would continue to pursuit ways to manage their pain. Participants acknowledged this battle with pain existed but they were not willing or wanting to accept that the pain would continue to exist regardless of the fight. In contrast to the Journey of Acceptance subtheme that largely encompassed the ACT-only participants this theme mainly consisted of the participants that had SCS surgery (SCS-ACT).

"So I think for me, the issue of, I don't know if I'm going to fully accept that I should be in pain or that the pain is going to be there all the time" Shaun, SCS-ACT

Typically the participants that continued to fight against the pain appeared to have a more medicalised view of their pain:

"Now as we are talking about this I will be pursuing the orthodox medical way because the pain and the problem that I have are developing and I need to see where I am going on from here" Anthony, SCS-ACT

In addition, there were some participants that expressed their disappointment and upset that they were still experiencing CNP after having SCS surgery. As part of the author's research into SCS I attended a number of the SCS consultations and it was noted that the neurosurgeons at the clinic were explicit in informing the patients that the surgery would not "cure" their pain and it would be likely that they would always experience some degree of pain. However, despite this message from the Neuromodulation clinic some of the SCS-ACT participants expressed anticipation that they would be pain free and were now continuing in their quest to find a cure, which was causing them distress:

"After the surgery I was expecting that I wouldn't still be in pain. You know it was a big procedure and I thought it would sort the pain out. Now it feels like I need to start all over again. It's hard, really hard." Laura, SCS-ACT

3.8.2 Theme 2: Benefits of the manual

The theme "Benefits of the Manual" encapsulated the reports from participants of positive changes they attributed to the intervention. For some of the participants they reported that they had recognised changes in the way they viewed their future and subsequent behaviour. However, the majority of the participants did not complete the manual and a number of these reported that the intervention in its entirety was not effective but they did discuss certain aspects that they found beneficial. This theme was included as it was felt that as a feasibility study it was pertinent to distinguish the aspects of the intervention the participants reported was beneficial so that this could be expanded on for any potential future study.

Hope

This sub-theme encapsulates the newly instilled hope that participants expressed they had taken from the intervention. Some participants discussed how after many failed medical interventions they had been left feeling hopeless and at times struggled to envisage their future. However, for some participants they reported that reading the manual had instilled some hope that they still had a future regardless of having CNP.

"Well for me, those past seven years are seven years of life you could, well you can't have it back, but you then don't waste seven more years. So you get to have some, get on with something that is quality of life for yourself. And you manage the pain in different ways, so the pain isn't the dominant factor." Joshua, ACT-only

However, it is important to note that the reported feeling of hope was not a prominent theme within the data and appeared to be expressed mainly by those in the ACT-only group. In fact, hope achieved by completing the manual was only expressed by a minority of the participants. Nevertheless a few other participants expressed that the Values exercise had given them more hope about at least one aspect of their life.

"I mean it was helpful because I was working towards going back to work after surgery. So some of the setting yourself goals and things to work towards, that was quite helpful….It broke it down and made me feel more positive in going back to work." Emma, SCS-ACT

Prompting Activity

This sub-theme reflects the behavioural changes that participants resulting from completing exercises from the self-help manual. A premise of the ACT intervention is that if you stop doing the things you enjoy then you will miss out on these things and will still be in pain. Therefore regardless of whether you engage in actives you are in pain. A number of participants were able to relate to how being in pain had impacted on their lives and meant they had stopped doing things they had previously enjoyed. On the basis of the manual some of these participants reported that they had started to introduce activities into their life again. These activities tended to be related to their values. For example, Brian discussed joining a cricket club, in his values he identified increasing his social life as an area he wanted to improve, this was a similar value for Joshua but for him his action was to join a pain management group in which he hoped to socialise with others that had CP. Suzie reported wanted to have something in her life that helped her with relaxation, in the interview she discussed how she had joined a local yoga group. Jack discussed that a value pertinent to himself was being a good parent but believed his pain had impacted on his relationships with his children. He reported during the interview that the biggest change for him was that he was now taking his children swimming:

"I went swimming with the kids. I use to swim a lot but it got to the point where it hurt too much and then I just got fat and lazy you know. So I did the 'well I would go but' and then I thought 'no, no let's do it'. So I went and did it and yes it was good. I am going to keep going with the kids." Jack, SCS-ACT

For other participants they spoke about that they were already active prior to completing the self-help manual and therefore did not feel the intervention added anything new for them. This is discussed further in the Relatability subtheme.

3.8.3 Theme 3: Obstacles

This theme encompasses the challenges that some of the participants experienced when completing the manual. As already discussed there was a large drop-out rate within the study therefore this theme may aid understanding as to why the majority of the participants did not complete the intervention. All of participants discussed at least one aspect of the intervention that they felt impeded on them completing the manual. Consequently, this theme was very prevalent in the interviews. In addition it was felt to be pertinent as a feasibility trial to identify any difficulties in completing the intervention. In the Obstacles to Completing the Manual there were three subthemes: Language, Length of the Manual and Relatability (relatability was also a subtheme for the Suitability theme).

Language

The majority of the participants commented on how the manual used "complex" and "technical" language. Although, this was not a problem for all the participants and they were able to understand the content of the material there was still some that noticed that this could be a barrier for others reading the manual:

"It's pretty wordy and I was alright because I've got A Levels and stuff…how you'd tailor it to different levels of understanding because it can turn you off a bit, just to look at all those words" – Emma, SCS-ACT.

Whereas for others the complexity and technical language used made the manual inaccessible for them and they struggled with comprehension of the material:

"Some of the words it uses I've never heard of before. It was really technical and parts of it went straight over my head. If it wasn't so complicated then I might have been alright." *Shaun, SCS-ACT*

There was also a secondary impact of the complex language in that a few of the participants were critical of themselves for not being able to understand the book:

"I think I must be really thick" – Laura, SCS-ACT

In this quote Laura reported that the manual had caused her to question her intelligence. A few of the participants were self-critical about their ability to understand the language used within the manual, often attributing the complexity to their lack of intellectual ability. Therefore to some extent it appeared the intervention had a negative impact on how the participants viewed themselves and their abilities.

Length of Manual

Another obstacle to completing the intervention that was discussed by some participants was the length of the manual. The manual has 15 chapters and 243 pages and for some they found that this was too long. A few participants commented that they found the chapters repetitive at times which added to the length of the manual:

"I found it slightly repetitive at times and it really drilled into it with the exercises, a bit repetitive" – Emma, SCS-ACT

In addition, it was also noted by some of the participants that due to the length of the manual it was very time consuming to complete the chapters on a weekly basis. Each section of the intervention required the participants to complete exercises during the week, these included keeping a daily diary of thoughts regarding the pain. This was also noted to be time consuming. A couple of participants that had the SCS surgery and where returning to work after being on sick leave found it difficult to allocate time to the intervention:

"It was ok when I was on the sick, I had more time but it is a lot to read when at work. Plus I am doing a university course as well so I just didn't have the time the book needs to do it justice" Jack, SCS-ACT

Relatability to the Content

This subtheme relates to the participants reporting that they found it difficult to associate with aspects of the self-help manual. Some participants did not feel the exemplars in the text represented their pain journey and how they feel about their experiences.

"She wouldn't interact with her children when she's got pain, you know. And I think that is silly that is you know what I mean? I would never do that. I couldn't relate to it at all" Amy, SCS-ACT.

In this quotation, Amy is discussing how in the text it is often discussed how the person with CP disengages with many facets of their life. Whereas, Amy did not feel this was representative of herself and she believed that despite living with CP she maintained positive relationships and had a fulfilling life. The manual presumes that due to a person having CP then their pain is all consuming and has a large impact on their life. However, this may have been the case for some participants; others found it difficult to relate to and was somewhat alienating.

Another aspect of the manual that a number of the participants reported made it difficult to relate to the material was the use of American language and exemplar's. A few of the participants reported finding that the Americanism of the manual "grated" on them and thus they found it harder to relate to the examples.

"I found it a bit American, if I am really honest with you, like group hugs and things like that, which is another thing I found challenging". Emma, SCS-ACT

3.8.4 Suitability

The theme Suitability captures participants perspectives regarding the appropriateness of a self-help intervention for themselves and other patients that have CNP and been assessed for SCS surgery.

Timing after surgery

This sub-theme is specific only to those that had SCS surgery (SCS-ACT). These participants started the self-help manual a week after their surgery and many of them commented that they felt that this was too soon. Participants reported that after the surgery they struggled more with pain and were lethargic due to medication and not being able to get sleep. They argued that completing the manual at this time was complicated by their reduced concentration.

*"I was struggling a little bit as well because I mean you're recovering from surgery, it's a time when you are physically quite weak and you know you are mentally quite tired" – Stuart, SCS-AC*T

Too late

Both the SCS-ACT and ACT-only participants commented about the long time they had been experiencing pain. According to self-report the mean amount of time the participants had been in CNP was twelve years. During this time many of them

reported that they had developed a number of strategies to help with their chronic pain so did not feel the book was of benefit. However, a number of the participants also pointed out that they believed a self-help intervention may have been more beneficial for themselves if they had received it earlier in their chronic pain journey.

"I mean like I said to you, I was doing them, I thought, well I do that anyway. If it starts hurting I get up and do something else or take my mind off it and do something else….I think if they've got the pain all the time, like I have, I think it's, well I think it depends what kind of pain you've got. Like I've had mine basically, most of my life, you know, you pick techniques and things up they teach you. But I suppose if anybody's had an accident, maybe, probably it would be helpful" Amy, SCS-ACT

In this passage, Amy reported that due to being in pain most of her life she had learnt various techniques to manage the symptomology as she believed she had to learn to have to live with her pain. She does make an interesting point that if she had not experienced pain for as long as she has done then maybe the manual would give her a different and useful perspective regarding CP. Amy was always very positive when discussing her pain and reported living a fulfilling life. However, not all the participants had the same view and approach than Amy, for some the longer they had been in pain, the more hopeless they felt about anything being effective:

"I feel like I've tried everything, but nothing seems to work. I kind of feel if this surgery doesn't work then what will? It is too late in the game to change my thinking about pain. I don't really see what can change now." Shaun, SCS-ACT.

In this quote, and throughout the interviews, Shaun discussed his pain within a medical context, although he oscillated between believing that his pain could be "cured" to being hopeless regarding his future. Shaun appeared very fixed in his views regarding pain and his ability to engage with the self-help manual was further impeded by the complexity of the language.

Format of the intervention

The majority of the participants reported that they would have preferred to have at least part of the intervention in a face to face format rather than via a self-help manual and telephone calls. This contact was suggested as either being seeing an individual therapist or within a group format with others that have chronic pain:

"It's quite a long book and takes you on quite a long way. And there needs to be some, for me, I felt there needed to be some personal contact throughout….. I mean I think it would be great if it could be something whereby two times in the book the actual people who are involved get together and have a meeting. Not just the, if you like, the practitioner and the patient, but all the patients involved". – Brian, ACT-only

Furthermore of the participants discussed the different number of interventions they had experienced and that for a few this has led to depression or some traumatic experiences. It was felt by a number of the participants that a self-help manual alone was not sufficient to be able to discuss not only the CNP but the secondary difficulties they have experienced:

"*I am not sure just a book on its own, you know would allow you to be in a good place to deal with some exercises. You might need a bit more, somebody to talk to"- Emma, SCS-ACT.*

In the interviews Emma discussed the number of losses and grief she had experienced throughout the course of her CNP, which she described this as being "traumatic". Emma felt that a self-help manual was not sufficient on its own to be able to address the secondary losses experienced by CNP sufferers.

4. EXTENDED DISCUSSION

To the author's knowledge, this study is the first investigation into the efficacy of ACT with patients that after having CNP for a number of years have undergone the expensive and evasive surgical procedure of SCS. As already discussed the majority of literature in ACT and pain uses non-specific CP samples, with little description given to medical conditions or the longevity of the symptomology. When the CP is neuropathic in its origin then it is typically more problematic, both for the sufferer and for clinicians trying to treat the pain (Finnerup et al., 2005). Patients undergoing SCS surgery have CNP that is usually due to CRPS and FBSS (Turner et al., 2004). As this study was specific in its sample recruitment and was for patients at the more extreme end of the CP continuum, a feasibility study was conducted prior to a full-scale RCT. There were four aims to this study: assessing the feasibility of conducting a full-scale RCT; to provide guidance on the sample size needed for a full-scale RCT to reach power; to uncover any potential ways the self-help manual could be improved for this population; and to assess effectiveness of ACT with the SCS population. These aims will be discussed in relation to CP and ACT literature alongside the clinical implications, study limitations and suggestions for further research.

4.1 Recruitment and Retention

The study identified difficulties in recruitment at the Neuromodulation clinic, with recruitment rate lower than had initially been predicted. Thirty patients had SCS surgery in the Neuromodulation clinic during the 12 month recruitment period, twelve of which were already assigned to another trial, leaving a potential recruitment pool of 18. Fourteen participants that were due to have SCS surgery consented to the study. As this was a feasibility study power was not required however, it provided important information regarding the feasibility of gaining power in the full-scale RCT. According to a power analysis, calculated from the results of this study 43 participants in each of the two groups (SCS-ACT and SCS-TAU) would need to be recruited. With a recruitment rate of 14 participants in a year, it would take a number of years to obtain enough participants to reach power on this single site.

In addition, a large number (77%) of the participants that received the ACT intervention did not complete the self-help manual. The majority of the participants (95%), did however, complete the post intervention measures and interviews, allowing an insight into their experiences of the ACT intervention. This is elevated drop-out prevalence than similar studies that have used the same self-help manual (Johnston et al., 2010; Thorsell et al., 2011). However, these studies used non-specific CP participants, it is established in the literature that CNP is more complex and therefore it is not surprising the current study has a higher drop-out rate. Furthermore, Thorsell et al. (2011) participants also had an initial 90 minute face-to-face session and a further concluding session following completion of the manual. It is likely that these two face-to-face sessions may have increased motivation to complete the intervention.

Other bibliotherapy studies have reported attrition rates as high as 70% with guided self-help interventions (Banasiak et al., 2007). A systematic literature review assessing attrition rates in bibliotherapy reported variable empirical results in the literature (Van Boejjen, Van Balkom, Van Oppen, Blakenstein, Cherpanath, & Van Dyck, 2005). In addition, attrition is not always outlined in other studies and where it is the definition of "drop-out" is variable (Cuijpers, Donker, van Straten, & Andersson, 2010). Therefore it is difficult to make comparisons in the literature regarding the attrition rate for this current study due to the lack of uniformity in the literature.

The most reported reason given for participants not adhering and completing the intervention was that they did not have the time needed to complete the weekly sections of the manual. The length of the manual was identified as a subtheme within the obstacles to completing the manual theme was also identified as a theme. In addition, two participants also reported they no longer wanted to continue with the manual due to struggling with comprehension (language was another subtheme identified in the obstacles theme) and a further two stated they did not find the manual beneficial and hence decided to discontinue with the intervention. Quigley (2011) noted in her qualitative exploration of barriers in bibliotherapy that there are

usually a number of reason for participants not completing self-help interventions. A tentative model was suggested to understand why participants disengaged, where a perceived lack of benefit was to consider it in terms of a “threshold” and/ or continuum of perceived limitations. Quigley (2011) suggested that as the number of limitations increases, confidence in the intervention as “solution to the problem” decreases and for those that disengage the limitations are seen as too great, for it to be worth their while continuing. Consequently this leads to participants dropping out if these perceived limitations are not addressed before reaching the threshold or point on a continuum. Therefore, it could be argued that the time the manual took to complete or its complexity are likely to be have been one of a few reasons why participants disengaged, although these may have been more pronounced than the other limitations.

The majority of the measures were returned allowing for pre-intervention and post-intervention comparison, however, this required the researcher attending the follow-up appointments and in some cases sending the measures on more than one occasion. Consequently the process of data collection was time consuming and thought may need to be given to how this could be achieved more time efficiently in the future. In addition, a number of the telephone session needed to be rescheduled, which also required additional time but also may have been indicative of issues with motivation or readiness for psychological intervention with this population.

4.2 Telephone Support Sessions

The initial therapeutic approach component in the *Living Beyond Your Pain* (Dahl & Lundrgen, 2006) manual was to achieve creative hopelessness. Creative hopelessness involves guiding the participant to reflect on how past efforts to change, control and avoid difficult thoughts, feelings and memories have not worked, and that the struggles with these difficult private experiences have actually impeded their ability to engage in valued life activities. The ideal outcome of the creative hopelessness stage is that the participants are able to recognise their “unworkable change agenda” which has been imparted in them by broader society, that is, that symptom control is prerequisite for living a happy, fulfilling and successful life (Eifert,

Forsyth, Arch, Espejo, Keller, & Langer, 2009). The idea is that once the participant ascertains this agenda is not effective, the rational for acceptance as an alternative for control and avoidance is established.

During the first weekly telephone support session it was clearly evident that the participants had undergone numerous medical treatments, this was highlighted by the participants devoting a lot of time to discussing these different interventions. Although the aim was to create creative hopelessness, instead it bought to the forefront that a number of the participants were still very much invested in the medical model of pain. It has been noted by Morley, Davies and Barton (2005) that with participants whom the elimination of pain is the primary or unobtainable goal, movement towards other goals may become blocked, which can lead to frustration and a sense of entrapment. Therefore this process of creative hopelessness was difficult to achieve. It is hypothesised that failure to achieve this in the first week may have impacted participant's motivation and willingness to complete the manual in the subsequent weeks.

It was also evident in the week one telephone calls that a number of the participants already had an active and value driven lifestyle and tried not to be restricted by their pain. If participants had been assessed prior to recruitment it would have been evident that these participants were not in clinical need of a psychological intervention for their pain and therefore would not have been recruited to the present study. Similar studies that have utilised bibliotherapy for CP participants have recruited participants that either were identified by a psychologist at a pain clinic (Thorsell et al., 2011), were on a waiting list to see a psychologist at a pain clinic after a clinical need had been identified (Johnston et al., 2010) or were screened using psychometric cut-off points (Lin, Lüking, Ebert, Buhrman, Andersson, & Baumeister, 2015). Therefore within the first week of telephone calls it was evident that future research may need to consider screening participants during recruitment.

One participant dropped out of the study after week one, it was not clear why this occurred due to the researched not being able to contact this participant. Although, in the first telephone support session it was evident that the participant felt that they were already reasonably active and had a positive outlook on his pain. Therefore it is hypothesised that the participant may not felt that the manual was relevant or beneficial to themselves and consequently decided to withdraw from the study.

Week two calls related to Chapter 3 in the self-help manual, this focused on values. This week was reported by the participants to be one of the most useful weeks as it received the lowest number “no not useful” responses to the question about usefulness of the chapter. Despite it being reported to be a useful chapter by many participants there were also reports that one of the chapter’s exercises was problematic. This exercise was where participants were asked to imagine their own funeral (Hayes et al., 2003). This provoked emotional response in three of the participants. For future research it may be worth considering whether this exercise is appropriate in a bibliotherapy format as it has the potential to cause emotional distress. One participant that dropped out in the study reported deciding not to continue with the manual after reading this exercise.

There were additional difficulties in week three of the self-help intervention. In the third week participants completed the Cognitive Defusion chapter. The aim of cognitive defusion is to get the participants to separate their thoughts from their behaviour and to see these thoughts for what they are: words without literal meaning (Hayes, & Strosahl, 2010). Cognitive defusion has been recognised as a fundamental feature of ACT (Mandavia, Masuda, Moore, Mendoza, Donati, & Cohne, 2015). However, the majority of the participants in this study reported finding the reading level hard and subsequently there were difficulties with comprehension. Similar findings regarding this chapter were reported in Johnston et al (2010) study. During this week it was evident that the use of telephone support sessions was important as some of these difficulties with comprehension could be addressed on the telephone. However, for five participants they no longer wanted to continue with the intervention following this chapter. Due to the high attrition rates associated with

this chapter, the reports of difficulty in comprehension and the similar findings of another study it is recommended that this it is considered in the future how this chapter could be adapted and simplified.

It was difficult to interpret the content analysis of the telephone calls for the remainder of the self-help intervention due to there being only a few participants completing the manual after week three. Therefore it is unlikely such interpretations would provide representative information. However, similar themes of difficulties in comprehension and relating to the content were discussed. The issues of being able to relate to the content was discussed in all of the weeks to varying degrees, participants reported finding it difficult to relate to the exemplars. The difficulty in relating to content in bibliotherapy may mirror the processes of not relating to a therapist in psychotherapy. Therapeutic alliance is regarded as an essential factor in therapeutic change (Gilbert, & Leahy, 2007). The significance of this construct in therapy has been highlighted in meta-analyses that have found a moderate but consistent relationship between therapeutic relationship and outcome across different types of treatment (Hovath & Symonds, 1991; Martin, Garske & Davis, 2000). It is argued that the therapeutic alliance in this form of intervention would be the relationship the participant has with the manual and how understood the participant felt. Therefore the non-completer rates may also be due to this alliance not being formed with the manual.

4.3. Interviews

The themes generated in the thematic analysis will be discussed in relation to the wider CP and ACT literature. The themes will also be discussed in regards to the insight they provide into the feasibility of the RCT and suggested adaptations that may need to be implemented to improve the research design and self-help manual.

4.3.1 Battle with Pain

This first theme “Battle with Pain” appeared to have an impact on the other themes within the interviews. The theme encapsulated the extent to which participants

accepted their pain, which subsequently appeared to influence how they experienced the self-help intervention. Within the theme was two sub-themes, each encompassing either end of a spectrum of acceptance. At one end of the spectrum included reports that the participants had started to accept the permanency of the pain and that the battle to control their pain was fruitless, this subtheme was titled "Journey of Acceptance". Whereas, at the other end of this spectrum was participants that continued to want to control their pain and refuted the potential benefits of a self-management manual, this subtheme was titled "Continued Fight".

Participants that experienced a growing acceptance regarding their pain also reported benefits of completing the manual within the interviews, which is discussed below (section 4.3.2). The "Journey of Acceptance" theme was largely reported by the ACT-only participants. Conversely, the participants that did not accept their pain and were aligned to the "Continued Fight" theme were mainly the SCS-ACT participants. The SCS-ACT participants were subsequently also less positive regarding the benefits of a self-management approach to their CNP. In addition, the participants that were less accepting of their pain also discussed the cycles of emotions that prevail as a consequence of the failed attempts to avoid or alleviate their painful symptoms. ACT postulates that it is the fight with pain that causes suffering rather than the experience of pain itself (Dahl & Lundgren, 2006). Therefore the fight against the pain appeared to be causing suffering for the SCS-ACT participants. When considering the differences between the participants that accepted compared to those that continued to fight their pain the relational frame theory and the transtheortical model literature was explored.

Relational frame theory posits that the ability for an individual to accept their CNP can be attributed to the extent to which they view themselves "as their pain". An ACT approach believes that it is through the process of cognitive defusion that enables the individual to detach themselves from the notion that they are the pain, thus allowing the process of acceptance to engender an openness to redefine them and reengage with valued life despite their pain. However, this process of cognitive defusion was something that was reported to be more difficult for the participants in

this study to understand, highlighting that the language and complexity of the manual was not only an obstacle to them completing the intervention but also to develop acceptance. In studies that have reported positive outcomes of ACT interventions it has been stated that cognitive defusion was a key process in enabling participants to adjust to their life with CP (Harrison, 2012). Therefore the lack of clarity surrounding defusion could explain why some participants may not have developed greater acceptance of pain when completing the self-help intervention.

The transtheoretical model of change could provide a different insight into why participants fell within the acceptance to continued fight continuum. Readiness to change is a central concept of the transtheoretical model of change and has been adopted to explain the process of change in psychotherapy (Prochaska & DiClemente, 1998). It is postulated that participants varied in their readiness to adopt a self-management approach to pain. Such readiness may have influenced their willingness or ability to participate in ACT intervention and have acceptance towards their pain. The participants in the SCS-ACT group had recently undergone a major operation to alleviate the intensity of their pain, whereas the ACT-only group had failed the SCS trial and subsequently exhausted all of their treatment options. Therefore the ACT-only group may be more ready to accept their pain whereas the SCS-ACT group had just invested considerable energy in a medical intervention that aimed to control their pain. However, for the participants to agree to complete in the intervention it suggests that they may have been at the contemplation stage whereas, to complete the self-help manual activities this would requires someone to be more aligned to the action stage of change. This may have been beyond some participant's level of readiness. It could even be argued that some of the SCS-ACT participants may even have been pre-contemplation but only agreed to participate in the study as they were recruited during a medical appointment and may not have fully comprehended the ACT approach to their pain. Whereas, the recruitment method differed with ACT-only and they had to respond to a letter to participate in the study, which could explain the differences in readiness to change between the SCS-ACT and ACT-only participants.

It is suggested that not one theory alone explains the differences in acceptance but that it is likely to be a combination of the beliefs regarding pain (this is discussed in the Journal Paper), the limitations of the self-help intervention and participants varying readiness to change.

4.3.2 Benefits of the manual

Hayes and Smith (2005) propose that acceptance involves psychological flexibility, including being in the present moment and changing or continuing behaviour in the services of chosen values. Consistent with the theory, the interviews highlighted that acceptance represented an overall attitude towards pain experience and a willingness to engage in valued activities despite their pain. The benefits of the manual that had been identified was that it had created hope for the future and increased participant's activity.

Participants reported that the manual had encouraged them to feel hopeful regarding having a valued life despite being in pain. Arch and Craske (2008) argue that the ultimate goal of ACT is for the individual to achieve a valued living, and that this is one of the major ways in which ACT differs from CBT, for which symptom reduction is the primary therapeutic objective. Therefore in that regard the aim of the ACT intervention had been achieved for some of the participants. Empirical evidence has shown long-term importance of the instillation of hope among adults. Higher hope adults report increased self-esteem (Curry, Snyder, Cook, Ruby, & Rehm, 1997) whereas, low levels of hope have been associated with depression and externalising behaviours (Snyder, Lopez, & Shorey, Rand & Feldman, 2003).

To understand the concept of hope the extant literature was considered. The main theoretical perspectives of hope in the literature is Snyder's Hope Theory (1994). The Snyder model proposes that hope "reflects the belief that one can find a way to realise desired goals (i.e. pathways) and become motivated to use those pathways (i.e. agency)" (Snyder, Rand, & Sigmon, 2002). The current study appears to reflect this model of hope. The ACT model does not use goals per se but values were

noted as being influential in those that expressed hope for their future and they were motivated to values-driven behaviour. Although, it is clear the Snyder model fits within a cognitive model, it can be adapted to consider within an ACT framework. The Snyder model of hope provides an insight into how this sense of hope was imparted in some participants.

Some of the participants in the study also reported a willingness to try to engage in previously avoided activities, this was described as a change in their behaviour. Willingness is one of the key functional goals in ACT interventions (Luoma, Kohlberg, Hayes, & Bunting, 2008). Hayes (2004) believes that willingness allows the person to make room for all experiences in life, whether that be good or bad in order to live a meaningful life. Furthermore it has been suggested that in the treatment of CP, willingly engaging with pain supports acceptance of pain; being open to all that there is and to be able to actively participate in valued life in the presence of pain (Dahl, & Lundgren, 2006).

4.3.3 Obstacles

Within the interviews the majority of participants discussed obstacles that may have impeded on completion of the self-help manual. Due to the high non-completer rates in the study it is not surprising that obstacles were identified within the interviews it was important to explore what had prevented participants completing the self-help intervention. Therefore these obstacles can also provide insight into the studies feasibility and if these are ways in which the design of the study or self-help manual can be adjusted in order to achieve better retention.

The complexity of the language used in the text was highlighted by many participants as a barrier to complete the manual. It was evident that the self-help manual required a high level of reading ability and a similar level of meta-cognitive and reflective skills to understand the concepts and recognise own individual behaviour in relation to the concepts discussed. The complexity of the manual was discussed in both the interview and weekly telephone support session. Johnston and colleagues (2010)

used the same self-help manual in their study and reported similar issues of complexity and comprehension. Therefore confirming that amendments to the manual may need to be completed in order to increase acceptability and avoid alienating some readers.

It is noted within the pain literature that confidence and self-efficacy can be impaired with people that experience CP (Jackson et al., 2014). Therefore with the language being complex and challenging this can further hinder an already potentially fragile self-efficacy. This was evident in some participants who reported they were “thick”, and blamed themselves and their abilities in understanding and completing the self-help intervention. The aim of the ACT intervention would be to increase pain self-efficacy however, if the language adopted is inaccessible then this could be counterintuitive.

The length of the manual and the time taken to complete the intervention was highlighted as another obstacle to complete the manual. In addition, four participants also reported that they could not continue with the self-help manual and telephone support sessions due to not having the available time the intervention required. Repetition was highlighted as a factor that added to the length of the manual, however, as noted a number of the participants reported finding the manual complicated, therefore, repetition could have been used to aid understanding. As with any manualised therapy, whether that be bibliotherapy or group interventions there are varying levels of ability and this is difficult to accommodate to suit all participants.

The length of the manual may not necessarily have been reflective of one of the faults in the text but rather indicative of the levels of motivation. A number of researchers have defined participant motivation as “a state of readiness for change prior to the introduction of treatment interventions” (Keijsers et al., 1999, p. 166). This concetualisation includes the acknowledgment of problems, commitment to change and acceptance of psychological intervention. Krause (1967) argued that

client motivation is indicated by participant's actual participation, co-operation and compliance during treatment. Therefore it could be hypothesised that not completing the intervention may be more reflective of the level of motivation and readiness to change or flaws in the intervention rather than solely the length of the text.

Perceived relevance and potency of self-help materials also affected participant's decision to disengage. Previous studies have highlighted similar doubts about the value and relevance of self-help materials, demonstrated by low uptake or participant report (Bower, Richards, & Lovell, 2001; Cuijpers et al, 2010; McKenna, Hevey & Martin, 2010). There are practical ways in which the manual could be adapted to feel more relevant to the participant group, such as Anglicising the text and using more age relevant exemplars; the mean age of the overall sample was 46.58 (SD=13.08), whereas the manual appears to be targeted for a younger audience. Finally, other participants felt that the manual was not relevant to themselves due to them not "dwelling" or being "consumed" by their pain. The participants were not screened for the intervention and therefore there were participants that may not have been suitable or needed a psychological intervention that were included in the present study.

4.3.4 Suitability

Due to the lack of screening of participants prior to recruitment it meant that a number of participants were included that may not have needed to have psychological therapy or been ready for a self-management approach. In addition to the absence of clinical need for the ACT intervention there were other identified reasons why the current study and self-help intervention may not have been suitable for the participants.

A key issue that was highlighted in this feasibility study was that the timing of the ACT intervention may not have been the optimal point in the SCS patient's treatment pathway. The SCS participants were recruitment during routine clinical appointments and started the self-help manual as soon as they had the SCS surgery. There were practical benefits for the study starting at this point; the post

intervention measures could be collected during routine appointments, which may have accounted for the high rate of data completion. However, part of the dropout rates of the ACT self-help manual in the SCS-ACT group may have in part been due to the timing of the study. Not only were the participant's invested in the medical model which impacted on the readiness to change but also these participants were recovering from surgery. Therefore, SCS-ACT participants were in increased pain, struggled with concentration due to pain relief medication and were required to be avoidant of activities. The recovery from intrusive surgery and requires patients to rest and allow the body to heal. As the pain-avoidance model highlights, not all pain avoidance is maladaptive and at times of acute pain and injury it is adaptive and aids recovery, it is when the avoidance becomes chronic that it becomes problematic (Letham et al., 1983). Participants may have utilised experiential avoidance prior to surgery, which was maladaptive, however, at the time of the intervention was a time when they needed to refrain from physical inactivity. Therefore the ACT intervention was conflicting with the post-surgical care information that the participants received. It is suggested that the intervention may have been more suitable prior to SCS or after recovery from surgery.

Another issue of timing within the study was that some of the participants felt that the ACT programme was too late in their CNP journey. Cognitive fusion would posit that the longer people live with their pain, the more fused their self-identify are with their thoughts about pain (Robinson, & Riley, 1999). If these thoughts have been fused for some time it is reasonable to assume that they are powerful and persistent thus making the process of cognitive defusion difficult. Furthermore, the longer a person has been in pain they may have learned that efforts are futile and instead of accepting their pain become passive and a learned helplessness is developed. Learned helplessness relates to having an external locus of control (Maier, & Seligman, 1976) and pertains to how individuals "learn" to be helpless in relation to managing a condition that is uncontrollable and which seems to undermine their well-being. Therefore this hopelessness may need to be identified and formulated prior to starting a self-management intervention.

Not all the participants stated the intervention was too late due to them being resigned to an external locus of control, for some of the participant's they had already developed their own strategies and may have already identified that avoidance was maladaptive. Once again this highlights the need for participants to be assessed prior to randomisation.

Participants also questioned whether the format of the intervention was suitable. Participants reported that they would have preferred a more personalised intervention that included face-to-face contact with either a therapist or a group programme with other CNP sufferers. It could be argued that if participants doubt the credibility and potency of the intervention this could have led to disengagement and lack of benefit. The extant literature has reported that participants can often feel that a bibliotherapy intervention is not sufficient in itself to be beneficial (Quigley, 2011).

Turner and colleagues (submitted) study reported that the SCS surgery patients had experienced multiple losses, including the loss of identity. The concept of losing aspects of the social self is extensively referred to in the CP literature (Smith & Osborn, 2007). The current participants may have felt that the bibliotherapy did not address these losses whereas in a group or individual format would provide participants with the social element they felt had been lost.

4.4 Assessing the Effectiveness of ACT

Due to small sample size, the ANOVA's and effect sizes conducted to assess the effectiveness of ACT with the participants should be viewed with caution. Therefore it was more appropriate to interpret and discuss the results of the individual level of analysis changes on the different outcome domains.

4.4.1. Self-efficacy

In a full-scale RCT of ACT with SCS patients it is anticipated that the primary outcome measure would be self-efficacy. Self-efficacy is important when considering the impact of pain on SCS patients as it is associated with lower levels of pain and disability (Denison, et al., 2004; Reid, et al., 2003), and is a protective mediating role between stress and depression (Maciejewski, et al.,, 2000). If the SCS patient feels more confident in their ability to perform a task despite being in pain, it is likely they will be more likely in the long-term to perform values-driven behaviours.

There was a higher prevalence of reliable change within the SCS-ACT and ACT-only group, compared to the SCS-TAU group on pain self-efficacy. Furthermore, over half of the SCS-ACT participants had reliable improvement on PSEQ. The results regarding self-efficacy were consistent with existing evaluations of ACT for CP (Thorsell et al., 2011) and for fibromyalgia (Wicksell, et al., 2012). Therefore suggesting that ACT may be an effective in improving self-efficacy with patients for a variety of CP conditions. However, both the sample size in this current study and related studies (Thorsell et al., 2011; Wicksell et al., 2012) was small and further exploration is required to provide more conclusive interpretations.

There was one SCS-ACT participant that reliably deteriorated in pain self-efficacy from pre to post intervention. It is hypothesised that this deterioration occurred as the participant had scored high on self-efficacy at pre-intervention and the lower score was due to her still recovering from surgery. Overall this participant was positive about her pain, led an active life and was confident in her abilities to perform daily tasks despite her pain. The participant still had high self-efficacy post-intervention but was realistic in her current abilities to perform tasks whilst in recover. Furthermore it was apparent in the intervention that if there had been an assessment of suitability prior to randomisation then it would be unlikely that a clinical need for psychological intervention would have been identified for the participant.

4.4.2. Mood

Forty-three percent of the SCS-ACT participants had reliable improvement on depression, a similar prevalence rate was also found in the SCS-TAU group (50%). Comparable results were also found with anxiety, with little differences between the groups. It would be expected that acceptance would lead to a larger reduction of depressive and anxiety symptomology. A possible explanation for this is the floor effect, as mentioned by Pradhan and colleagues (2007). When participants with lower levels of depression and anxiety are included in the study, there is less room for improvement. On further examination of the pre-intervention measures, it was apparent that 63% of the participants scored normal or mild on the measure of depression and anxiety. Therefore, the majority of the participants would have been unable to achieve reliable change due to these floor effects. Similar studies found small effect sizes when participants were not screened prior to randomisation (Johnston et al. 2010). Alternatively, other studies have only included participants which pre-morbid levels that are deemed to be problematic (Forman, Herbert, Moitra, Yeomans, & Geller, 2007).

4.4.3. Pain Severity

A large proportion of the SCS-ACT (71%) participants had reliable improvement on pain severity from pre-to-post intervention compared to SCS-TAU (50%) and ACT-only (0%). It is difficult to ascertain whether a larger sample would have found a statistically significant difference between SCS-ACT and SCS-TAU or if the improvements in pain severity were solely related to the SCS surgery. However, if the ACT self-intervention was solely the cause of reduced perceived pain severity then similar findings would be expected within the ACT-only group. Whereas no ACT-only participants in the current study had reliable improvements on pain severity

There is mixed results in the literature regarding pain severity being reduced following an ACT intervention. Some studies have reported that ACT interventions reduce reported pain severity (Luciano et al., 2014; Thorsell et al., 2011; Trompetter et al., 2014) however, the majority of studies report no differences (Burhman et al.,

2013; Dahl, Wilson, & Nilsson, 2004; Johnstone, et al., McCraken, Sato, & Taylor, 2013; 2010; Wicksell et al., 2008; Wicksell et al., 2015). Furthermore a systematic literature review of the efficacy of ACT in CP reported small effect sizes on pain severity (Veefolf et al., 2011). It is worth noting that although IMMPACT recommends the assessment of pain intensity, pain reduction is not a primary focus of acceptance-based therapies. Therefore it could be argued that a measure of pain severity offers very little information regarding efficacy of ACT for CP and may not be appropriate.

4.4.4 Pain Interference

A striking finding in the results was that all the SCS-ACT achieved reliable improvement in pain interference. Although the high prevalence is surprising, one of the main aims of an ACT intervention would be to reduce the amount that pain interferes with daily functioning. It appeared in the results that the reduction of pain interference may have been due to having a reduction in pain from the SCS and the ACT intervention prompting the participants to not allow pain to interfere with their daily functioning. While no other research examined ACT with participants that were also undergoing a medical procedure, the results of this study can be examined in the context of non-specific CP. Within the CP literature other studies have reported that ACT significantly reduces pain interference (Trompetter et al., 2014, Wetherall et al., 2010; Wicksell et al., 2008, Wicksell et al., 2009).

4.4.5. Health Related Quality of Life

There were minimal differences in HRQoL in all three treatment groups from pre-to-post intervention. Only one participant in the study achieved reliable improvement on the EQ-5D values index, which measured HRQoL. Thus highlighting that even when the pain intensity had reduced, quality of life did not. Similar findings were found in Wicksell and colleagues (2013) study with participants diagnosed with fibromyalgia receiving 12 weekly ACT group sessions. The results highlighted an improvement on many areas of functioning however, HRQoL was one of the few measures where a significant interaction was not found. There were minimal

changes in mental and emotional functioning in the study, which may account for why there has been minimal changes on this domain as well.

4.4.6. Summary

It is noteworthy that all of the participants in the SCS-TAU group demonstrated reliable improvement in at least two outcome measure. Given the longstanding nature of the CNP experienced by these participants, the lack of benefit from previous treatments, and the stringent statistical criteria that must be met to achieve reliable change (Jacobson & Truax, 1999), the fact that all these participants achieved reliable change in two measure is important and suggests that the combination of SCS and ACT intervention may have some benefit. A larger sample size is required to further explore the benefits of combining SCS surgery with a self-help intervention.

4.5. Implications of the study

The current study illustrates the importance of completing a feasibility study prior to a full-scale RCT. A number of flaws and limitations in the study design have been identified and saved resources from completing a larger scale study that would have struggled with recruitment and retention. In addition, according to Glasgow, McKay, Piette, and Reynolds (2001), identifying barriers to "accepting" a particular intervention or model is helpful in the development and implementation of successful future self-management programmes for patients with chronic illnesses. Self-management practices are believed to promote physical and emotional health, therefore health care providers should be aware of what interferes with or helps patients to engage in these activities or interventions. The barriers and facilitators identified in this study may apply, not only to patients undergoing SCS surgery, but also to the care of patients with many other chronic conditions.

There is emerging literature in the areas of social science and medicine that advises the need for caution in accepting a "one size fits all" approach inherent in a medical-political climate which endeavours to derive clinical decisions and guidelines

exclusively from an evidence base (Harldorsen, Grasdal, Skoven, Risa, Kronholm, & Ursin, 2002). Therefore it is important to consider the factors which facilitate and impede interventions such as an ACT self-help for CNP, as what works for one person with pain may not work for another (Sanders, 2000).

4.6. Study Limitations & Future Research

The main limitation to the current study was that the author conducted a number of roles within the research; including completing the telephone support sessions, interviewing the participants and interpretation the data. Consequently the results will have been subjected to responder bias from the participants as well as the author's own biases. The author received regular supervision and discussed the data analysis with the studies supervisors in an attempt to reduce researcher bias. However, despite the author being cautious of bias, by simply completing the interviews there is a possibility this impacted on participant's responses.

The current study utilised mixed methods design, however, due to the small sample size the inferential statistics conducted have questionable reliability. Partial eta-squared was used to estimate effect size. However, this measure of effect size has some limitations, the main one being that it tends to be upwardly biased, especially when the sample size is small (Murray & Dosser, 1987). Due to the sample sizes being small in this study it is likely that the partial eta-squared may have overestimated the effect sizes. Therefore the quantitative results in this study should be viewed cautiously and results should be considered on more an individual level analysis.

Due to this small sample size and questionable reliability of the inferential statistics, it is pertinent that the qualitative data provided a greater insight into the feasibility of the RCT rather than relying solely on the quantitative data. One methodology issue commonly cited when qualitative research and the small sample sizes is the limited generalisability across groups. As qualitative research aims for a deeper understanding of a phenomenon, being able to generalise the findings to the more

general population was not one of the studies aims. However, Curtin and Fossey (2007) have affirmed that transferability should apply to qualitative research if "detailed descriptions of the participant's experiences are provided to enable the reader to make comparisons with other individuals and groups". It can be argued that the current study provided accounts of the salient features of the participant's experiences pre, post and during the self-help intervention, therefore comparisons to other ACT based interventions for SCS participants and more non-specific CP can be made in future research.

The current feasibility study highlighted a number of adjustments that are recommended prior to conducting a future RCT with the SCS surgery patients. It is recommended that a further feasibility trial is conducted but a number of changes are investigated to see if this improves recruitment, retention and outcomes. These recommended alterations include:

- Consideration is given to the timing of a future study in the SCS patient's treatment pathway. The current study was conducted straight after the patients had SCS surgery. The interviews highlighted that this was may not have been an optimal timing for a self-management intervention due to recovery from the operation and the patients being invested and fixed in the medical model at this time. A future feasibility trial could be completed pre SCS surgery, when patients are first assessed in the clinic and before they have the trial implantation. Alternatively SCS participants could be recruited after a period of time has elapsed since the participants have had SCS. Given that the effects of SCS can reduce over time often at approximately 12 months (Cameron, 2004; Ohnmeiss & Rashbaum, 2001; Taylor, et al., 2006), then previously treated SCS patients are likely to have different perspectives on their pain than the SCS-ACT participants in the current study.
- Assessment measures completed prior to recruitment to ascertain whether a clinical need for a psychological intervention for CNP is warranted.
- A measure of acceptance is included to the outcome measures as during the interviews of the current study it became apparent that the participants which were more accepting of the pain benefited more from the self-management

intervention. It would therefore be interesting to assess this within the quantitative analysis.

- To build upon the findings from this study it would be necessary to conduct a longitudinal study design to provide additional information about the nature of the transition of the individual's journey with acceptance after they have completed the ACT self-help manual
- With an aim to improve retention of the participants in the study it is recommended that the first week's support session is completed face-to-face rather than over the telephone. This session could serve to provide participants a space to begin to foster an atmosphere of creative hopelessness (Hayes et al., 1999), i.e. addressing what treatments haven't worked and why. In addition, this session could provide an opportunity for participants to review their own as well as others previous experiences, with a view to empowering participants to generate a more hopeful outlook in adopting the ACT approach.
- A number of adjustments to the self-help manual are completed in order to increase its accessibility to participants and to appear more relevant to themselves. These adjustments include assessing whether the imaging funeral exercise could be replaced with a less emotive exercise, simplification of the language, examples given of subjects that are more akin to the participant's age group and representative of the SCS population, and Analgising the book.
- The interviews conducted by someone independent to the research or a different researcher that has completed the telephone support sessions.

4.7. Conclusions

The results of this feasibility study suggest that in accordance with MRC (2008) guidelines further exploration and a feasibility trial needs to be completed prior to a full-scale RCT is considered. A key justification for developing a refined-feasibility study is that all the SCS-ACT participants had reliable improvement on at least two outcome measure. Furthermore there was qualitative feedback that for some

participants the ACT intervention had given them hope for the future and increased their activity.

Stemming from the current study, a number of modifications have been suggested that could improve future feasibility research. The main aim of future feasibility trial would be to explore ways to increases recruitment and retention of the participants as well as exploring ways to modify the current ACT manual. Not until these issues are resolved would it be advisable for a full-scale RCT is completed.

To conclude, larger sample sizes are required in future studies in order to obtain more conclusive outcomes on the effectiveness of ACT with SCS surgery patients and to produce more reliable effect sizes in order to inform sample sizes for wider-scale trials. It is hypothesised that by addressing the obstacles, amending the manual and the other issues discussed accordingly, that recruitment and retention in the next stage of research will be more successful.

5. REFLECTIVE SECTION

In this section I will summarise my reflections throughout the course of the research journey. Within this, I will refer to the development of the project, the challenges that I faced during recruitment and telephone support sessions and my reflections on the epistemological position adopted within the research.

5.1. Research Development

The research project was considered by two research supervisors prior to me commencing the DClinPsy course. The neurosurgeon at the Neuromodulation clinic in which the participants were recruited from had previously been involved with another thesis on the course that explored the psychological experience of SCS surgery. Having previously worked mainly in forensics prior to starting the course I was keen to explore a different area of psychology. Health psychology and specifically SCS was novel to me, therefore I was interested in this area so I could expand my knowledge. I soon became engrossed in reading the SCS and CNP literature and was interested in learning more about what psychological intervention had to offer with this population.

During the research planning, I attended the Neuromodulation clinic meetings to learn about the SCS process and the journey patients had prior to having surgery. This allowed me to have an insight into the medical procedures and the SCS devices. When attending these meeting I was surprised by the lack of psychological assessments of the patients prior to surgery, especially due to this being advocated in SCS guidelines. Despite the dearth of psychological input the neuromodulation team at the clinic appeared open-minded and welcoming of psychological research in SCS.

5.2. Recruitment

The recruitment process proved to be very challenging. It was anticipated that participants would be recruited within an approximate six month timeframe.

However, it transpired that the recruitment numbers and this timeframe were over ambitious and the recruitment pool ended up being smaller than had been anticipated. Therefore I recruited over a longer period and still did not achieve the original target sample size. In addition, during the recruitment, there was some confusion about the recruitment protocol with the research team at the clinic so it was important that I regularly communicated the protocol. It also meant I needed to attend the clinic regularly to reiterate the protocol and remind the clinic about the research. These difficulties presented me with the reality of working in a multidisciplinary research team with busy clinicians whose priority, unlike mine, was not my research. These recruitment difficulties emphasised the importance of me being proactive in communicating information in different formats to ensure all members of the research team were aware of the protocol.

Despite my attempts to embed myself in the clinic there were a couple of occasions where patient appointments had been cancelled and the clinic had not informed me. I attended the clinic in the aim of recruiting participants that expressed an interest in the study to the clinician and consequently when the appointments had been cancelled it had been a futile journey as there was no potential participant I could recruit. These instances of missed communication and wasted journeys were frustrating but due to my reliance on the clinic to recruit participants I felt pressured to maintain good relationships with the team.

5.3. Telephone support calls

I found conducting the support session interesting, although these also came with similar frustrations. Some of the telephone calls needed re-scheduling and due to these telephone calls being scheduled around my placement and university timetable it was at times frustrating and difficult to always be as flexible as I would have liked to have been.

The telephone calls were a different experience as I tried to avoid how I would normally approach therapy. When typically delivering a psychological intervention I

like to be integrative in my approach. However, with these calls it was pertinent that I stuck to the self-help manual topics and used these as support session with a set structure rather than falling into an integrative therapist role. This new role for the telephone call was tested when one participant discussed his experiences in a car crash and the associated trauma. I approached this differently than I would have done in therapy session, although potentially the psychological need was to explore the trauma but this study required me to stay with only exploring the impact and cognitions of the pain.

5.4. Interviews

I found conducting the interviews interesting and participants had discussed aspects of the ACT self-help manual that they had not previously mentioned in the support sessions. However, there was a slight uncomfortableness about conducting these interviews after delivering the support session and exploring how they had found an intervention that I had partly been supporting. Upon reflection if this experience had felt slightly uncomfortable for myself then it is likely this was also the case for some of the participants. Although, there was some benefits to this approach in that I had already developed a relationship with the participants and I was aware of some of the difficulties they may have had with the intervention if I was to complete this study again I would explore how me conducting the interviews could have been avoided.

5.5 Analysis

On numerous occasions during the analysis I needed to remind myself that the study aims were not to assess the effectiveness of the ACT intervention but to assess the feasibility. Furthermore when completing the interviews I had to keep in mind these aims and restrict my own curiosity in exploring efficacy. I believe my own epistemological position evolved through training so the position I started at the beginning of this research had subtly changed over the course of the study and I believe if I had started the research.

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APPENDECIES

Appendix A: Guidelines for authors submitting to the Behaviour Research and Therapy journal

Full guidelines for authors can be viewed at: https://www.elsevier.com/journals/behaviour-research-and-therapy/0005-7967?generatepdf=true

INTRODUCTION

Behaviour Research and Therapy encompasses all of what is commonly referred to as cognitive behaviour therapy (CBT). The focus is on the following: theoretical and experimental analyses of psychopathological processes with direct implications for prevention and treatment; the development and evaluation of empirically-supported interventions; predictors, moderators and mechanisms of behaviour change; and dissemination and implementation of evidence-based treatments to general clinical practice. In addition to traditional clinical disorders, the scope of the journal also includes behavioural medicine. The journal will not consider manuscripts dealing primarily with measurement, psychometric analyses, and personality assessment.

The Editor and Associate Editors will make an initial determination of whether or not submissions fall within the scope of the journal and/or are of sufficient merit and importance to warrant full review.

The CONSORT guidelines (http://www.consort-statement.org/?) need to be followed for protocol papers for trials; authors should present a flow diagramme and attach with their cover letter the CONSORT checklist. For meta-analysis, the PRISMA (http://www.prisma-statement.org/?) guidelines should be followed; authors should present a flow diagramme and attach with their cover letter the PRISMA checklist. For systematic reviews it is recommended that the PRISMA guidelines are followed, although it is not compulsory.

PREPARATION

Article structure

Divide your article into clearly defined sections. Each subsection is given a brief heading. Each heading should appear on its own separate line. Subsections should be used as much as possible when crossreferencing text: refer to the subsection by heading as opposed to simply 'the text'. Appendices If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

Essential title page information

• Title. Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.

• Author names and affiliations. Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lowercase superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.

• Corresponding author. Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.

• Present/permanent address. If an author has moved since the work described in the article was done, or was visiting at the time, a 'Present address' (or 'Permanent address') may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

Abstract

A concise and factual abstract is required with a maximum length of 200 words. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, References should be avoided, but if

essential, then cite the author(s) and year(s). Also, non-standard or uncommon abbreviations should be avoided, but if essential they must be defined at their first mention in the abstract itself.

TABLES

Please submit tables as editable text and not as images. Tables can be placed either next to the relevant text in the article, or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules.

REFERENCES

Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either 'Unpublished results' or 'Personal communication'. Citation of a reference as 'in press' implies that the item has been accepted for publication. Web references As a minimum, the full URL should be given and the date when the reference was last accessed. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list. Reference management software Most Elsevier journals have their reference template available in many of the most popular reference management software products. These include all products that support Citation Style Language styles (http://citationstyles.org), such as Mendeley (http://www.mendeley.com/features/reference-manager) and Zotero (https://www.zotero.org/), as well as EndNote (http://endnote.com/downloads/styles). Using the word processor plug-ins from these products, authors only need to select the appropriate journal template when preparing their article, after which citations and bibliographies will be automatically formatted in the journal's style. If no template

is yet available for this journal, please follow the format of the sample references and citations as shown in this Guide. Users of Mendeley Desktop can easily install the reference style for this journal by clicking the following link: http://open.mendeley.com/use-citation-style/behaviour-research-and-therapy When preparing your manuscript, you will then be able to select this style using the Mendeley plugins for Microsoft Word or LibreOffice.

Reference style

Text: Citations in the text should follow the referencing style used by the American Psychological Association. You are referred to the Publication Manual of the American Psychological Association, Sixth Edition, ISBN 978-1-4338-0561-5, copies of which may be ordered from http://books.apa.org/books.cfm?id=4200067 or APA Order Dept., P.O.B. 2710, Hyattsville, MD 20784, USA or APA, 3 Henrietta Street, London, WC3E 8LU, UK. List: references should be arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year must be identified by the letters 'a', 'b', 'c', etc., placed after the year of publication.

Appendix B: Ethics Approval Letter

[redacted]

26 February 2014

Dr Thomas Schroder
Associate Professor in Clinical Psychology; Co-Director (Academic & Research), Trent DClinPsy Programme
University of Nottingham
Institue of Work, Health and Organisations
Jubilee Campus
University of Nottingham
NG8 1BB

Dear Dr Schroder

Study title:	**A feasibility randomised control trial of Acceptance and Commitment Therapy for Spinal Cord Stimulation Surgery Patients**
REC reference:	**14/EM/0012**
Protocol number:	**13135**
IRAS project ID:	**133420**

Thank you for your letter of 17 February 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager, [redacted]

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Evidence of insurance or indemnity	Henderson Corporate	31 July 2013
Interview Schedules/Topic Guides	1.0	16 December 2013
Letter from Sponsor	University of Nottingham	05 December 2013
Letter of invitation to participant	1.0	16 December 2013
Other: Investigator's CV	Surajit Basu	
Other: Investigator's CV	Dr Roshan das Nair	04 December 2013
Other: Investigator's CV	Nima Golijani Moghaddam	05 March 2013
Other: Investigator's CV	Samantha Akiens	04 December 2013
Other: Investigator's CV	Dr Thomas Schroder	04 December 2013
Other: Self Help Manual - Letter and Completion Table	1.0	16 December 2013
Other: Contact Details Form		
Other: Living Beyond Your Pain - Harbinger Self Help Workbook		
Participant Consent Form	2.0	10 February 2014
Participant Information Sheet: Non SCS Participants	2.0	10 February 2014
Participant Information Sheet: SCS Participants	2.0	10 February 2014
Protocol	1.0	16 December 2013
Questionnaire: Pain Self Efficacy Questionnaire (PSEQ)	Validated	
Questionnaire: EQ-5D-5L Health Questionnaire	Validated	
Questionnaire: HAD Scale	Validated	
Questionnaire: Brief Pain Inventory	Validated	
REC application	133420/536738/1/827	14 January 2013
Response to Request for Further Information	Email	17 February 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

14/EM/0012	**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]

Email:nrescommittee.eastmidlands-nottingham1@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: [redacted]

Appendix C: NHS Approval Letter

research & innovation [redacted] NHS

Research & Innovation

[redacted]

Mr Roshan Das Nair
IWHO international House
Room B13 Jubilee Campus
Wollaton Road
Nottingham

NG8 1BB

13th May 2014

Dear **Mr Roshan Das Nair**

Re: 14CP001
CSP
REC 14/EM/0012
A feasibility randomised control trial of Acceptance and commitment therapy for spinal cord stimulation

The R&I Department have reviewed the following documents and NHS permission for the above research has been granted on the basis described in the application form, protocol, and supporting documentation. The documents reviewed were:

Participant Information Sheet Non SCS Participants v2.0 dated 10 February 2014
Participant Information Sheet SCS participants v2.0 dated 10 February 2014
Consent form v2.0 dated 10 February 2014
Interview schedules/topic guides v1.0 dated 16 December 2013
Letter of Invitation to Participant v1.0 dated 16 December 2013
Self help manual, letter and completion table v1.0 dated 16 December 2014
Harbinger self help workbook
Protocol v1.0 dated 16 December 2014

We are here for you

[redacted] NHS
NHS Trust

Pain Self Efficacy Questionnaire
EQ-5D-5L Questionnaire
HAD scale
Brief Pain Inventory

Your study now has NHS permission , on the understanding and provision that you will follow the conditions set out below.

Conditions of Approval

The Principal Investigator is responsible for

1. Compliance with all relevant laws, regulations and codes of practice applicable to the trial including but not limited to, the UK Clinical Trials Regulations, Medicines for Human Use (Clinical Trial) Regulations 2004, principles of Good Clinical Practice, the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' (1996 version), the Human Rights Act 1998, the Data Protection Act 1998 the Medicines Act 1968, the NHS Research Governance Framework for Health and Social Care (version 2 April 2005). Should any of these be revised and reissued this will apply. Copies of the up-to-date regulations are available from the R&I Office or via the R&I website http://nuhrise.org

2. Submission of study amendments to the Ethics committee and MHRA in accordance with the IRAS guidelines. Amendments and information with regards to changes in study status must be sent to R&I, (this includes changes to the local study team). Within 35 days from the receipt of a valid amendment submission, NUH will inform you if may not locally implement the amendment. If no objections are raised NHS permission is valid and the amendment may be implemented.

   When submitting documents for studies adopted into the NIHR portfolio please send the information to [redacted]
   When submitting documents for all other studies please use the email address [redacted]

3. Ensuring all study personnel, not employed by the Nottingham University Hospitals NHS Trust hold either honorary contracts/letters of access with this Trust, before they have access to any patients or staff, their data, tissue or organs or any N[redacted]acilities.

4. In accordance with the Department of Health's Plan for Growth, for initialising and delivering research within the NHS the 'first patient, first visit should occur 70 days from receipt of a valid submission in R&I. Therefore for all research where :

   - The sponsor is a commercial partner
   - [redacted] holds a funding contract with the National Institute for Health Research (NIHR)

- The research is classed as a "clinical trial "on the IRAS filter page.

The research team is expected to collaborate with the department of R&I in reporting recruitment data to [redacted]

1. For GTAC-approved studies, the NHS permission should be forwarded to GTAC via the sponsor. GTAC should then issue a site authorisation letter which must be received by each site prior to recruitment commencing. A copy of this letter must be forwarded to R&I.

2. Comply with requests from [redacted] R&I to allow monitoring of research to comply with the Research Governance framework.

3. Record *all* types of adverse events (including Suspected Unexpected Serious Adverse Drug Reaction - SUSARS) in the patient medical records and study documentation and report to the sponsor as required by the protocol. Further guidance can be found in R&I SOP 11 - "Adverse Event Monitoring, Recording and Reporting for investigators".

4. Report any Serious Breach of the UK Clinical Trial regulations in connection with the trial or Serious Breach of the protocol, immediately after becoming aware of the breach to the study sponsor.

For NUH sponsored studies only, the Chief Investigator is responsible for:

i. All duties as detailed in the "Clinical Trial Delegation of Sponsorship responsibilities to Chief Investigator" agreement.
ii. Contacting the sponsor for review of all amendment documentation prior to submission to NRES and MHRA. Please note that according to NRES and MHRA regulations, all submissions of amendments need to be signed by the authorised sponsor's representative. All relevant documentation should be emailed to [redacted]
iii. Send copies of the completed Annual Safety, Progress reports and End of Study reports required by the Ethics Committee and the MHRA (if appropriate) to the Quality Assurance manager a[redacted]&I.
iv. Not[redacted]R&I of all SAEs by completing and sending the *"Serious Adverse Event reporting form"* to R&I **(only via fax, e-mail or by hand),** within 24hrs of becoming aware of the event. If the event is defined as a SUSAR then a follow up report must also be submitted to R&I, via the above channels-**no longer than 7 days after the original report was submitted**
v. Reporting any Serious Breach of the UK Clinical Trial regulations in connection with the trial or Serious Breach of the protocol, immediately after becoming aware of the breach to NUH R&I as sponsor. Further guidance can be found in R&I SOP 12 "Protocol Violation and Serious Breach Reporting"

This approval letter constitutes a favourable Site Specific Assessment (SSA) for this site.

Please note that the R&I department maintains a database containing study related information, and personal

[redacted] NHS
NHS Trust

information about individual investigators e.g. name, address, contact details etc. This information will be managed according to the principles established in the Data Protection Act.

Yours sincerely,

[redacted]

[redacted]

We are here for you

Appendix D: Letter of Access

[redacted] NHS

NHS Trust

[redacted]

RSCH 500

29Th May 2014

Miss Samantha Aikens
Institute of Work, Health and Organisations
University of Nottingham
International House
Jubilee Campus
Wollaton Road
Nottingham
NG8 1BB

Dear Miss Aikens

Re: Letter of Access for Research

Study Title:	A feasibility RCT of ACT for Spinal Cord Stimulation Surgery Patients
Chief Investigator	Dr Thomas Schroder
Local Collaborator at NUH:	Dr Roshan Das Nair
R&D Ref:	14CP001
Sponsor:	University of Nottingham

Letter of access for research

As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this NHS organisation that the necessary pre-engagement check are in place in accordance with the role you plan to carry out in this organisation. This letter confirms your right of access to conduct research through [redacted]e purpose and on the terms and conditions set out below. This right of access commences on **29/05/2014 until 28/05/2015** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to [redacted]mises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through [redacted]will remain accountable to your employer **Derbyshire Healthcare NHS**

[redacted] NHS
NHS Trust

Foundation Trust but you are required to follow the reasonable instructions of your nominated manager **Dr Roshan Das Nair** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance wit[redacted]s policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with [redacted] in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on [redacted] **Hospitals** premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and the Trust **R&I office** prior to commencing your research role at the Trust.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

[redacted] will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.
Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or suitability to work with adults or children, or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs

[redacted] NHS Trust

you through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

[redacted]
Senior Research Manager

cc: HR department of Employing Organisation

Appendix E: Covering letter sent out to ACT-only Participants

Dear

The Department of Neurosurgery at the [redacted] has sent you this information pack on behalf Samantha Akiens. She is currently training to be a Clinical Psychologist for the NHS with the University of Nottingham. She wanted me to contact you because you have recently undergone spinal cord stimulation surgery and she would like to invite you to take part in her research study

This research is looking at the practicalities of including a psychological self-help therapy in the surgical pathway. If you take part in the study you will be randomly put into a group where you have a self-help book to complete or you will have treatment as usual. If you are chosen to have the self-help book you will be sent this in the post and will receive a weekly telephone call by one of the researchers. During these calls you will be asked how you are finding the book and be given support and guidance. Enclosed is an information sheet regarding the study. If after reading the information sheet you would like to participate in the study then please complete the enclosed questionnaires and consent form and return them in the self-addressed envelope. You will then be contacted by the researcher.

Yours sincerely

Neuromodulation MDT Specialist Clinic

[redacted]

[redacted]

Appendix F: ACT-only Participant Information Sheet

Title of Study: A feasibility randomised control trial of acceptance and commitment therapy for spinal cord stimulation surgery patients

Name of Researcher: Samantha Akiens

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our researchers will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

The purpose of the study is to assess the practicalities of completing a randomised control trial on the effectiveness of a psychological intervention with patients that have chronic neuropathic pain and been assessed for spinal cord stimulation surgery.

Why have I been invited?

You are being invited to take part because you have chronic neuropathic pain and have been assessed for spinal cord stimulation surgery. We are inviting 50 participants like you to take part.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

If you take part in the study then you will need to fill out questionnaires on three separate occasions. The questionnaires will be sent to you with in the post and you will need to return them in the self-addressed envelope. The questionnaires will ask you about your mood, how much pain you've experienced and how much activities you have been able to do. They are to monitor if there have been any changes since completing the self-help book.

You will be sent a published self-help manual for designed for people that have chronic pain. The book will be divided into 6 sections and each week you will need to read one section and complete the activities. Samantha Akiens will also call you

once a week, at a time that is convenient to you and support you with the work and you can discuss any difficulties you are having with the manual. If you give permission then these phone calls will be recorded. After you have completed the book you will be interviewed on the phone about how useful you found the manual. It would be really useful to get feedback on how the manual could be improved and what you found most useful.

Expenses and payments

Participants will not be paid to participate in the study

What are the possible disadvantages and risks of taking part?

A possible disadvantage of taking part in the study is that it will require some of your time to complete the questionnaires and if you also have the self-help manual this will require even more of your time.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help other people that have had spinal cord stimulation surgery get additional support from a self-help manual. Also you may find the book useful in helping you develop ways to manage your pain.

What happens when the research study stops?

The results will be written up as part of my course requirements at the University of Nottingham. It will also be submitted for publication in a scientific journal. You will not be personally identifiable and your confidentiality will not be breeched.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting NHS Complaints. Details can be obtained from your hospital.

Will my taking part in the study be kept confidential?

Ethical and legal practice will be followed and all information about you will be handled in confidence.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham

who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

All research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. Withdrawing from the study will not have an impact on your future care. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

The results of the study will be written up as part of Clinical Psychology doctorate at the University of Nottingham. It is also intended that the results will also be published in a journal.

Who is organising and funding the research?

This research is being organised and funded by the University of Nottingham

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the University of Nottingham Research Ethics Committee.

Further information and contact details

Researcher: Samantha Akiens, Trainee Clinical Psychologist, under the supervision of Dr Roshan das Nair
Email: lwxsa7@nottingham.ac.uk
Address: Doctorate in Clinical Psychology, School of Medicine, Jubilee Campus, Wollaton Road, Nottingham, NG8 1BB.
Patient Advice and Liaison Service (PALS). Website: https://www.nuh.nhs.uk/patients-and-visitors/patient-advice-and-liaison-service/
Telephone number: 0800 183 0204

Appendix G: SCS Participant Information Sheet

Title of Study: A feasibility randomised control trial of acceptance and commitment therapy for spinal cord stimulation surgery patients

Name of Researcher: Samantha Akiens

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our researchers will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

The main purpose of the study is access whether it is practical to complete a larger study in this area. This study and the potential larger future study will be looking at whether there is any benefits of introducing a psychological intervention into the care of patients with chronic neuropathic pain that have been assessed for spinal cord stimulation surgery.

Why have I been invited?

You are being invited to take part because you have chronic neuropathic pain and have had spinal cord stimulation surgery. We are inviting 30 participants like you to take part.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

If you decided not to take part in the study or withdraw this will have no impact on the treatment and any surgery you receive at the surgery.

What will happen to me if I take part?

If you take part in the study then you will be randomly put in either a group where you are given a self-help book to complete or you will have treatment as usual. The way this is decided a researcher will pick an envelope at random; this is so it is fair to everyone. You will need to fill out questionnaires on three separate occasions. The questionnaires will be sent to you in the post and you will need to return them in a self-addressed envelope. The questionnaires will ask you about your mood, how much pain you've experienced and how much activities you have been able to do. They are to monitor how you have been getting along since the surgery.

If you are not having the self-help book you will only need to complete the questionnaires to participate in the study. After the study has finished if you wish to have a copy of the self-help manual then this will be made available.

If you are chosen to have the self-help book then you will be given a published self-help manual for designed for people that have chronic pain. You will be asked to start the self-help book after it has been sent in the post. The book will be divided into 6 sections and each week you will need to read one section and complete the activities. Samantha Akiens will also call you once a week, at a time that is convenient to you and support you with the work and you can discuss any difficulties you are having with the manual. If you give permission then these phone calls will be recorded. After you have completed the book you will be interviewed on the phone about how useful you found the manual. It would be really useful to get feedback on how the manual could be improved and what you found most useful.

Expenses and payments

Participants will not be paid to participate in the study

What are the possible disadvantages and risks of taking part?

A possible disadvantage of taking part in the study is that it will require some of your time to complete the questionnaires and if you also have the self-help manual this will require even more of your time. The self-help manual will be completed over a six week period and it is estimated that it will take approximately one hour a week to complete the manual.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help other people that have had spinal cord stimulation surgery get additional support from a self-help manual. If you are in the group that receives that self-help manual then you may find this is useful in helping you develop ways to manage your pain.

What happens when the research study stops?

The results will be written up as part of my course requirements at the University of Nottingham. It will also be submitted for publication in a scientific journal. You will not be personally identifiable and your confidentiality will not be breeched.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting NHS Complaints. Details can be obtained from your hospital.

Will my taking part in the study be kept confidential?

The study will be written up as part of Clinical Psychology doctorate. In the result direct quotes that you have said during the interview may be included in the results. However, your name will not be included with any quotes or within the write up.

Ethical and legal practice will be followed and all information about you will be handled in confidence.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

All research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. Withdrawing from the study will not have an impact on your future care at the neurosurgery clinic. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

The results of the study will be written up as part of Clinical Psychology doctorate at the University of Nottingham. It is also intended that the results will also be published in a journal.

Who is organising and funding the research?

This research is being organised and funded by the University of Nottingham

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the University of Nottingham Research Ethics Committee.

Further information and contact details
Researcher: Samantha Akiens, Trainee Clinical Psychologist, under the supervision of Dr Roshan das Nair
Email: lwxsa7@nottingham.ac.uk
Address: Doctorate in Clinical Psychology, School of Medicine, Jubilee Campus, Wollaton Road, Nottingham, NG8 1BB.
Patient Advice and Liaison Service (PALS). Website: https://www.nuh.nhs.uk/patients-and-visitors/patient-advice-and-liaison-service/
Telephone number: 0800 183 0204

Appendix H: Consent Form

Title of Study: A feasibility randomised control trial of Acceptance and Commitment therapy for spinal cord stimulation patients.

REC ref: ***(to be added after approval given)***

Name of Researcher: Samantha Akiens

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number ……dated..... for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I understand and agree that if I was to have Acceptance & Commitment Therapy I will need to complete a self-help book and have weekly telephone support. ☐

5. I understand and agree to these weekly telephone calls being recorded for training and quality purposes. ☐

6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from Principal Investigator)	Date	Signature
_____	_____	_____
Name of Principal Investigator	Date	Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

Appendix I: Demographic information sheet

Please complete these details so someone from the research team is able to contact you and to provide us with more information about your pain and how it affects your daily life

Name	**M / F**
Date of Birth	**Age**
Address **Postcode**	
Contact Telephone Number	
Ethnic Group	

Where is your pain?

How long have you had this pain?

What treatments and operations have you previously had due to this pain?

Which of the following best describes your current situation? Please tick the relevant box

Working / training full time	
Working / training part time	
Not working / training because of pain	
Not working / training through choice (e.g. retired, homemaker	

If working, are there any problems at work because of your pain?

Appendix J: Covering Letter sent with ACT manual

Title of Study: A feasibility randomised control trial of Acceptance and Commitment therapy for spinal cord stimulation patients.

Dear xxxx

Enclosed is the self-help manual for chronic pain called *Living Beyond Your Pain*. This booklet has been split into 6 sessions so that you can complete each session weekly. Below is a table showing you what sections need to completed each week. Also in this table is a space where you can write the time and date that I will be calling you. If you have any questions regarding any of the topics in this book then please raise these during the telephone calls.

Week	Chapters	Time and Date of Telephone call
1	Introduction Chapter 1 & 2	
2	Chapter 3	
3	Chapter 4	
4	Chapter 5	
5	Chapter 6 & up to page 136 Chapter 7	
6	From 136 of Chapter 7 & Chapter 8	

Good luck with completing the book and I shall speak to you soon.

Best wishes

Samantha Akiens

Appendix K: Annotated Transcript

Interview with [redacted]

Q: So overall, how did you find the self-help book?

A: I found it interesting. It made me think of things that I'd never thought about before. I've learnt a lot, especially in the beginning of the book. Yes, I have, I didn't think, I thought, oh gosh, this, I don't understand. But keep reading and yes, you do understand it. And I suppose I've, you know, accepted everything but, as I say, it's just the last bit that I fell down a bit on, knowing how to put something down to the acceptance and the permitted action plan for obstacle one, you know. I thought, oh what does that mean? As I say, my husband's helped me, so we've got through that.

Q: Yes. And you said you've learnt a lot, what's the main things do you think you've learnt from the book?

A: About a valued life. You don't really think about, that you've got a valued life when you're in so much pain. But just sitting reading the beginning of the book and about your mental structure, avoidance behaviours and you value illnesses. You know, it's just amazing what I've learnt, there's no getting away from it. I mean I know there's people in far worse situations than me but, you know, yes, I've learnt a lot, yes I have done.

Q: And what were your expectations about doing the book before you started?

A: Oh I was a bit, oh a bit shy and I thought, oh dear, you know, is this for me? Is it going to help me? But I think, I think it will. I got to a point where I thought, oh I can't be bothered. And I thought, no, don't think along those lines. But no, I think, yes, I think it will help, yes, definitely.

Q: And prior to doing the book did you think, even though you were a bit shy about it, did you think it would help?

A: When, sorry?

Q: Before you started reading, did you think it would help then?

A: No, I thought, what's reading a book got to do with it? Because I haven't, well this is what my husband, Mike, wants to have a word with you about. Have you heard about a book, X Pain? My husband's going to take you through that.

Q: Oh OK.

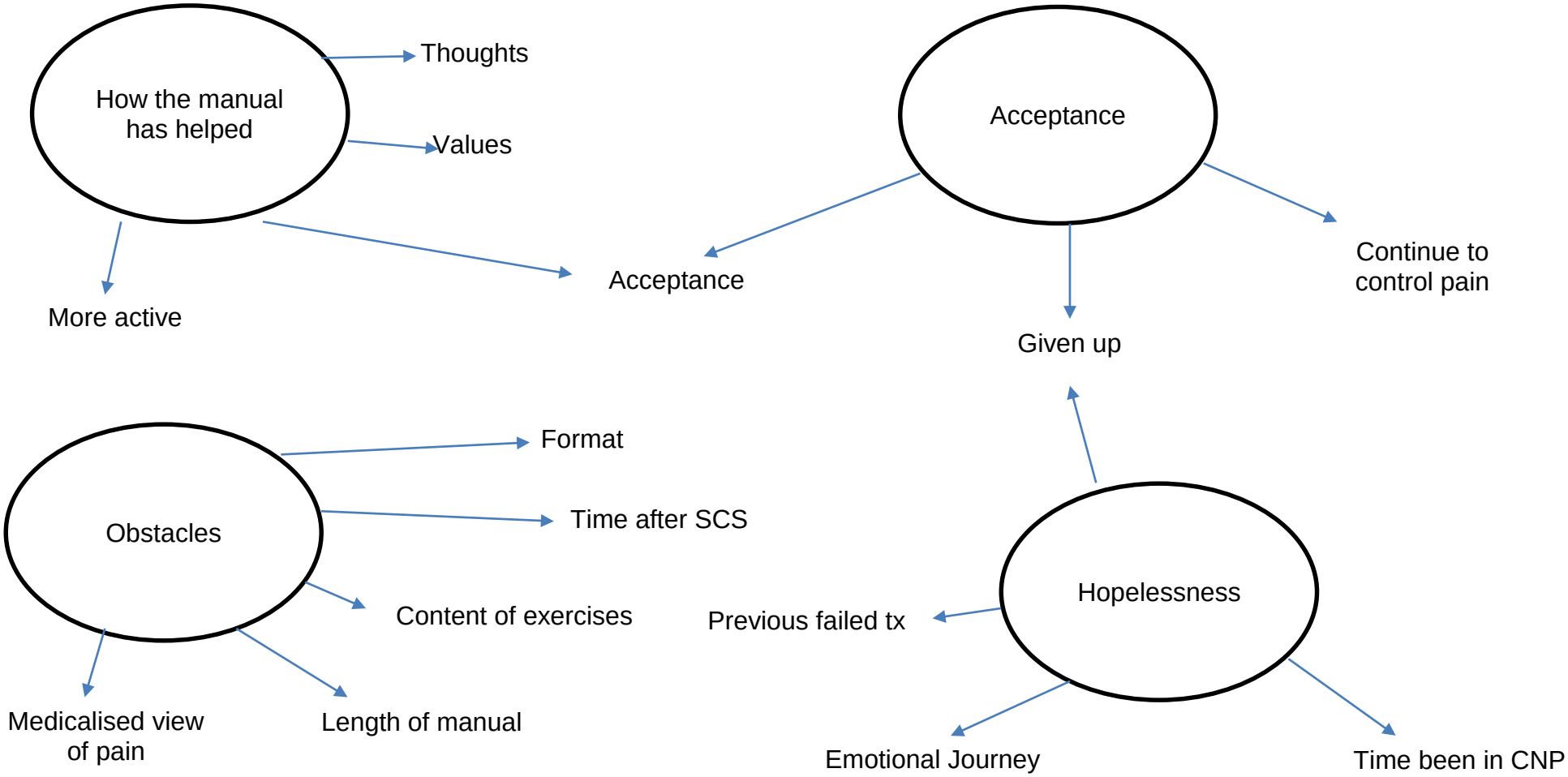
A: And I thought, oh it's just one of these books you read and how's it going to help me with the pain, you know. Although I'm reading it, I've still got the pain. But it does make you think differently, it makes you think deeper about yourself.

Appendix L: Codebook

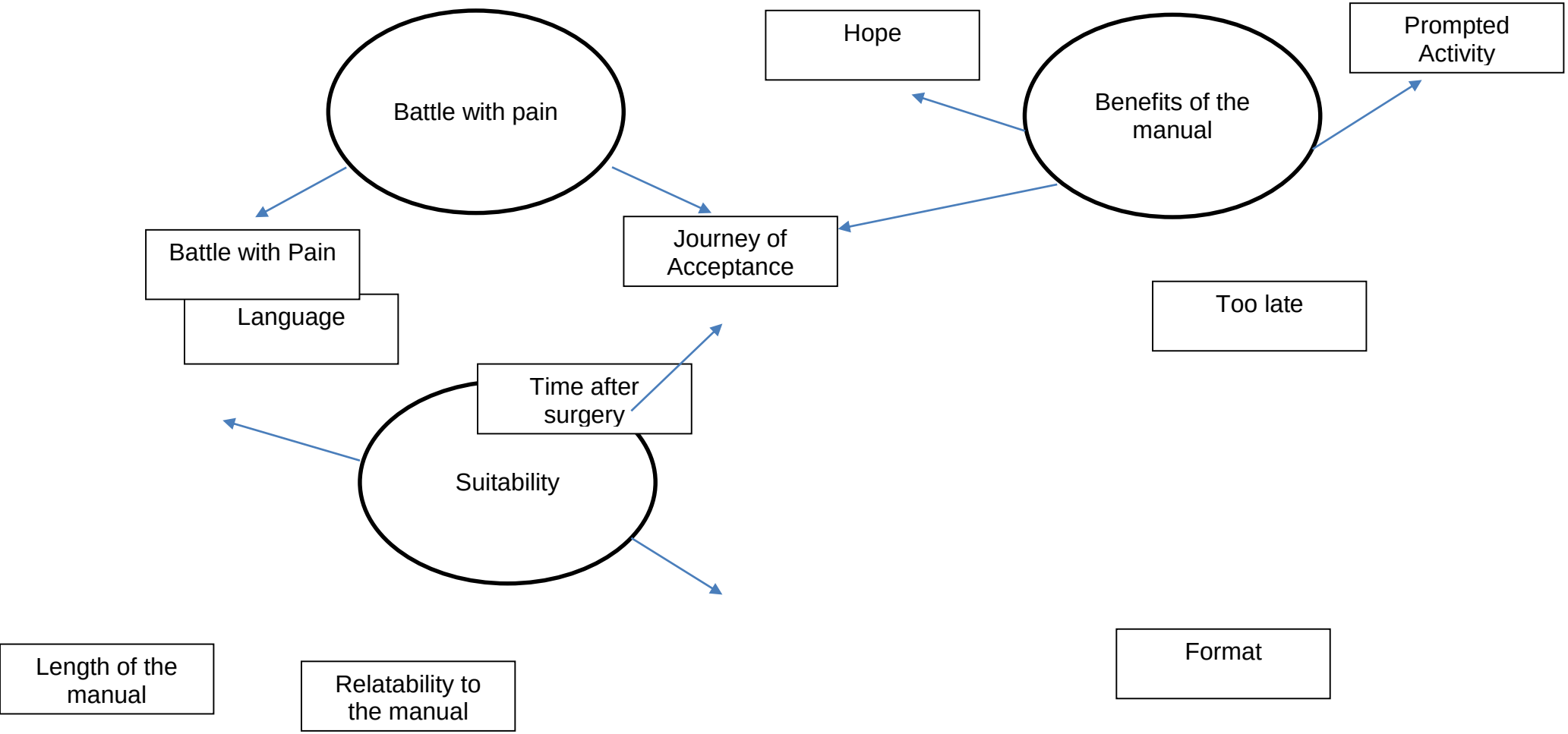
No.	Initial Code	Data Extract (line number)
1	Taken something away from it	
2	Not the solution	
3	Controlling pain the answer	
4	Prompted reflection	
5	Acceptance - difficulty in doing this?	
6	Pain battle	
7	ACT not useful in isolation	
8	Values	
9	Identified areas to continue working on	
10	Using a book - impersonal	
11	Length of book	
12	Journey	
13	Would have liked personal contact during intervention	
14	Struggling with motivation	
15	Acceptance new way of thinking	
16	Difficulty with funeral exercise	
17	Certain exercises not helpful	
18	Depression related to pain	
19	Social life impacted by CP	
20	Exercise elicited negative view of self	
21	Americanisms	
22	Exercises – long	
23	Motivation	
24	Avoidance	
25	Manual has a biased view – non medication	
26	Preference for the medical model	
27	Actively making changes	
28	Reflecting on other areas of life	
29	Used in a group format	
30	Found the content excellent	
31	Found beneficial	
32	Developed understanding of pain, different way of viewing pain	
33	Loss of life to pain	
34	How long had CP for	
35	Comparison to other psychological interventions	
35	Depth of detail in the manual	
36	Something to refer back to afterwards	
37	Internalising content	
38	Change in attitude towards pains	
39	Academic	
40	Support from others that have CP	

41	Emotional impact of CP	
42	Timeframe for completing ACT not achievable	
43	Impacts of medication on concentration	
44	Trauma	
45	Commitment needed	
46	Manual not helpful – no benefit	
47	Already developed strategies to manage pain	
48	Relatability	
49	Doesn't get rid of the pain	
50	Pain already improving	
51	Repetitive	
52	Timing of the intervention after SCS	
53	Fatigue after SCS	
54	Don't think it is specific to SCS	
55	Greif associated with pain	
56	1:1 contact for support	
57	Difficulty in comprehension of manual	
58	Thinking about things differently	
59	Felt supported	
60	New positive outlook	
61	Needed help to understand	
62	Timing – where they are at in their life	
63	Complicated	
64	Confusing	
65	Think about pain more during ACT	
66	Already keep active	

Appendix M: Early Thematic Map



Appendix N: Refined Thematic Map



Appendix O: Definition of Themes

Name of Theme	Definition	What was of interest/ Relevance to the research question
Theme One: Battle with Pain	This theme encapsulates the "fight" participants experienced in trying to control their CNP and where they currently feel they are in this battle. Whether they accept the pain or continue to fight it	This appeared to provide an insight into why some participants reported benefiting from the manual compared to those that were more negative towards the approach.
Acceptance	Refers to participants stating that they are fighting less with the pain and are more acceptant that the pain will be present in their life	Important to understand what aided acceptance, which is a key objective of ACT.
Continued fight	Refers to the participants reporting that they are going to continue trying to cure or fight against their chronic pain.	Understanding why some participants could not or did not want to foster acceptance.
Theme Two: Benefit of the manual	Refers to the positive experience, knowledge and outcomes that has occurred from completing the self-help intervention.	Important to ascertain what was effective about the intervention when considering future studies
Sub-theme: Hope	Refers to participants feeling more hopeful about their future, this may be in spite of their pain.	Hope is key to recovery. Important to ascertain what aided in the development of hope so that future interventions can build on this.
Prompting activity	Refers to participants reporting that they have engaged in a certain activity more since reading the book or references to them being less avoidant.	Importance of living a valued filled life driven by values-based goals, what aided this and the impact this has on the participants well-being
Theme Three: Obstacles	Refers to what prevented and got in the way of participants completing the manual	As this is a feasibility study importance to find ways to improve retention and the self-help manual. This theme encapsulates what may have hindered acceptance and suggest

		ways to improve for future RCTs
Language	Refers to participants reports that the language was complex.	Important to know that the manual may have alienated some of the participants, This theme could infer alterations for future studies.
Length of the manual	Refers to participants reporting that they found the manual too long or that it took too much time to complete.	Aids understanding of high drop-out rates as this was reported as a common reason for not completing,
Relatability to the content	The extent to which the participants felt the manual was useful for themselves and their pain and whether they were able to relate to material and examples given.	This manual has never been used in a SCS participant group therefore important to ascertain whether it is appropriate.
Theme Four: Suitability	Reflects the participants' experiences and opinions as to whether the current intervention is suitable to those that have CNP and been assessed for SPS surgery.	To assess whether it is suitable to complete further self-help intervention studies with the participant group.
Time after surgery	Refers to the participants that had SCS surgery and how suitable the intervention was to have once recovering from this operation.	Important information regarding the treatment design and its limitations.
Format of the intervention	Refers to the intervention being delivered in a self-help bibliotherapy. How the participants may have preferred the intervention to be delivered i.e. group and face: face.	The current format of intervention is being increasingly used in CP therefore it was important to gather the participant's perspectives regarding the format.
Too late	Those that have been assessed for SCS surgery have typically been in CP for a significant amount of time. During this time they may have adopted their own strategies or believe that they have been in CP for too long for this form of intervention to be beneficial	To assess the suitability of conducting the current intervention with participants that have been in CNP for a number of years.