Adjustment to Chronic Neck Pain – The Important Role of Cognitive Factors.

A thesis submitted to the University of Manchester for the degree of Doctor of Philosophy in the Faculty of Medical and Human Sciences.

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Chronic neck pain (CNP) is a common and disabling condition, accounting for substantial healthcare and societal costs. Previous studies have demonstrated that certain cognitive factors are related to levels of adjustment (levels of disability, pain and depression) in chronic pain conditions. However, this association has not been adequately explored in patients with CNP. The aim of study one was to determine the relationship between specific cognitive factors and levels of adjustment in participants with CNP. Furthermore, study two explored whether the relationship between the cognitive factors and levels of adjustment differed between those patients with idiopathic CNP and those with Chronic Whiplash Associated Disorder (CWAD). Finally, study three compared the efficacy of a physiotherapy led intervention, specifically designed to modify cognitive factors to a conventional physiotherapy intervention.

Study one: Hierarchical multiple regression analyses were performed. Greater catastrophizing and lower functional self-efficacy beliefs were associated with greater levels of pain and disability. Additionally, lower functional self-efficacy beliefs were also associated with greater levels of depression.

Study two: Data were dichotomised into two groups: those with CWAD and those with idiopathic CNP. T-tests were performed to compare differences in the cognitive scores and the same regression analyses as study one were performed for each sub-group. No significant differences existed between the two groups in terms of levels of pain, disability, depression or the cognitive factors. In both groups greater catastrophizing and lower functional self-efficacy beliefs were related to levels of disability. Likewise, lower self-efficacy beliefs were related to levels of depression in those participants with idiopathic CNP and those with CWAD. However, amongst those with idiopathic CNP, greater levels of catastrophizing and lower levels of pain vigilance and awareness were related to greater pain intensity. In contrast, amongst those with CWAD, none of the cognitive measures were significantly related to levels of pain intensity.

Study three: Participants were randomly allocated to either a progressive neck exercise programme or an intervention which specifically targeted the modification of cognitive factors. T-tests revealed that treatment targeting cognitive factors resulted in greater improvements in pain and pain-related fear. Moreover, χ² tests revealed that a greater proportion of patients made clinically meaningful reductions in pain and disability in the group targeting cognitive factors.

This thesis highlights that cognitive factors play an important role in determining levels of adjustment in patients with CNP. Furthermore, treatments designed to specifically target these factors result in superior clinical outcomes when compared to conventional physiotherapy interventions.
Declaration

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<td>CCM</td>
<td>Communal Coping Model</td>
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<td>CLBP</td>
<td>Chronic Low Back Pain</td>
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<td>CNP</td>
<td>Chronic Neck Pain</td>
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<td>CPSS</td>
<td>Chronic Pain Self-efficacy Scale</td>
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<td>CWAD</td>
<td>Chronic Whiplash Associated Disorder</td>
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<td>FAM</td>
<td>Fear Avoidance Model</td>
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<td>HADS</td>
<td>Hospital Anxiety and Depression Scale</td>
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<td>HADS-d</td>
<td>Hospital Anxiety and Depression Scale depression subscale</td>
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<td>IBMT</td>
<td>Interactive Behavioural Modification Therapy</td>
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<td>KMO</td>
<td>Kaiser-Meyer-Olkin</td>
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<td>LBP</td>
<td>Low Back Pain</td>
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<td>MCIC</td>
<td>Minimum Clinically Important Change</td>
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<tr>
<td>METs</td>
<td>Metabolic Equivalents</td>
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<td>mNDI</td>
<td>modified Neck Disability Index</td>
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<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<tr>
<td>MVC</td>
<td>Motor Vehicle Collision</td>
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<td>NDI</td>
<td>Neck Disability Index</td>
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<td>NPQ</td>
<td>Northwick Park Neck Pain Questionnaire</td>
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<td>NRS</td>
<td>Numeric Rating Scale</td>
</tr>
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<td>PCS</td>
<td>Pain Catastrophizing Scale</td>
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<td>PNEP</td>
<td>Progressive Neck Exercise Programme</td>
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<td>PSWD</td>
<td>Pulsed Short Wave Diathermy</td>
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<td>PTSS</td>
<td>Post Traumatic Stress Symptoms</td>
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<td>PVAQ</td>
<td>Pain Vigilance and Awareness Questionnaire</td>
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<tr>
<td>RCT</td>
<td>Randomised Control Trial</td>
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<tr>
<td>SMART</td>
<td>Specific, Measurable, Achievable, Realistic, Timed</td>
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<td>TSK</td>
<td>Tampa Scale for Kinesiophobia</td>
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<td>UK</td>
<td>United Kingdom</td>
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<td>VAS</td>
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<td>Variance Inflation Factor</td>
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<td>WAD</td>
<td>Whiplash Associated Disorder</td>
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Dedication

I would like to dedicate this PhD to Becky. Thanks for all of your support and encouragement and for keeping me going when times were tough.

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Studies one and two: The relationship between cognitive factors and levels of adjustment in patients with chronic neck pain.

1.0 Introduction

1.1 Prevalence of neck pain in the United Kingdom

Epidemiological studies have suggested that neck pain is a common and disabling condition in the United Kingdom (UK). In a large, well designed study, Croft and colleagues\textsuperscript{1} collected data relating to the presence of neck pain from patients registered with two general practices in Manchester, UK. Postal questionnaires were sent to 7669 patients, of whom 4393 provided data regarding neck pain. Of those providing data, 17.9\% experienced neck pain at some point during the previous year, with many experiencing episodic or recurrent symptoms. Similarly, Walker-Bone and co-workers (2004)\textsuperscript{2} conducted another large-scale trial, mailing questionnaires to 9696 patients registered with two general practices in Southampton, UK. Useable data were returned by 6038 (62.3\%) of those receiving the questionnaire, with 21\% of participants experiencing neck pain within the last seven days and 14\% reporting difficulties in performing their usual activities because of neck pain.

In a further epidemiological study conducted in the West Pennine region of Greater Manchester, Webb and co-workers\textsuperscript{3} reported that 13.8\% of participants recalled having neck pain in the previous month, with 5.9\% reporting that they had experienced neck pain for five years or more. Pain was described as moderate or severe by 7.8\% of the participants, 7.5\% found their pain disabling and 2.8\% were consequently unemployed. Moreover, a longitudinal study\textsuperscript{4} collected follow up data from 4501 patients registered with general practices in South Manchester. The study reported that 31\% of participants had experienced neck pain within the last month, with 48\% of these participants reporting ongoing symptoms when followed up after one year.
The aforementioned studies collected data from different urban areas of the UK. Given that generally similar trends were observed, the results reported are likely to generalise to the majority of the UK population, although it cannot be excluded that incidence may differ amongst more rural populations. Moreover, given that the studies employed robust methodology and recruited large numbers of participants, it is likely that these results can be considered reliable. In view of this, it would appear that up to 31% of the UK adult population experience neck pain at any one time, with many experiencing recurrent or chronic symptoms. Furthermore, between 7.5% and 14% of the population appear to experience some degree of disability because of their neck pain.
1.2 Costs related to chronic neck pain

Previous studies have demonstrated that indirect costs related to disability are responsible for the majority of expenditure associated with patients with chronic pain conditions\textsuperscript{5,6}. Whilst no studies have specifically explored the economic burden associated with neck pain in the UK, Borghouts and colleagues\textsuperscript{7} estimated that the total annual cost of neck pain in the Netherlands was US$ 686.2 million, approximately 1\% of Dutch healthcare budget and 0.1\% of total GDP. Fifty percent of costs were estimated to be related to disability caused by neck pain, whilst direct healthcare expenditure accounted for a further 23\% of total costs. Data reported by Borghouts were derived from a number of sources in order to ensure that financial estimates reflected actual costs as closely as possible. Although some assumptions were required in their calculations, the study was well conceived and it is likely that their estimates are a fair reflection of actual neck pain-related costs in the Netherlands.

Given that both the Netherlands and the UK are developed Western European countries, it is plausible that a similar proportion of healthcare and societal expenditure may be attributable to neck pain in the UK. Moreover, it would appear that neck pain-related disability accounts for the majority of expenditure. It is therefore imperative to identify factors associated with prolonged disability in patients with neck pain, so efficacious interventions can be developed to help to reduce levels of disability. This may, in turn, result in reductions in both healthcare and societal costs which result from neck pain related disability.
1.3 Factors associated with neck pain and disability

1.3.1 Are epidemiological and health-related factors associated with neck pain and disability?

Several demographic and health-related factors have been shown to be related to the onset of neck pain and neck pain-related disability in large, well designed epidemiological studies. Webb and colleagues demonstrated that older age and female sex were related to neck pain, whilst South Asian ethnicity was associated with neck pain-related disability in a high-quality longitudinal study of 4515 recruited from a comprehensive sample of the Greater Manchester population. Moreover, Hansson et al reported data on 1822 Swedish participants sick listed because of neck or back pain. In this study, return to work was most strongly predicted by self-reported quality of life score, with those with the lowest quality of life least likely to return to work. Although this study utilised appropriate methodology for the population of interest, it should be noted that only sick listed patients were recruited to the study. It is therefore unclear the extent to which quality of life influences prognosis in non-sick listed individuals.

In a further study, Côté and collaborators reported factors associated with neck pain in the Canadian population. Several co-morbidities were associated with the presence of neck pain. Specifically, cardiovascular and digestive disorders, concomitant headaches and low back pain were all associated with neck pain. Furthermore, Côté also reported associations between neck pain and cigarette smoking, better general health and involvement in a motor vehicle collision (MVC). Bot and co-investigators explored predictors of outcome in participants recruited from the Dutch general population. Factors found to be associated with worse outcome at one year follow up included less intense pain at baseline, longer pain duration at presentation, bilateral shoulder pain, older age, paraesthesia of the hands, other musculo-skeletal symptoms, worse perceived health, worse quality of life and low vitality.
Finally, Gun et al reported on factors associated with prolonged disability after whiplash injury\textsuperscript{10}. The study recruited 147 patients post MVC and followed up 135 after 12 months, identifying factors related to poor outcome. It should be noted that this study recruited a much smaller sample than the studies discussed previously. Moreover, as only patients with Whiplash Associated Disorder (WAD) were included, findings may not be applicable to patients with idiopathic CNP. Nevertheless, Gun reported that low baseline function scores, consulting a lawyer, prior claim for a MVC and requiring treatment by a physiotherapist or chiropractor were associated with worse outcome.

From the studies discussed previously, it is evident that health and demographic factors are important determinants of both the presence and persistence of pain, and of greater levels of neck pain-related disability. Specifically, female sex, greater pain duration, South Asian ethnicity, being a current smoker, poor general health, lower quality of life, less vitality, concurrent LBP, headaches, other musculoskeletal, cardio-vascular or digestive co-morbidities and involvement in a motor vehicle collision (MVC) have all been shown to be related to poor patient outcomes.
1.3.1 Are motor vehicle collisions related factors related to neck pain and disability?

Interestingly, although involvement in a MVC has been associated with the onset of neck pain and greater levels of chronic disability\(^1,3\), some studies suggest that collision related factors are not strongly related to either pain severity or duration, or to long terms level of level of disability\(^10-13\). In the aforementioned longitudinal study, Gun et al reported no significant association between the direction of collision, presence of a headrest, patients’ position in the car or whether the vehicle was drivable after the accident\(^10\). Similarly, in a two year follow up study, participant’s subjective rating of crash severity was not related to outcome. In contrast, the authors reported that an inclined or rotated head position at the time of the collision was more prevalent amongst symptomatic participants at two year follow up\(^11\).

However, it should be noted that the above study recruited only approximately 57% of individuals estimated to have been involved in MVC in the study area. Moreover, participants were recruited via physicians, who referred the participants to the research team. It is feasible that this led to sample bias; i.e. those participants involved in MVC who did not experience pain after the collision would not have been recruited into the trial. Many of these participants may have had a rotated or inclined head posture at the time of the accident, but experienced no pain symptoms. On this basis, an inclined or rotated head posture can only be considered to be associated with pain amongst symptomatic patients, rather that the whole population.

Kasch and co-workers explored the relationship between seatbelt and headrest use, difference in weight of vehicles and difference in speed of vehicles in a follow up study of 141 patients with neck injury after a MVC. No significant associations were reported between any of these variables and levels of pain and disability at six month follow up\(^12\). Moreover, Malik and Lovell explored the incidence of WAD in high energy MVC resulting in significant lower limb or pelvic fractures. Interestingly, only 5.5% of participants reported neck pain after the collision, with symptoms being transient in nature\(^13\). This study implies that
ongoing neck pain following a MVC cannot be solely accounted for by the degree of trauma experienced in the collision. Logically, if CNP following MVC was simply the result of a musculo-ligamentous injury, it would be expected that significant symptoms would arise from high energy collisions. That this was not the case suggests that other factors may play an important role in determining long term pain and disability after MVC. Indeed, Atherton and colleagues demonstrated that when multivariable modelling was employed, psychosocial distress and pre-crash health factors were greater predictors of persistent neck pain than crash-related factors\textsuperscript{14}.

In view of the studies discussed previously, it would appear that involvement in a MVC increases the incidence of neck pain and associated disability. However, this cannot be accounted for solely by seatbelt or headrest use, position in the car, severity of collision or speed of the vehicles involve. An inclined or rotated head position at the time of the collision may influence outcome to some extent, but is unlikely to be the primary defining factor in explaining why some individuals involved in MVC experience chronic symptomology whilst others do not. Therefore, it is likely that other factors are involved in the onset or persistence of neck pain in patients involved in MVC.
1.3.2 Are mechanical factors related to neck pain and disability?

It has been postulated that certain mechanical factors, such as limitation of cervical motion, decreased muscle strength and reduced muscle endurance may be significant determinants of pain in chronic musculoskeletal disorders, such as WAD or idiopathic CNP. For example, in the aforementioned study, Kasch and co-workers demonstrated an inverse relationship between cervical range of movement and neck pain in the six months following MVC. In contrast, Ylinen and colleagues reported no association between range of motion and neck pain and disability in 179 patients with non-specific CNP. It should be noted however that, although Ylinen et al employed robust methodology and recruited an adequate sample size, the study population was exclusively female clerical workers aged 25-53. Indeed the authors themselves acknowledge that female cervical musculature is relatively weaker than in males and deteriorates beyond the age of 60. It is therefore feasible that the associations between range of movement and neck pain may differ in males and in older populations. However, it is also feasible that similar associations may exist and further research is warranted to clarify this point.

Falla and co-investigators demonstrated a reduction in cervical muscle endurance in patients with CNP, as compared to matched controls. However, the population examined in this study was somewhat small, with only 10 patients included in each group, limiting the strength of the conclusions that can be drawn. Conflicting results have been reported regarding levels of muscle activation in patients with WAD. A methodologically sound study of 66 participants with WAD and 20 healthy controls reported increased muscle activation in participants with WAD as compared to healthy controls. Contrastingly, Nederhand et al reported no increased muscle activation patterns in a robust longitudinal study of 92 participants with WAD. Moreover, Nederhand reported that muscle activation was actually decreased in those reporting the greatest levels of pain and disability.

The aforementioned studies demonstrate that, although physical factors may play some role in the development and maintenance of neck pain, they are
unlikely to fully account for levels of pain and disability. Moreover, given that conflicting findings have been reported relating to the relationship between patterns of muscle activation and levels of pain and disability, strong conclusions cannot be drawn as to whether muscle activation is an important determinant of CNP. On the basis of this, it is apparent that mechanical factors alone can not fully explain the persistence of neck pain in some patients.
1.3.3 Are degenerative changes and soft tissue abnormalities related to pain and disability?

Some authors have suggested that degenerative changes of the cervical spine may account for levels of pain and disability in patients with CNP\(^16\). Despite the common use of radiological investigations in these patients, previous studies have been unable to consistently demonstrate a significant relationship between levels of pain intensity, disability, and degeneration of the cervical spine. Marchiori and colleagues\(^{15}\) reported no significant association between intervertebral degenerative changes and levels of pain and disability when they examined their whole population. Sub group analysis did reveal a significant association between degeneration and disability in females with neck pain of between one and five years duration, but not in men or women with neck pain for less than one year or more than five.

However, significant methodological considerations exist with this study\(^{15}\). Firstly, the mean age of the population was only 33.4, meaning that the extent of inter-vertebral degenerative changes was likely to be minimal in many participants, given that such degenerative changes are more prevalent in individuals aged 40 and above\(^{19}\). Consequently, significant relationships between more advanced degenerative changes and levels of pain and disability may not have been considered and the results are therefore unlikely to be generalisable to the population as a whole.

Secondly, multiple comparisons were examined when exploring sub-group interactions, however, no Bonferroni corrections were performed. This may mean that the significant association observed between inter-vertebral degeneration and levels of disability in women with neck pain for between one and five years was a type I error. Further credence can be leant to this notion given that no relationship was observed between degeneration and disability in women with neck pain for greater than five years. Given that inter-vertebral degeneration is known to worsen with increasing age\(^{19}\), it is unlikely that this association would disappear completely in female participants once pain had been present for five years or more.
Finally, Marchiori and co-workers did not consider the relationship between zygapophysial joint degeneration and levels of pain and disability. This limitation was addressed by Peterson and co-workers in a study of 180 patients with CNP\textsuperscript{16}. Additionally, Peterson et al recruited an older population (mean age=49), in which degenerative changes were more likely to be prevalent and which is more likely to be representative of the UK population as a whole. The study reported no significant association between levels of pain and disability and degenerative changes of the zygapophysial joints, uncovertal joints or inter-vertebral discs on plain x-ray. Similar results were also reported by a well designed study of 251 patients undergoing magnetic resonance imaging (MRI) scans of the cervical spine\textsuperscript{17}. MRI scans are considered to be the most sensitive method of imaging the cervical spine\textsuperscript{19} and the study benefitted from employing validated measures of pain and disability. Furthermore, the mean age of the participants (44) meant that patients with significant degenerative changes were likely to have been included. No correlations were observed between functional ability and pain and levels of inter-vertebral or zygapophysial degeneration in this study.

Other authors have suggested that atlanto-odontoid osteoarthritis is a significant cause of sub-occipital pain\textsuperscript{18}. Moreover, Zapletal and colleagues posited that atlanto-odontoid osteoarthritis is often obscured by the skull on plain x-ray, accounting for the lack of significant association between degenerative changes and pain in the studies discussed previously. The authors presented results from 210 computerised tomography scans of the atlanto-odontoid junction, with all scans were performed for reasons other than neck pain. The presence and grade of atlanto-odontoid osteoarthritis was significantly associated with sub-occipital pain, however, pain was assessed simply by asking patients if they had pain in the sub-occipital area. Sub-occipital pain was not clearly defined by the authors and it is therefore unclear to what extent sub-occipital pain can be considered synonymous with neck pain. Moreover, it is unclear whether the measure of pain utilised by the authors is validated for this population, whilst no measure of disability was included in the study.
It has also been postulated that abnormalities of the soft tissues of the cervical spine may be related to levels of pain and disability. However, such abnormalities have been shown to be common in asymptomatic subjects and not predictive of development of neck pain. For instance, a study conducted with 31 high school graduates revealed that many asymptomatic participants exhibited disc degeneration, disc protrusion and annular tears on MRI scan. Moreover, at 7 year follow up, such abnormalities were again common and no association between pain and disc protrusion, disc degeneration or annular tear was demonstrated. Only disc herniation was shown to be significantly associated with greater pain intensity. Furthermore, a study (n=20) comparing discography to MRI findings demonstrated that nine out of ten pain free subjects had bulging or torn annuli on MRI scan at at least one cervical level, whilst a study of 50 asymptomatic participants demonstrated that joint effusion at C1-C2 level and asymmetry of the alar ligaments, cranio-cervical junction and C1-C2 joint is common in pain free subjects. These studies recruited relatively small sample sizes, meaning that results should be interpreted with caution. However, given the consistent theme amongst these studies, it would appear that soft-tissue abnormalities of the cervical spine are relatively common and do not appear to be significant determinants of neck pain and disability.

In light of the above findings, it would appear that degenerative changes of the inter-vertebral disc, zygapophysial joints and uncovertabral joints are not significantly related to levels of pain or disability. Atlanto-odontoid osteoarthritis may contribute to sub-occipital pain, however, it is unclear whether this is a common cause of neck pain and further research is warranted. Finally, soft tissue abnormalities of the cervical spine appear to be common and do not appear to be significantly related to neck pain in most instances.
1.4 Summary of the contributing factors and sequelae of neck pain

It is apparent from the studies discussed previously that CNP results in significant healthcare and societal costs, many of which are attributable to disability associated with this condition. Several epidemiological and health-related factors have been implicated in the development and persistence of neck pain, however, many of these factors are not amenable to treatment (for example, a person cannot change their pain duration). Involvement in a MVC appears to increase the risk of developing CNP, although impact related factors do not appear to underpin the onset or severity of pain. Mechanical factors, degenerative changes and soft tissue abnormalities do not fully account for the onset of neck pain, nor do they account for the degree of variability in disability observed in these patients. Consequently, alternative models are required to adequately explain the high prevalence of disability amongst patients with chronic neck pain.
2.0 The Role of cognitive factors in chronic pain.

Despite the high prevalence of chronic neck pain, only a small percentage (14%) of these patients experience chronic disability\textsuperscript{2}. It is therefore evident that disability levels cannot be explained by epidemiological and health-related factors alone. Consequently, alternative theories have been proposed to explain levels of disability in individuals who experience chronic pain. Much of the research examining the causes of disability in patients with chronic pain has been conducted in participants with chronic low back pain (CLBP) or samples of patients with heterogeneous chronic pain conditions. Therefore, the following section will discuss the literature relating to participants with other chronic pain conditions, as well as those with chronic neck pain.
2.1 The fear avoidance model

The fear avoidance model (FAM) was proposed by Lethem et al\textsuperscript{23} to explain the apparent disparity between pain intensity and disability in patients with chronic low back pain. It was further extended by Vlaeyen and colleagues\textsuperscript{24}, who proposed the contemporary model of fear avoidance which pervades in the literature. The model (Fig. 1) suggests that when a patient encounters a painful experience they respond with varying degrees of catastrophizing. Those who do not interpret pain as threatening confront their pain, which ultimately leads to recovery. However, those patients who interpret pain as dangerous and/or harmful develop fear of movement/(re)injury leading to avoidance of activity and ultimately to disuse, disability and depression\textsuperscript{24}. Since the initial inception of the Fear Avoidance Model, subsequent versions of the model have been proposed. For instance, a recent model suggests that hypervigilance to pain should form an integral facet of the FAM\textsuperscript{25}, although there is currently a lack of strong empirical support to support this. Much of the literature that has explored the relation between cognitive factors and levels of adjustment has used the FAM as a theoretical basis. Therefore, the following section will review the relation between each of the cognitive variables associated with the FAM and levels of adjustment.

A structured literature search was performed using the Medline database in January 2005. The search terms “catastrophizing” or “catastrophising” or “catastrophization” or “fear avoidance” or “fear” or “pain related fear” or “fear of pain” “Kinesiophobia” or “pain vigilance” or “pain awareness” or “vigilance and awareness” or “hypervigilance” and “pain” or “back pain” or “neck pain” or “disability” or “depression” or “adjustment” or “function*” were entered into the Medical Search Headings (MeSH) database of Medline. Where possible these terms were exploded and entered into the Medline search. However, not all of the search terms of interest were included in MeSH sub-headings. Therefore the search was also undertaken with the aforementioned terms entered directly into the Medline database to ensure that all relevant articles were identified. The literature search was then repeated every six months to ensure that any
relevant new literature was included in the search. The final search was undertaken in January 2011, after which point final preparation of the thesis was undertaken.

Articles which included the search terms outlined above in the title or key words were identified and, where available, the abstracts were obtained. The abstracts were then reviewed and any articles which employed methodology exploring the relationship between the aforementioned cognitive factors (pain-related fear, catastrophizing, pain vigilance and awareness and self-efficacy beliefs) and levels of pain, disability or depression were obtained and critically appraised.

No restrictions were placed on where study participants were recruited from (e.g. healthcare setting or the general population) and studies employing cross-sectional and longitudinal methodology, as well as sub-analyses from other studies (e.g. randomised controlled trials) were included. However, editorials and opinion articles were not included in the search, as they did not present new empirical data. In instances where the abstract could not be reviewed the full article was obtained and reviewed to ensure that relevant articles were not excluded. A manual search of the reference lists of each article was then undertaken to ensure that any articles which had not appeared in the original search were identified.
Figure 1 The fear avoidance model (Vlaeyen et al, 1995)
2.2 Catastrophizing

Catastrophizing has been defined as “an excessively negative orientation toward pain”\(^{26}\). According to the Fear Avoidance Model\(^ {24}\), the extent to which an individual catastrophizes ultimately determines whether they confront or avoid pain. Specifically, the model proposes that confrontation ultimately leads to recovery, whereas avoidance leads to chronic disability.

2.2.1 The role of catastrophizing in chronic pain populations

Several studies have examined the relation between catastrophizing and levels of pain intensity in participants with chronic pain conditions. Severeijns and colleagues\(^ {27}\) reported on 211 patients with CLBP, chronic musculoskeletal pain or chronic non-musculoskeletal pain referred for treatment at a pain management clinic. Catastrophizing was found to be a strong predictor of pain intensity in all three clinical populations. Moreover, the strength of the relation between catastrophizing and pain did not differ significantly between the three groups, suggesting that the mechanisms which underpin the relation between catastrophizing and pain may be independent of the pain condition that the patient is experiencing.

In support of these findings, a further study explored the relationship between catastrophizing and pain intensity in 100 patients with CLBP referred for treatment in a pain management clinic. This study had an additional advantage, in that the effects of physical pathology were controlled for prior to assessing the influence of catastrophizing. Indeed, catastrophizing was still found to be significantly related to pain intensity, even after controlling for the effects of physical pathology\(^ {28}\). In further support of the above findings, Woby and colleagues\(^ {29}\) reported that catastrophizing was significantly related to pain intensity in 178 patients with CLBP referred for out-patient physiotherapy. These studies benefit from recruiting participants from clinical populations, meaning that the results are likely to be relevant to other patients treated in a
pain clinic or physiotherapy environment. However, it could be argued that the highly specific treatment context from which these studies recruited their participants means that the results cannot be applied to other populations.

However, this limitation is addressed, at least in part, by population based study of patients with musculoskeletal pain. Boersma and Linton\textsuperscript{30} performed a cluster analysis of 81 participants, reporting that participants in the group with the greatest level of catastrophizing experienced higher levels of pain than those with either medium or low levels of catastrophizing. In contrast, Linton\textsuperscript{31} reported a weaker relationship between catastrophizing and pain intensity in a sample of 209 patients with CLBP recruited from the general population. It should be noted that psychological distress was strongly related to pain intensity in this study. Moreover, the study’s author argued that there is significant conceptual overlap between catastrophizing and psychological distress and that this may explain the non-significant relation between catastrophizing and pain observed in that study\textsuperscript{31}. In spite of this, the above studies suggest that catastrophizing is strongly associated with levels of pain in populations referred for rehabilitation, although this relationship may be of a smaller magnitude amongst the general population.

A possible mechanism underpinning the relationship between catastrophizing and the development of chronic pain may be provided by studies which have explored brain activity using functional magnetic resonance imaging (fMRI) scans. Such studies have demonstrated an association between greater catastrophizing and altered activity in the cortical regions associated with pain interpretation in both healthy volunteers\textsuperscript{33} and patients with fibromyalgia\textsuperscript{34}. Specifically, increased activity was observed in the cortical regions associated with affective, attention and motor aspects of pain, whilst greater catastrophizing was also associated with decreased top-down modulation of pain. These changes in levels of activation of specific brain regions may underscore why catastrophizing has consistently been associated with increased pain intensity in patients with chronic pain.
In addition to the association between catastrophizing and pain intensity, several studies have also explored the relation between catastrophizing and disability in patients with chronic pain. Sullivan and colleagues\textsuperscript{35} reported on 86 participants recruited from a chronic pain clinic with chronic neck, shoulder or back pain following a MVC. They reported that, after accounting for the effects of pain, catastrophizing explained an additional 4% of the variance in disability and an additional 9% of work disability. Whilst this study highlights the association between catastrophizing and disability, the findings of Sullivan and colleagues would suggest a relatively weak relationship.

However, other studies have reported stronger associations between catastrophizing and disability. Indeed in a study of 211 patients referred for treatment in a hospital pain clinic, Severeijns et al\textsuperscript{27} reported that catastrophizing accounted for 18% of disability, even after controlling for the effects of age, pain duration, pain intensity and physical impairment. Moreover, Severeijns and colleagues reported that there was no significant difference in the association between catastrophizing and levels of disability in three groups of patients with different types of chronic pain (CLBP, chronic musculoskeletal pain and chronic non-musculoskeletal pain). This suggests that the effects of catastrophizing on disability may be independent of the condition experienced by the patient.

Two further studies support the notion of a strong relation between catastrophizing and disability. In a well designed study of 1208 patients with heterogeneous chronic pain conditions, Lamé et al\textsuperscript{36} reported that catastrophizing was strongly related to levels of disability and quality of life, even when pain intensity and other psychological variables were considered. As with the studies discussed above, Lamé and colleagues recruited participants from a hospital clinic environment. However, Boersma and Linton\textsuperscript{30} performed cluster analysis of 81 participants with musculoskeletal chronic pain problems who were recruited from the general population. The analysis identified five distinct clusters, with those patients with the greatest levels of catastrophizing also reporting the greatest levels of disability. It should be noted however that, although the methodology employed by Boersma and
Linton is sound, their method of recruitment may mean that their sample is not truly representative of the general population. They recruited participants via a newspaper advertisement, which may have led to responder bias, with individuals who were more affected by their symptoms being more likely to respond. Moreover, as only 81 participants were included in the study, a larger sample would be required before these results could be confidently extrapolated to the entire population.

In contrast to the studies discussed previously, not all studies have reported an association between catastrophizing and levels of disability. Peters et al\textsuperscript{28} reported that catastrophizing did not significantly add to the prediction of disability when the effects of physical pathology were accounted for in a study of 100 patients with CLBP referred to a pain management centre. Similarly, Woby and co-workers\textsuperscript{29} reported that catastrophizing did not account for unique variance in disability in 178 patients with CLBP who were referred for physiotherapy. However, it is noteworthy that both of the above studies considered other cognitive variables alongside catastrophizing. Whilst Peters et al did not report a significant association between catastrophizing and disability, pain-related fear did add to the prediction of disability levels. Moreover, Woby and co-investigators also considered other cognitive variables alongside catastrophizing, reporting that reduced functional self-efficacy beliefs displayed the strongest association with levels of disability.

It is possible that the relation between catastrophizing and disability is mediated by other factors, such as pain-related fear or self-efficacy beliefs, thus reducing the strength of the association between catastrophizing and disability when these factors are considered. This may account for why some studies have not reported a significant relationship between catastrophizing and disability. Indeed, Cook et al\textsuperscript{38} demonstrated that pain-related fear mediated the relationship between catastrophizing and disability in patients with chronic pain. To the author’s knowledge, no previous studies have explored whether self-efficacy mediates the relation between catastrophizing and disability. However, a previous study reported that self-efficacy beliefs mediated the relation between pain-related fear and disability\textsuperscript{37}. In view of the relationship between
catastrophizing, pain-related fear and disability proposed by the FAM, it is possible that self-efficacy beliefs mediate the relation between catastrophizing and disability in a similar manner.

In light of the studies discussed previously, a general trend appears to support an association between catastrophizing and levels of disability, although the strength of this relationship may differ amongst different populations. Specifically, a weaker relationship was observed in Sullivan and colleagues cohort of participants recruited following a MVC. It is plausible that catastrophizing exerts a lesser influence on levels of disability in participants who experience pain following a MVC than in other populations, however, future studies are required to adequately delineate this relationship.

However, the aforementioned studies do not provide explicit evidence of a causative relationship between catastrophizing and levels of pain and disability. To address this concern, several studies have collected data pertaining to levels of catastrophizing in pain-free populations, who have then been followed up at a later time point. For example, Linton\(^\text{31}\) collected data from 1914 participants, representative of the Swedish general population. Amongst those free of pain at baseline, those displaying greater levels of catastrophizing were three times more likely to develop pain at one year follow up.

This finding supports an earlier large, well designed population-based study of 1571 participants, thought to be representative of the Dutch general population. The study reported that participants who were free of pain at baseline but still displayed elevated levels of catastrophizing were 1.7 times more likely to have CLBP and three times more likely to have severe LBP at three month follow up\(^\text{26}\). Moreover, participants with greater catastrophizing had a three fold risk of developing back pain with disability. Similarly, Severeijns et al\(^\text{32}\) recruited 1888 participants from the Dutch population in a well designed longitudinal study. In this study, catastrophizing amongst pain free participants was associated with development of chronic pain at six month follow up. Although the magnitude of this relationship (OR=1.2) was somewhat smaller than reported in other studies,
this still highlights that catastrophizing may play a significant role in the
development of chronic pain conditions.

Taken together, the above studies support findings from cross sectional
analyses examining the relationship between catastrophizing and levels of pain
and disability. It therefore appears that, not only does catastrophizing play a
role in the development of chronic pain, it also predisposes individuals who
excessively catastrophize to experience increased levels of pain and disability.

As discussed earlier, the FAM conceptualises catastrophizing as a cognitive
process which affects disability via its influence on an individual’s behaviour.
However, other authors have argued that rather than being a cognition,
catastrophizing is a coping strategy employed by individuals with chronic pain.
Sullivan et al\textsuperscript{39} proposed the Communal Coping Model (CCM) of pain
catastrophizing, postulating that individuals with high levels of catastrophizing
exaggerate pain expression in an effort to solicit greater social support and
empathy from others. However, by exaggerating pain responses in this
manner, individuals who catastrophize to a greater extent may inadvertently
increase the aversive experience of pain. Moreover, increased social support
resulting from catastrophizing further encourages this mal-adaptive style of
coping, resulting in greater levels of disability.

Previous studies have reported a significant association between
catastrophizing and perceived level of social support\textsuperscript{40} and greater interpersonal
problems\textsuperscript{41}. However, it should be noted that the study of Keefe and
colleagues\textsuperscript{40} was conducted in patients with gastrointestinal cancers. The
potentially life-threatening nature of carcinoma may mean that responses from
these participants may not generalise to other chronic pain conditions which do
not result in imminent mortality.

Sullivan and co-workers\textsuperscript{42} also demonstrated that student volunteers with higher
levels of catastrophizing displayed greater pain behaviour during a cold pressor
test when they were being observed than when they were not. The presence of
an observer did not influence pain behaviour in participants exhibiting low levels
of catastrophizing, suggesting that patients with higher levels of catastrophizing alter their behaviour depending on the social interactions. However, these studies do not provide conclusive support for the CCM, they merely demonstrate that as well as influencing adjustment, catastrophizing also influences social interactions. If catastrophizing is indeed a mal-adaptive form of coping, it would be expected that social interactions would underpin the relation between pain, disability, depression and catastrophizing. However, in a study of 1356 chronic pain patients, Buenaver et al\textsuperscript{43} reported that interpersonal relationships did not strongly mediate the relation between catastrophizing and levels of adjustment. This suggests that processes suggested by the CCM are not the primary mechanism by which catastrophizing influences adjustment in patients with chronic pain.

Furthermore, previous studies which have carried out factor analysis on various purported coping strategies have consistently shown that catastrophizing correlates poorly with other coping strategies\textsuperscript{39}. Moreover, individuals with high levels of catastrophizing do not appear to differ from those with lower levels of catastrophizing with respect to the coping strategies they employ\textsuperscript{39}. Together, these findings appear to suggest that catastrophizing is distinct from coping styles and that inter-personal and social relationships cannot fully account for the relation between catastrophizing and adjustment. This would seem to imply that catastrophizing is a unique cognitive process, as the FAM would suggest, rather than a coping response as advocated by the CCM.

The association between catastrophizing and depression has been explored less extensively than its relation to pain and disability. However, previous studies have reported that greater levels of catastrophizing are related to greater depressive symptoms. In the study described previously, Severeijns and colleagues\textsuperscript{27} reported that catastrophizing was strongly related to psychological distress, including a measure of depression in patients with CLBP, chronic musculoskeletal pain and chronic non-musculoskeletal pain. In agreement with this finding, Buenaver et al\textsuperscript{43} reported that catastrophizing was strongly related to depressive symptoms in 1365 patients with chronic pain. The FAM suggests that catastrophizing leads to fear of movement/(re)injury and
avoidance behaviour and it is this which ultimately results in depression\textsuperscript{24}. A previous study employing structural equation modelling supported the mediating role of pain-related fear between catastrophizing and depression in older patients, however, in middle aged patients the model fit was significantly improved by allowing catastrophizing to directly predict depression\textsuperscript{38}. This suggests that, at least in middle aged patients, greater catastrophizing results directly in greater levels of depression.

It is understandable that constantly ruminating about the negative consequences of pain, a lack of feeling of control over pain and a belief that pain is only going to worsen would be related to an increase in depressive symptoms. This has led some authors to argue that catastrophizing is a symptom of depression, rather than a separate construct\textsuperscript{44}. However, in a study of 85 patients with chronic musculoskeletal pain conditions, path analysis suggested that catastrophizing mediated the relation between depression and the evaluative and affective aspects of pain, though not the sensory aspect\textsuperscript{45}. Geisser and associates highlight that this supports the viewpoint that catastrophizing is a psychological construct in its own right, rather than merely being a symptom of depression.

The above studies therefore appear to support the proposed relationship between catastrophizing and levels of depression. However, further research is required to fully delineate whether a causative relationship exists between catastrophizing and levels of depression.
2.2.2 The role of catastrophizing in patients with neck pain

The studies discussed previously suggest that levels of catastrophizing may be important determinants of levels of adjustment in patients with chronic pain conditions. In addition, several studies have explored the relationship between catastrophizing and adjustment in patients with neck pain. For example, Söderlund et al\textsuperscript{46} conducted a RCT in which patients with acute neck pain following a MVC were randomised to receive one of two different home exercise programmes. Participants who displayed greater levels of catastrophizing at entry to the trial were likely to report persistence of symptoms (defined as pain intensity greater than 1 on an 11 point numeric rating scale; NRS) at six month follow up, regardless of treatment received.

In contrast to the above study, Kivioja and co-workers\textsuperscript{47} reported that catastrophizing score at onset of pain was not related to the persistence of pain at one year in participants reporting acute neck pain following a MVC. However, it is noteworthy that Kivioja and colleagues assessed persistence of neck pain by means of a simple dichotomous outcome (pain present yes/no), rather than a NRS or VAS. The sensitivity and responsiveness of this dichotomous outcome is unclear, which may restrict the conclusions that can be drawn from this study. Feasibly, in the study of Kivioja et al, some participants may have had very mild ongoing pain but still responded “yes” on the dichotomous measure. Those participants would then be indistinguishable from participants who experienced more severe ongoing pain. In contrast, the reliability and responsiveness of NRS are well established in chronic pain populations\textsuperscript{48}. It is therefore feasible that differences in tool used to measure pain outcome accounted for the disparity in the findings of the studies of Kivioja\textsuperscript{47} and Söderlund\textsuperscript{46}.

An alternative explanation for the differences reported in the studies discussed above is that levels of catastrophizing at onset of pain are related to levels of pain intensity six months following a MVC but not at one year. However, Sullivan and co-workers\textsuperscript{49} explored the relationship between current levels of catastrophizing and levels of pain intensity in patients who continued to
experience CNP following a MVC. They reported that even after controlling for the effects of certain demographic factors, catastrophizing was significantly related to pain intensity in a sample of 65 participants with CNP who were referred for treatment in a chronic pain clinic. This finding would appear to suggest that, as with patients with other chronic pain conditions, patients with CNP who report greater levels of catastrophizing tend to experience greater pain intensity than those who do not.

As well as exploring the relationship between catastrophizing and levels of pain intensity, several studies have explored the association between catastrophizing and levels of disability in patients with neck pain. Nederhand and colleagues\(^\text{50}\) reported that patients with acute neck pain following a MVC who displayed higher catastrophizing were more likely to experience ongoing disability six months later than those who catastrophized less. Moreover, a well designed study which examined 147 participants with sub-acute neck pain (less than 3 months duration) following a MVC reported that greater levels of catastrophizing were significantly associated with greater levels of disability\(^\text{51}\). Moreover, pain-related fear was found to significantly mediate the relationship between catastrophizing and disability, further supporting the assertions made in the FAM.

Studies which have explored the association between catastrophizing and disability in patients with CNP have also reported a positive association. For example, in a cross-sectional study of 86 participants with CNP referred to a chronic pain treatment centre, Sullivan and co-workers\(^\text{35}\) reported that greater levels of catastrophizing were significantly related to greater levels of disability. Moreover, a similar study of 65 participants with CNP\(^\text{49}\) reported that psychological factors, including catastrophizing, significantly explained 37% of participants reported disability levels.

The cross sectional and longitudinal studies discussed above suggest that catastrophizing contributes to levels of pain and disability experienced by patients with CNP. Moreover, Hill and colleagues\(^\text{62}\) demonstrated that catastrophizing is also an important determinant of outcome in patients
undergoing treatment. In their analysis of 346 participants who had participated in a RCT assessing different types of physiotherapy treatment, catastrophizing was found to be a significant predictor of a failure to make a clinically important reduction in disability following rehabilitation. Similarly, Karels et al. explored participants’ perceived recovery following treatment for neck and shoulder disorders. Again, greater levels of catastrophizing were associated with a lack of perceived recovery in these participants. These studies appear to suggest that catastrophizing presents a significant barrier to recovery in patients who experience CNP.

Although the studies discussed previously suggest an association between catastrophizing and levels of pain and disability in patients with neck pain, there is a paucity of data exploring the role of catastrophizing in accounting for levels of depression in this population. Nieto and colleagues reported that levels of catastrophizing were significantly related to levels of depression in 147 participants with sub-acute neck pain, however, no studies have explored this relationship in patients with CNP. As previous studies suggest that catastrophizing is an important determinant of levels of depression in other chronic pain conditions, future studies are required to delineate whether similar associations are observed in patients with CNP.

From the studies discussed previously, it would appear that levels of catastrophizing may be important determinants of levels of pain and disability in patients with CNP. However, much of this work has been carried out on participants experiencing CNP following a MVC (WAD). It is unclear whether the same associations would be observed in participants with idiopathic CNP. Moreover, no previous studies have explored the association between catastrophizing and levels of depression in patients with CNP. Therefore, it is imperative that future studies establish the relationship between levels of pain and disability in patients with both CWAD and idiopathic CNP. Moreover, studies are required to delineate the relationship between levels of catastrophizing and depression in patients with both CWAD and idiopathic CNP.
2.3 The role of pain-related fear

The following section will discuss previous studies which have explored the relationship between levels of adjustment and pain-related fear. Previous studies have employed different measures of pain-related fear and used different terminology to describe this concept. Therefore, in this thesis, the terms fear avoidance beliefs about work and physical activity, fear of movement/(re)injury and kinesiophobia will be considered synonymous and will be referred to as pain-related fear. Pain-related fear differs from catastrophizing in that catastrophizing is best considered as an overly negative orientation towards pain, whereas pain-related fear is an avoidance of specific movements or physical activities by individuals who fear that by performing that activity they will increase their pain or suffering.¹⁴

2.3.1 The role of pain-related fear in chronic pain populations

Empirical support for the relation between pain-related fear and disability was first provided by Waddell and colleagues in a study of 184 patients with CLBP. Specifically, fear avoidance beliefs about work and physical activity were shown to be strongly related to levels of disability, even after accounting for the effects of pain intensity. Furthermore, pain-related fear was only weakly related to biomedical factors such as pain intensity, pain duration or duration of current episode. This suggests that, rather than being directly related to the intensity of pain experienced, pain-related fear is an independent cognition which can directly influence levels of adjustment.

Further support was provided for the relationship between pain-related fear and levels adjustment by Vlaeyen and colleagues. They presented findings from 103 patients with CLBP who were awaiting behavioural-orientated rehabilitation. In this study, participants were asked to hold a 5.5kg for as long as possible. Participants who displayed higher levels of pain-related fear were able to hold the weight for a significantly shorter period of time than those with lower levels
of pain-related fear. Similar findings were reported in a further study examining
the relation between pain-related fear and physical performance\textsuperscript{55}. Fifty-nine
patients with CLBP were randomised into two groups and asked to perform a
simple leg exercise which was not considered to cause an increase in pain.
One group was told that no pain would result from the experiment, whilst the
other was told that a small and harmless increase in pain may occur. The
group who were told that the exercise may increase pain displayed greater
pain-related fear and significantly lower behavioural performance.

Whilst the studies discussed previously highlight the relationship between
greater levels of pain-related fear and inferior physical performance on specific
physical tasks, they do not provide explicit evidence of a relationship between
pain-related fear and functional disability. In an effort to address this limitation,
several studies have utilised self-report measures to explore the relationship
between levels of disability and pain-related fear. For example, a study of 104
patients referred to a specialist rehabilitation clinic reported that pain-related
fear was more strongly associated with disability than current pain intensity\textsuperscript{56}.

Moreover, similar findings have been reported in studies of patients with CLBP
who have been referred for physiotherapy. Woby and co-workers reported two
independent samples of patients undergoing physiotherapy rehabilitation, both
of whom exhibited significant associations between pain-related fear and levels
of self-reported disability\textsuperscript{29,57}. In addition, Grotle and colleagues\textsuperscript{58} explored the
relationship between pain-related fear and disability in a well designed cross-
sectional study of patients with acute and chronic spinal pain. Moreover, the
participants were recruited from different clinical environments, thus improving
the generalisability of the study. The study recruited 123 and 233 patients with
acute and chronic pain respectively. Pain-related fear was significantly related
to both self-reported disability and work loss in both groups of patients.

However, whilst cross-sectional studies such as those discussed previously
demonstrate significant associations between pain-related fear and disability,
they do not demonstrate a causative relationship. To address this limitation
Picavet and co-workers\textsuperscript{26} explored the relation between baseline pain-related
fear and disability at six months in a sample of participants randomly recruited from the Dutch general population. They found that, in participants with LBP at baseline, pain-related fear predicted current LBP, chronic LBP, severe LBP and LBP with disability at six month follow up. Moreover, those participants who were free of LBP at baseline but displayed high pain-related fear were more likely to develop LBP with disability at six months follow up\textsuperscript{26}. These findings suggest that some participants may have a predisposition for exhibiting pain-related fear, or that pain-related fear is not just a consequence of pain per-se.

Further support for a causative association between pain-related fear and disability was provided by a second longitudinal study. Boersma and Linton\textsuperscript{30} employed cluster analysis to explore the relation between levels of pain-related fear, depression and disability in 81 participants with spinal pain (87% of whom experienced LBP). Participants completed baseline questionnaires assessing pain intensity, disability, pain-related fear and depression and completed the same questionnaires seven months later. The study identified five distinct clusters, with participants in the clusters with high levels of pain-related fear and depression or high levels of pain-related fear alone, exhibiting the greatest levels of disability and sick leave. Participants in the clusters with medium levels of pain-related fear or depression reported lower disability than the first two clusters, but greater disability than the final “low risk” cluster, who displayed low levels of pain-related fear and depression.

Further support for the FAM has been provided via studies that have targeted the reduction of pain-related fear. For instance, Vowles and Gross\textsuperscript{60} found that individuals with chronic pain (68% LBP, 14% neck pain) who participated in an inter-disciplinary functional restoration programme exhibited significant improvements in their work ability. Furthermore, reductions in pain-related fear were significantly associated with improvements in work-ability, even after accounting for reductions in pain. Similar findings have been observed in studies deriving data from patients who had participated in a physiotherapist-led programme employing cognitive-behavioural techniques. Fifty-four CLBP patients completed a rehabilitation programme, which resulted in significant
decreases in disability. Reductions in fear avoidance beliefs about work and physical activity were independently associated with reduced disability, after accounting for the effects of pain and demographics\(^6\). In a further study of 137 participants completing the same intervention, reductions in pain-related fear were again found to be related to reductions in levels of disability\(^5\).

In addition to the relationship between pain-related fear and disability, the Fear Avoidance Model also posits that pain-related fear will lead to the development of depression\(^2\). Indeed, when first proposing the FAM, Vlaeyen and colleagues\(^2\) reported a correlation between greater levels of pain-related fear and greater levels of depression in their initial study of 33 patients with CLBP. Furthermore, a large study of patients with heterogeneous chronic pain conditions reported that the relationship between levels of catastrophizing and levels of depression was mediated by levels of pain-related fear\(^3\). This study appears to support the relationship between catastrophizing, pain-related fear and depression proposed by the FAM\(^2\). In contrast, Woby and co-investigators did not find a significant association between reductions in pain-related fear and changes in depression in patients undergoing physiotherapy based rehabilitation\(^5\). It should be noted however that the primary aim of the programme was not to reduce depression and this study does therefore not provide robust evidence to disprove a relationship between pain-related fear and catastrophizing. Further study is therefore warranted to further clarify the relationship between pain-related fear and depression.

The aforementioned studies therefore seem to indicate that pain-related fear plays a significant role in the development of chronic pain. Moreover, greater pain-related fear appears to result in greater levels of self reported disability in participants with chronic pain conditions. Reductions in disability following rehabilitation can be attributed, at least in part, to reductions in pain-related fear. Pain-related fear may also be a significant determinant of levels of depression, however, further studies are required to clarify this point.
2.3.2 The role of pain-related fear in neck pain

Many of the studies examining the relationship between pain-related fear and disability in patients with CNP have recruited patients with WAD shortly after the onset of pain. For example, Nederhand et al\textsuperscript{50} reported that a dichotomised (high/low) score on a measure of pain-related fear was related to recovery at six month follow up in a study of 90 patients with acute WAD. In Nederhand’s study, recovery was defined as a neck disability index score below 15 at six month follow up. In contrast, in a further study of participants with WAD, Sterling et al reported no significant relationship between levels of pain-related fear and disability six months after the onset of pain\textsuperscript{62}.

In contrast to the study of Nederhand, Sterling and colleagues included a greater number of physiological and psychological measures which were employed as predictors of outcome. This may account for the disparity in the findings of the two studies. However, it is noteworthy that a later study which followed up the participants of Sterling’s original study two to three years after the initial onset of pain revealed significant differences ($p<0.05$) in levels of pain-related fear between participants who continued to experience disability and those who did not\textsuperscript{63}. Specifically, participants who continued to experience disability exhibited greater levels of pain-related fear than those who were not disabled. This finding was not examined further or discussed by the authors of the study, but might indicate that pain-related fear is related to disability in patients who continue to experience chronic pain following injury, but plays a lesser role in the transition from acute to chronic pain in patients with WAD.

In support of the above notion, a previous study examined the relationship between psychological variables, pain and function in various stages of chronicity in a sample of participants with heterogeneous chronic pain conditions\textsuperscript{30}. The study reported that pain-related fear did not explain a significant proportion of the variance in disability in the first year of chronicity. Subsequently however, fear was found to explain 7% of variance in disability between one and three years and 12% of the variance in participants who had experienced pain for over three years. Interestingly, between 68-80% of the
participants in the groups experienced neck pain, suggesting these findings may generalise to patients with chronic neck pain.

In studies that have considered all participants with CNP, regardless of type of onset, a significant relation has been reported between pain-related fear and disability. In a cross-sectional study of 58 female computer workers with neck and shoulder disorders, Huis in t’ Veld et al\textsuperscript{64} reported a significant relationship between pain-related fear and levels of disability. However, as this study included only females involved in regular computer use, it is unclear whether these results generalise to males, or to other professions. Previous studies have also explored the predictive utility of pain-related fear in determining future disability. Landers and colleagues\textsuperscript{66} reported a significant association between levels of pain-related fear when first presenting for physiotherapy treatment and disability at 12 week follow up in a sample of 79 patients with predominately chronic neck pain. Similar findings were reported by Lee and co-workers\textsuperscript{67} in their randomised controlled trial of 120 patients with CNP who underwent two types of physiotherapy intervention. Initial levels of pain-related fear were significantly related to both baseline disability and disability at six week follow up in both of the treatment groups.

Cleland and co-workers\textsuperscript{65} explored the relationship between pain-related fear and levels of pain and disability in 78 participants referred for neck pain rehabilitation. They assessed pain-related fear using three different measures; the physical activity and work sub-scales of the fear avoidance beliefs questionnaire and the Tampa Scale for Kinesiophobia (TSK). Their study reported that fear avoidance beliefs about work were related to levels of disability and pain, whereas fear avoidance beliefs about physical activity were not significantly related to either variable. Pain-related fear, as measured by the TSK was significantly related to pain intensity, but not to levels of disability. The authors concluded that, although aspects of pain-related fear were related to levels of disability in patients with CNP, this relationship may be of a smaller magnitude than in patients with CLBP.
Similar findings were reported in a study which specifically explored whether the relationship between pain-related fear and disability differed between those participants with CNP and those with CLBP\textsuperscript{68}. The study reported that greater levels of pain-related fear were significantly related to disability in both participants with CLBP and CNP\textsuperscript{68}. In contrast, pain-related fear was significantly related to levels of pain intensity in those participants with CLBP, but not in those with CNP. This may suggest that some differences exist in the relationship between pain-related fear and levels of adjustment between participants with CLBP and those with CNP. Future studies are therefore required to clarify the association between pain-related fear and levels of adjustment in participants with CNP.

To the author’s knowledge, no studies have examined the relation between pain-related fear and depression in patients with CNP. However, Nieto and co-investigators\textsuperscript{51} reported that pain-related fear significantly mediated the relationship between catastrophizing and depression in a sample of 147 participants with sub-acute WAD (pain duration<3 months). Moreover, as outlined previously in section 2.3.1 (p44), pain-related fear appears to contribute to levels of depression amongst samples of participants with heterogeneous chronic pain conditions. In view of this, it is possible that similar associations may be observed in patients with CNP, however, this relationship requires further investigation. Future studies are therefore required to explore whether levels of pain-related fear significantly contribute to levels of depression.

In light of the studies discussed previously, it would appear that pain-related fear might be significantly related to levels of pain and disability in participants with CNP, but may play a lesser role in the transition from acute to chronic pain. Conflicting findings have been reported in respect of the relationship between pain-related fear and disability in patients with WAD, whilst many studies have considered patients with CWAD separately to those with idiopathic CNP. Consequently, it is unclear whether the relationship between pain-related fear and disability differs between these two clinical sub-groups. Important
differences may exist with respect to the extent to which pain-related fear contributes to disability in patients with idiopathic CNP and in those with WAD.

Future studies are required to establish the relationship between levels of pain-related fear and disability in patients with CNP. Furthermore, future studies should also explore whether differences exist in the relationship between pain-related fear and disability in patients with idiopathic CNP and patients with CWAD. If the relationship between pain-related fear and levels of adjustment differs between these two clinical sub-groups, different treatment approaches may be required to optimise patient outcome. On this basis, study one of this thesis will aim to delineate the extent to which pain-related fear contributes to levels of pain, disability and depression in patients with CNP. Moreover, study two will aim to delineate whether differences exist in the relationship between pain-related fear and disability, depression and pain in patients with idiopathic CNP and those with CWAD. Establishing whether such differences exist would allow interventions to be tailored to maximise treatment efficacy for both of these clinical sub-groups.
2.4 The role of pain vigilance and awareness in chronic pain populations

Some authors have argued that increased pain vigilance and awareness should constitute part of the Fear Avoidance Model. Studies examining pain vigilance and awareness have also used the terms hypervigilance and somatic awareness to describe an increased awareness and attention to pain, characterised by frequent scanning of the body for painful sensations. Studies undertaken in other chronic pain populations have suggested that a significant relationship exists between pain vigilance and awareness and levels of disability. For example, McDermid et al demonstrated that participants with fibromyalgia exhibited significantly lower tolerance to painful and auditory stimulation. They postulated that this was attributable to a generalised hypervigilance to bodily sensations, however no explicit measure of pain vigilance was employed in this study. When vigilance and awareness to pain was directly assessed, using the Pain Vigilance and Awareness Questionnaire, vigilance to pain was found to be mediated by pain intensity and catastrophizing. This supports the adapted FAM proposed by Leeuw and colleagues, suggesting that pain catastrophizing will lead to pain-related fear, which in turn leads to hypervigilance to pain. In further support of this notion, Goubert et al reported that catastrophizing and pain-related fear mediated the relationship between neuroticism and pain vigilance and awareness. Moreover, increased pain vigilance and awareness was found to be associated with greater pain severity.

However, there is currently a paucity of data examining the relationship between pain vigilance and awareness and levels of adjustment in patients with CNP. Therefore, study one will aim to establish the relation between vigilance to pain and levels of disability, pain intensity and depression in CNP. Moreover, study two will aim to delineate whether the relationship between pain vigilance and awareness differs significantly between participants with CWAD and those with idiopathic CNP.
2.5 The role of self-efficacy beliefs

As outlined previously, the utility of the Fear Avoidance Model has been demonstrated in a variety of chronic pain conditions. The Fear Avoidance Model originally proposed by Vlaeyen and colleagues does not consider the influence of an individual’s confidence in performing a specific activity, otherwise known as self-efficacy. Bandura defined self-efficacy as

“The conviction that one can successfully execute the behaviour required to produce the outcomes” (Bandura 1977, p.193)

However, Woby et al proposed a modified version of the FAM, in which self-efficacy beliefs were a key determinant of levels of adjustment. Although fewer studies have examined the relationship between self-efficacy beliefs and levels of adjustment, it is feasible that reductions in self-efficacy could result in greater levels of pain, disability and depression. On this basis, the following section will review previous studies which have explored the relationship between self-efficacy beliefs and levels of adjustment. A further literature search was undertaken in January 2006 in which the search terms “self-efficacy” or “self efficacy” or “confidence” and “pain” or “back pain” or “neck pain” or “disability” or “depression” or “adjustment” or “function*” were entered. The same search strategy outlined on page 29 was then employed to identify appropriate articles.
2.5.1 The role of self-efficacy in chronic pain populations

As outlined previously, it has been suggested that self-efficacy may be an important determinant of levels of pain, disability and depression in patients with chronic pain conditions. Indeed, it has been demonstrated that self-efficacy in performing a series of physical tasks was related to functional performance in a study of 40 participants with CLBP\textsuperscript{75}. The participants were asked to rate their ability to carry out ten physical tasks, which they were then asked to perform. The participants’ perceived self-efficacy in completing these activities explained 30% of the variance in actual physical performance. Furthermore, Lackner and Carosella\textsuperscript{76} performed a similar study where participants were asked to lift a weighted tray from the floor to waist height and then from waist height to eye level. The weight of the tray was then progressively increased until the patient reported excessive discomfort or fatigue. Once more, participants’ perceived self-efficacy in lifting the tray explained unique variance lifting ability when they performed the task\textsuperscript{76}.

Although the above studies demonstrate that self-efficacy in performing a task is related to performance in experimental conditions, they do not demonstrate whether this is also true of day to day functional activities. In an effort to address this, the relationship between self-efficacy beliefs and self-reported disability was examined by Arnstein and co-investigators\textsuperscript{77} in a cohort of 479 participants with CLBP. Participants were recruited from primary and tertiary care settings and self report measures of disability and self-efficacy were completed. Self-efficacy beliefs were found to explain between 14% and 22% of the variance in disability in various samples examined within the study\textsuperscript{77}. Similarly, the relationship between self-efficacy beliefs and disability has also been examined in conjunction with variables associated with the FAM. Ayre and Tyson (2001) reported that self-efficacy beliefs explained a greater portion of the variance in disability than pain-related fear in a sample of 121 participants with CLBP\textsuperscript{78}.

The aforementioned studies are supported by a study of two primary care samples where the relative importance of fear avoidance variables (fear of
movement/re-injury and catastrophizing), pain intensity and self-efficacy were compared\textsuperscript{79}. After accounting for the effects of pain intensity, the fear avoidance variables were entered into a multiple regression analysis model, followed by perceived self-efficacy. The process was then reversed, with self-efficacy entered in the second step and the fear avoidance variables in the final step. It was found that self-efficacy explained a greater proportion of unique variance than the fear avoidance variables in both samples (Sample 1: 24\% versus 7\%; Sample 2: 21\% versus 6\%).

In further support of the notion that self-efficacy beliefs may exert a stronger influence on levels of disability than the cognitive factors associated with the FAM, Woby and colleagues\textsuperscript{29} examined 178 participants referred for out-patient physiotherapy. In this study, self-efficacy beliefs emerged as a stronger predictor of disability than either pain-related fear or catastrophizing. Together, these findings would appear to suggest that self-efficacy beliefs are significantly related to levels of disability in patients with chronic pain conditions. Moreover, it is plausible that self-efficacy beliefs may exert a stronger influence on levels of disability than the cognitive variables associated with the FAM.

In addition to the association between self-efficacy and disability discussed above, previous studies have also demonstrated a significant association between levels of self-efficacy and levels of pain intensity in a variety of chronic pain conditions. A study of 79 patients with fibromyalgia reported that greater self-efficacy beliefs were associated with lower levels of pain intensity, even after accounting for symptom severity\textsuperscript{80}. Similarly, a study of 128 patients with rheumatoid arthritis reported that self-efficacy beliefs accounted for 28\% of the variance in pain intensity, after controlling for the effects of demographics and disease severity\textsuperscript{81}. Moreover, in a similar study of 178 patients with CLBP referred for physiotherapy, lower self-efficacy beliefs were significantly related to greater levels of pain intensity\textsuperscript{29}.

In contrast to the findings supporting a relationship between self-efficacy and pain, Turner et al\textsuperscript{82} reported that self-efficacy beliefs about pain management were not related to current pain intensity in a sample of elderly retirement
community residents with heterogeneous chronic pain conditions. It is noteworthy however that Turner et al explored self-efficacy beliefs about pain management, whereas previous studies have explored the role of functional self-efficacy beliefs. This may suggest that it is functional self-efficacy beliefs, rather than self-efficacy beliefs about pain management, that are important determinants of levels of disability and pain intensity. Future studies should explore the relative influence of both functional and pain management self-efficacy beliefs within the same sample of participants in order to establish which specific construct displays the strongest association with levels of adjustment.

Few studies have explored the relationship between self-efficacy beliefs and levels of depression in chronic pain patients. However, Lefebvre and colleagues\textsuperscript{81} reported that lower levels of self-efficacy were associated with low daily mood in a study of rheumatoid arthritis patients. Moreover, a study of 126 patients with heterogeneous chronic pain conditions reported that lower self-efficacy beliefs were an important mediator between pain intensity and levels of depression\textsuperscript{83}. Furthermore, a study of elderly residents with heterogeneous chronic pain conditions reported that lower self-efficacy beliefs about pain management were associated with greater levels of depression\textsuperscript{82}. 
2.5.2 The role of self-efficacy beliefs in chronic neck pain

The role of self-efficacy beliefs has not been explored extensively in CNP populations. However, Kyhlbäck et al.\textsuperscript{84} reported in a study of participants with WAD that lower self-efficacy beliefs at baseline predicted levels of disability at three month and one year follow up. Furthermore, self-efficacy has been shown to be related to levels of disability in patients with chronic WAD (CWAD) undergoing intensive in-patient rehabilitation\textsuperscript{85}. Moreover, in a randomised control trial of two exercise regimes, lower self-efficacy beliefs at baseline were associated with increased disability at six month follow up, regardless of group allocation\textsuperscript{46}.

In light of these findings, it would appear that self-efficacy beliefs are significantly related to disability in patients with chronic WAD. However, it is unclear whether self-efficacy beliefs contribute to levels of disability, pain and depression in patients with idiopathic CNP. Moreover, previous studies of patients with CLBP suggest that self-efficacy beliefs may exert a greater influence on levels of disability than variables associated with the FAM (pain-related fear, catastrophizing and hypervigilance). In view of this, it is imperative that future studies examine self-efficacy beliefs and the variables associated with the FAM within the same patient population. Moreover, future studies should aim to delineate whether differences exist in the relationship between self-efficacy beliefs and levels of disability in patients with idiopathic CNP and patients with chronic WAD.

The studies discussed in section 2.5.1 suggest that lower self-efficacy beliefs might contribute to levels of pain intensity, disability and depression in patients with heterogeneous chronic pain conditions. However, there is a dearth of data examining the relationship between self-efficacy beliefs and levels of pain intensity and depression in patients with CNP. Future studies are required to establish whether similar associations between self-efficacy beliefs and levels of pain intensity and depression are observed in patients with CNP.
Therefore, study one of this thesis will examine the relationship between self-efficacy beliefs and levels of disability, pain and depression in patients with CNP. Moreover, study two will explore whether differences exist in the relation between self-efficacy beliefs and levels of disability, pain and depression in patients with idiopathic CNP and patients with CWAD.
2.6 Summary of the role of cognitive factors in chronic pain

The utility of the Fear Avoidance Model has been demonstrated in studies of patients with CLBP and heterogeneous chronic pain conditions. However, few studies have explored the utility of the Fear Avoidance Model in patients with chronic neck pain and conflicting results of the role of pain-related fear have been reported. Self efficacy beliefs have been shown to be related to levels of disability in participants with WAD, however, no studies have compared the relative influence of the cognitive variables associated with the FAM (catastrophizing, pain-related fear and pain vigilance and awareness; henceforth referred to as explanatory FAM variables) and self-efficacy beliefs within the same population of patients with CNP. This may account for the conflicting results that have been reported in the literature and therefore future research should focus on examining all of the explanatory FAM variables and self-efficacy beliefs within the same population in order to provide a better insight into the relative importance of each factor.

Furthermore, previous studies have frequently examined the relationship between cognitive and levels of adjustment separately in patients with CWAD and idiopathic CNP. As no previous studies have examined whether mode of onset (i.e. idiopathic or WAD) influences the relationship between cognitive factors and levels of adjustment, it is unclear whether this sub-grouping of patients is justified. On the basis of this, analyses are required to establish whether the relationship between levels of adjustment and the cognitive factors differs between those patients with idiopathic CNP and those with chronic whiplash associated disorder.
3.0 Aims

3.1 Study one:
To examine the extent to which self-efficacy beliefs and the explanatory FAM variables were related to levels of adjustment (levels of disability, pain and depression) in patients with chronic neck pain.

3.1.2 Study two:
Patients with idiopathic CNP and CWAD are often managed differently in routine physiotherapy practice. Indeed, different guidelines exist for the treatment of these two clinical sub-groups of patients with CNP\(^{147}\). Moreover, many previous studies have examined these two groups separately (see section two). However, it is currently unclear whether this clinical sub-grouping based on mechanism of pain onset is warranted.

On the basis of this, the aim of study two was therefore to explore whether the relationship between self-efficacy beliefs, the explanatory FAM variables and levels of adjustment differed between those patients with idiopathic CNP and those with chronic whiplash associated disorder (CWAD).
3.2 Hypotheses:

The hypotheses for studies one and two were developed based on the findings from the previous studies discussed in section two. Not only were studies which had explored the relationship between cognitive factors and levels of adjustment in CNP considered, but also those studies which recruited patients with other chronic pain conditions.

3.2.1 Study one:

Section two highlighted that previous studies have indicated that certain cognitive factors may be related to levels of adjustment in CNP. Moreover, given the evidence from previous studies of other chronic pain conditions demonstrating an association between cognitive factors and adjustment, the hypothesis for study one was as follows:

The cognitive measures (self-efficacy beliefs and the explanatory FAM variables) will account for a significant proportion of variance in disability, pain and depression after controlling for the effects of demographics (age, sex, pain duration and nature of onset).

3.2.2 Study two:

Section two of this thesis demonstrated that certain cognitive factors have been shown to be associated with levels of adjustment in both patients with idiopathic CNP and CWAD. However, no previous studies have explored whether this relationship differs between these groups. Given that associations between cognitive factors and adjustment have been observed in many different pain conditions and that no previous studies have clearly demonstrated that this relationship differs between patients with idiopathic CNP and CWAD, the hypothesis for study two was as follows:
Cognitive measures will be significantly associated with levels of adjustment in both participants with idiopathic CNP and CWAD. Specifically, the cognitive measures will account for significant proportions of variance in pain, disability and depression in both of these clinical sub-groups.
4.0 Methods

4.1 Participants

Several different criteria have been advocated when deciding upon sample size in regression analyses. Most simply, some authors suggest that data should be collected from ten participants for each variable entered into a multiple regression analysis\textsuperscript{96}. In order to fulfil this criterion, a minimum of 100 participants would be required for study one. However, alternative criteria have also been proposed. Some authors argue that in order to test the overall fit of a model a sample size of $50 + 8k$, whereby $k$ is the number of predictor variables, should be applied. Alternatively, if $\beta$ values of individual predictor variables are of interest, then the equation $104 + k$ is appropriate\textsuperscript{96}. Employing this methodology the required sample sizes would be 130 and 114 respectively.

Finally, Miles and Shevlin suggest that the required sample size will depend on the anticipated effect size\textsuperscript{125}. Cohen argued that an effect size can be considered to be large if 25\% or more of the variance in the data is explained by the model\textsuperscript{126}. Given that previous studies of patients with neck pain which have employed regression analyses have reported models explaining up to 40\% of the variance in data\textsuperscript{35,51}, it was anticipated that medium to high effect sizes would to be observed for the proposed models. Assuming a medium effect size for a model with ten predictor variables, 150 participants would be required according to Miles and Shevlin’s criteria\textsuperscript{125}. If a large effect size was assumed, 60 participants would be adequate for a model with ten predictor variables. On
this basis, the most conservative figure was assumed and the study aimed to recruit 150 participants to study one.

Due to limitations in data collection timeframes and study funding, it was not practical to collect data for 150 participants with both idiopathic CNP and CWAD. However, as discussed earlier, should the models demonstrate a large effect size, a considerably smaller sample size would be required to provide meaningful data. Consequently, the conclusions that can be drawn from study two were dependent on the effect sizes observed in each model and therefore whether each sub-analysis was adequately powered. Sufficient funding was obtained to allow a two year data collection period, therefore data was collected for the entirety of this period, as a greater sample size is considered to increase the robustness of results from regression analyses. Therefore, data were collected between June 2005 and July 2007 at North Manchester General Hospital, Cornerstones Health Centre and Fairfield General Hospital.

The focus of the study was to provide clinically meaningful data to inform physiotherapy practice. As the population of interest was those patients who are referred for physiotherapy because of CNP, all participants were recruited from physiotherapy departments. Participants were not recruited from the general population as previous studies suggest that clinical populations may differ from the general population with regards to the relationship between cognitive factors and levels of adjustment. Moreover, participants were not recruited from patients consulting their general practitioner as previous studies also suggest that the relationship between cognitive factors and adjustment
may also differ between different treatment contexts\textsuperscript{29,35}.

All patients with neck pain referred for out-patient physiotherapy were contacted by post prior to their first appointment and invited to participate in the study. Those agreeing to participate were asked to attend their first assessment 30 minutes early so that they could complete a battery of self-report measures that assessed demographics, pain, disability, depression and cognitive factors (specific details of these measures are provided on p61-65). Socio-demographic information that was recorded included age, sex, pain duration, current work status, marital status, onset of neck pain (idiopathic or WAD) and ethnicity. All patients were aged 16 or over and only those reporting neck pain for at least 3 months were eligible for inclusion in the study. Exclusion criteria were inability to read English or complete the questionnaire, presence of red flags (see Figure 2), evidence of serious pathology (e.g.; carcinoma, fracture/dislocation, spondyloarthropathy or other inflammatory disorder) or a previously diagnosed serious psychiatric disorder, such as bipolar disorder, schizophrenia or dementia. Patients with red flags or other indicators of serious pathology were excluded as the study population of interest was those patients with chronic neck pain in the absence of defined serious pathology. Patients with diagnosed serious psychiatric disorder were excluded as, given the psychological nature of the variables under examination, responses from these patients may not be representative of the general population.
Figure 2. Red Flags (Moore et al, 2005)\textsuperscript{147}

- Bilateral paraesthesia in the upper or lower limbs
- Gait disturbance; e.g. tripping or coordination difficulty
- Spastic paresis
- Positive Lhermittes sign, i.e. Shooting pain or paraesthesia into lower limbs or all four limbs with cervical flexion
- Hyper-reflexia
- Nerve root signs at more than two adjacent levels
- Progressively worsening neurological signs
  e.g. motor weakness, areflexia and sensory loss
- Symptoms of upper cervical instability
- Non mechanical neck pain which is severe and unremitting

4.2 Ethical approval

Ethical approval was provided by the North Manchester Local Research Ethics Committee, ref: 05/Q1406/21 and the Pennine Acute Hospitals NHS Trust Research and Development department.
4.3 Outcome measures

The outcome measures used in studies one and two of this thesis are outlined below.

4.3.1 Neck disability Index (NDI)

4.3.1.1 Current pain intensity: Question one of the NDI

Pain intensity was measured by item one of the Neck Disability Index (NDI)\textsuperscript{86}. This item comprises of a six point Likert scale, with scoring alternatives ranging from “I have no pain at the moment” to “the pain is the worst imaginable at the moment”. Potential scores for pain intensity ranged from 0-5. Question one of the NDI was chosen as it is a neck-pain specific measure of pain intensity and offers clear, descriptive options relating to the severity of current neck pain.

4.3.1.2 Disability: Questions two to ten of the NDI

Disability was measured by the remaining nine items of the NDI, hereafter referred to as the modified Neck Disability Index (mNDI). The NDI was selected as the disability measure in this study as it is assess a variety of functional, physical and social activities. For example, questions assess a participant’s ability in personal care, concentration and recreational activities. Participants were asked to rate how their neck pain affected their ability to carry out each of these tasks on a six point scale, ranging from “able to do without any extra pain”
to “unable to do at all”. Participants were instructed to tick only one box, selecting the answer that most closely reflected their level of disability. Moreover, the NDI disability score is calculated as a percentage, allowing scores to be adjusted for missing items and thus enabling comparison between completed and incomplete scales without imputing data. Total scores on the NDI of 0 to 4 are considered to show no disability, 5 to 14 mild disability, 15 to 24 moderate disability, 25 to 34 severe disability and scores over 34 are classed as complete disability. The NDI has been shown to have excellent psychometric properties, demonstrating high internal consistency (Cronbach’s alpha = 0.92) and no statistically significant ordering or sequencing effects in a sample of acute, sub acute and chronic neck pain patients (Vernon et al, 1998). Correlation between baseline scores and two-day re-test was found to be good (r=0.89, p=0.05). Moreover, the mNDI employed in this study demonstrated excellent internal consistency (Cronbach’s α=0.87).
4.3.2 Depression: Hospital Anxiety and Depression Scale (HADS)

Depression was assessed using the depression sub-scale from the Hospital Anxiety and Depression Scale (HADS)\(^ {87} \). The HADS depression sub scale (HADS-d) was selected as it is a brief a seven item self-report measure that is specifically designed for assessing depression in non-psychiatric hospital environments. In a review of studies examining internal consistency of the HADS, Bjelland and co-workers\(^ {88} \) reported Cronbach’s alphas consistently above 0.6, indicating that the measure possesses adequate internal consistency. Scores of less than 8 on the sub-scale are not considered to represent significant depression, scores of 8 to 10 are considered doubtful cases and scores greater than 11 are thought to be indicative of definite depression\(^ {87} \).
4.4 Cognitive measures

4.4.1 Catastrophizing: Pain Catastrophizing Scale (PCS)

Catastrophizing was measured by the Pain Catastrophizing Scale (PCS)\textsuperscript{89}, a 13 item questionnaire scored on a 5 point Likert scale, recording frequency of catastrophic cognitions about pain. The PCS has been shown to possess good internal consistency (Cronbach’s $\alpha>0.75$)\textsuperscript{90} and has been validated in both men and women\textsuperscript{91}. Moreover, the PCS displayed excellent internal consistency in the current study (Cronbach’s alpha=0.94). The PCS was selected as it assesses three separate dimensions of catastrophizing\textsuperscript{91}, as opposed to scales employed in other studies, which have utilised uni-dimensional measures (e.g. the catastrophizing sub-scale of the coping strategies questionnaire\textsuperscript{57}). It is the contention of the current author that it was important to assess all hypothesised aspects of catastrophizing so that important associations between catastrophizing and levels of adjustment were not excluded from the study.

4.4.2 Pain-Related Fear: Tampa Scale for Kinesiophobia (TSK)

Pain-related fear was assessed by the Tampa Scale for Kinesiophobia (TSK)\textsuperscript{92}. This measure consists of 17 items with levels of agreement measured by four point Likert scales, ranging from strongly agree to strongly disagree. Items 4, 8, 12 and 16 are inversely scored and greater scores represent higher levels of pain-related fear. The TSK was selected as it is a widely used tool, both in
clinical practice and in physiotherapy based research and has previously been shown to be associated with levels of adjustment in CLBP patients assessed in a physiotherapy environment\textsuperscript{29,128}. The English version of the TSK demonstrates good internal consistency (Cronbach’s Alpha = 0.82) and test-retest reliability (Intraclass correlation = 0.82, Standard Error of Measurement = 3.16);\textsuperscript{93}. Furthermore, the TSK displayed acceptable internal consistency in the current study (Cronbach’s Alpha = 0.67).

4.4.3 Pain Vigilance and Awareness: Pain Vigilance and Awareness Questionnaire (PVAQ)

Vigilance and awareness was assessed using the Pain Vigilance and Awareness Questionnaire (PVAQ)\textsuperscript{73} a 16 item questionnaire assessing vigilance and awareness to pain. Higher scores represent greater levels of vigilance and awareness. The PVAQ was selected as it is currently the only validated measure of pain vigilance and awareness. However, the psychometric properties of the PVAQ has been shown to be good in a sample of patients with chronic pain conditions (Cronbach’s alpha = 0.83)\textsuperscript{73}, and were very good in the current study (Cronbach’s Alpha = 0.84).
4.4.4 Self-Efficacy Beliefs: Chronic Pain Self-Efficacy Scale (CPSS)

Self-efficacy was measured using the Chronic Pain Self-Efficacy Scale\(^9^4\). The CPSS is a self-report measure, modified from the Arthritis Self-Efficacy Scale\(^9^5\) for use in all chronic pain populations. The CPSS was selected as it allows discrimination between different aspects of self-efficacy beliefs. Specifically, two sub-scales, physical function and pain management, were used in this study. Higher scores on the CPSS sub-scales represent greater levels of confidence in performing physical tasks and managing pain. Both sub-scales display good internal consistency (Cronbach’s alpha = 0.91 for physical function and 0.86 for pain control\(^9^4\)).

The original CPSS was scored on a 10 point Likert scale on which patient’s had to rate their belief that they could carry out each statement. One end of the scale was anchored 10 = very uncertain and the other 100 = very certain. The scales used in this study were modified slightly to give a nine point scale anchored 0 = “totally unconfident” at one end and 8 = “totally confident” at the other. This was done as previous research has indicated that participants reported greater ease of interpretation with this version of the scale, as well as allowing participants to select a mid-point option\(^2^9\). The anchor points were changed from “very uncertain” and “certain” to “Totally confident” and “Totally unconfident” to clarify to the participants that the CPSS was assessing their confidence in carrying out an activity, rather than their functional ability per se. The modified version of the CPSS displays excellent internal consistency (Cronbach’s alpha = 0.88) and test-retest reliability (intra class correlation =
0.88\textsuperscript{29}). In the current study, both the pain management (Cronbach’s Alpha = 0.85) and physical function (Cronbach’s Alpha = 0.86) sub-scales displayed excellent internal consistency.
4.5 Statistical analysis

All statistical analyses outlined below were undertaken with the support and guidance of a biomedical statistician. It should be noted that the term “explanatory fear-avoidance variables” refers collectively to the variables which have been suggested to be related to levels of adjustment in the fear-avoidance model (i.e. catastrophizing, pain-related fear and pain vigilance and awareness). Given the cross-sectional nature of this study, this term is not intended to imply causality, rather it reflects the theoretical relationship proposed by the fear-avoidance model.

4.5.1 Correlational analyses

Histograms were produced to ensure normal distribution of data to ensure that parametric tests could be performed. Pearson product-moment correlation coefficients were calculated in order to identify significant between-variable relationships.

4.5.2 Multiple regression analyses

Hierarchical multiple regression analyses were performed to delineate the relationship between the cognitive factors (self-efficacy beliefs and the explanatory FAM variables) and levels of pain, disability and depression. Hierarchical multiple regression analyses were employed so that the effects of demographics and pain intensity (in the disability and depression analyses)
could be controlled for, prior to assessing the influence of the cognitive factors. These factors were controlled for as they have previously been shown to be related to levels of neck pain (see section 1.3). Moreover, multiple regression analyses allowed several cognitive factors to be entered into the model together in order to establish the joint contribution that they made to explaining variance in levels of adjustment. Furthermore, performing this type of analysis also enables the unique contribution of variable to be calculated for the final model by examination of the β values.

However, it should be noted that certain limitations exist with performing hierarchical regression analysis. Primarily, some variables which are included in the model may not be significantly associated with levels of adjustment. However, when using hierarchical multiple regression analysis, these factors are retained in the final model. This may potentially decrease the power of the model and therefore limit the conclusions that can be drawn. This limitation could be addressed by employing alternative methods, such as forward, stepwise or backward regression. In such methods predictor variables are added or removed from the model in a number of steps, so that in the final model, only variables which are significantly associated with outcome are retained.

However, whilst such methods would ensure that the models maintained maximum statistical power, hierarchical analyses were employed in preference for a number of reasons. Firstly, previous literature has suggested that all of the predictor variables under examination in this study may be associated with
levels of adjustment. The specific aim of the current study was to establish which of these variables had the strongest associations with levels of adjustment. In order to assess this, all variables were included in the model. Moreover, some authors have argued that, where clear theoretical evidence exists for the inclusion of a variable in a model, any such variables should be included\textsuperscript{96}. Finally, employing forward regression has been associated with a greater incidence of type II errors than other types of regression\textsuperscript{96}.

In light of the above factors hierarchical multiple regression analysis was selected to assess the relationship between levels of adjustment and the cognitive factors. Moreover, $t$-tests were performed to establish whether scores on the cognitive measures and measures of adjustment differed significantly between participants with idiopathic CNP and CWAD. All statistical analyses were carried out on SPSS for windows version 14.0 (SPSS, Inc., Chicago, IL, USA.).

4.5.3 Missing data

Hollis and Campbell\textsuperscript{98} suggested that in cases of missing data, some form of data imputation is preferable to excluding cases altogether. Accordingly, where less than 10\% of data for a particular measure were missing, the mean score for the remaining items on that scale was imputed in place of the missing data\textsuperscript{97}. However if greater than 10\% of data were missing, it was considered that a reliable mean could not be calculated. Moreover, imputing the mean score for
the whole population is likely to bias the results, by decreasing the proportion of variance that can be explained by each variable\textsuperscript{97}. Consequently, in instances where more than 10% of data were missing from a particular scale, the measure was excluded from the subsequent regression analyses. However, the remaining completed questionnaires were still included in the analyses.
4.6 Study one: The relationship between cognitive factors and levels of adjustment in all patients with CNP

Study one examined the relation between the cognitive factors (self-efficacy beliefs and the explanatory FAM variables) and levels of adjustment in patients with CNP. Accordingly, three multiple regression analyses were carried out. Hierarchical regression was performed in order to delineate what proportion of the variance in outcome was explained by each block of variables. This method also allowed for the effects of demographics (age, sex, pain duration and nature of onset – i.e. idiopathic onset or WAD) to be accounted for prior to assessing the influence of the cognitive factors. Age, sex, pain duration and nature of onset were controlled for as previous studies (discussed previously in chapter 1.4) have demonstrated that these factors are associated with levels of adjustment in patients with CNP. The dependent variable in the first analysis was level of disability, as measured by the mNDI. In the second analysis current pain intensity was the dependent variable, whilst in the third, level of depression (as measured by the HADS-d), was the outcome measure.

4.6.1 Regression model with disability (mNDI) as the dependent variable

Demographics (age, sex, pain duration and nature of onset) were entered in step one and current pain intensity was entered in step two. Finally, the cognitive measures (PCS, TSK, PVAQ and the CPSS sub scales) were entered
in step three. Significance level was set at $p<0.05$. Beta weights were examined to establish if any of the individual factors explained unique variance in disability. Standardised betas with a $p$ value of less than 0.05 on $t$-test were considered to explain unique variance in disability.

4.6.2 Regression model with current pain intensity as the dependent variable

Multiple regression analysis was carried out in two steps to assess the relation between cognitive factors and pain intensity. Demographics were entered in step one and the cognitive factors in step two. The dependent variable was question one of the NDI (current pain intensity).

4.6.3 Regression model with depression as the dependent variable

Multiple regression analysis was carried out in three steps to assess the relation between the cognitive factors and depression. In step one, the demographic factors (age, sex, pain duration and nature of onset) were entered. In the second step current pain intensity was entered, followed by the cognitive measures in the final step. The dependent variable was the depression sub-scale of the Hospital Anxiety and Depression Scale (HADS-d).
4.7 Study two: Does the relationship between cognitive factors and levels of adjustment differ between participants with idiopathic CNP and CWAD?

4.7.1 Between group comparisons

Unpaired t-tests were performed to delineate whether significant differences existed between participants with idiopathic CNP and CWAD with respect to the scores on the measures of pain, disability and depression. Moreover, t-tests were also performed to establish whether scores on the cognitive measures differed significantly between groups, whilst a $\chi^2$ test was performed to establish whether the ratio of males:females differed between the groups. $T$-tests were employed where data met the assumptions of parametric data, whereas $\chi^2$ tests were employed where the outcome of data were dichotomous$^{96}$.

4.7.2 The relationship between levels of adjustment and cognitive factors in patients with idiopathic chronic neck pain and chronic whiplash associated disorder

Study two explored whether the relationship between levels of adjustment and the cognitive factors differed between those patients with idiopathic CNP and those with CWAD. In order to delineate whether any differences existed, all analyses outlined in section 4.3 were repeated, firstly including only those participants with idiopathic CNP and secondly only those with CWAD. All statistical methods employed were identical to those outlined in section 4.3,
except nature of onset was excluded from the analyses in study two, as participants were already dichotomised according to nature of onset of pain.
5.0 Results

5.1 Participants

Three-hundred and fifty-three participants were invited to participate in the study, of which 162 consented (46%). Of those consenting, complete data were available for 149 participants, who formed the study group. The mean age of the sample was 47.6 years (range 16 to 85, SD=14.6), 82 (55%) were female and the mean pain duration was 45.8 months (range 3 to 480, SD 80 months). Fifty-five participants (37%) reported whiplash associated disorder, with the remainder reporting idiopathic CNP. Table 1. shows participants’ characteristics, whilst Table 2 shows participants’ baseline scores on the cognitive measures. No data were collected regarding patients’ reasons for non-participation, due to ethical considerations, whereby patients were free to decline to participate without giving a reason. Moreover, as data were collected by self report measures, no demographic data were therefore available from non-participants, prohibiting comparison between participants and non-participants. A histogram was produced and visual inspection revealed that data were normally distributed, meaning that data met the assumptions of parametric data and parametric statistical tests were therefore employed where appropriate.
5.2 Preliminary examination of the data

In all the multiple regression analyses in studies one and two, Durbin-Watson scores were acceptable, average variance inflation factor (VIF) was not substantially greater than one and largest VIF did not exceed ten. This indicates that the assumption of independent errors was met and the data were not affected by multicollinearity. Moreover, none of the analyses had a greater number of residuals than expected falling more than ±2 outside of the expected value and no cases fell more than ±3 from the expected values. This indicates that no individual cases exerted undue influence on the results. Further details of these data can be found in appendix one.

5.3 Study one: The relationship between cognitive factors and levels of adjustment in participants with CNP

One-hundred and forty-nine participants with CNP were included in the study one analyses. Demographic characteristics and scores on the cognitive measures are shown in Table 1. (p84) and Table 2. (p85), whilst correlations between disability, pain, depression and the cognitive factors are shown in Table 3. (p86).
Table 1. Participant characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>47.6 (15)</td>
<td>16-85</td>
<td></td>
</tr>
<tr>
<td>Pain duration (Months)</td>
<td>45.8 (80.3)</td>
<td>3-480</td>
<td></td>
</tr>
<tr>
<td>Current pain intensity</td>
<td>1.8 (0.9)</td>
<td>0-4</td>
<td></td>
</tr>
<tr>
<td>Modified NDI %</td>
<td>35 (17.7)</td>
<td>0-88</td>
<td></td>
</tr>
<tr>
<td>Unmodified NDI</td>
<td>35 (16.5)</td>
<td>0-84</td>
<td></td>
</tr>
<tr>
<td>Depression (HADS-d)</td>
<td>5.7 (3.8)</td>
<td>0-15</td>
<td></td>
</tr>
<tr>
<td>Sex:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>82 (55)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>67 (45)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Onset</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Idiopathic CNP</td>
<td>94 (63)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CWAD</td>
<td>55 (37)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full time</td>
<td>66 (44)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part time</td>
<td>26 (17)</td>
<td></td>
<td></td>
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<tr>
<td>Full time in the home</td>
<td>5 (3)</td>
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<td></td>
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<tr>
<td>Student</td>
<td>4 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Semi-retired</td>
<td>1 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>19 (13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>6 (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed due to ill health</td>
<td>19 (13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital Status</td>
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<td></td>
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</tr>
<tr>
<td>Married/Living as married</td>
<td>101 (68)</td>
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<td></td>
</tr>
<tr>
<td>Single</td>
<td>23 (15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>17 (12)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>7 (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnic Group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>137 (92)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian/Asian British</td>
<td>9 (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>1 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixed</td>
<td>1 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1 (1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2. Scores for cognitive measures for all participants with CNP

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophizing (PCS)</td>
<td>18.7 (11.9)</td>
<td>0-49</td>
</tr>
<tr>
<td>Pain-related fear (TSK)</td>
<td>38.5 (9.9)</td>
<td>17-68</td>
</tr>
<tr>
<td>Pain Vigilance and Awareness (PVAQ)</td>
<td>41.6 (14.3)</td>
<td>10-76</td>
</tr>
<tr>
<td>Pain Management Self-Efficacy (CPSS-pm)</td>
<td>22.5 (10.1)</td>
<td>0-40</td>
</tr>
<tr>
<td>Functional Self-Efficacy (CPSS-pf)</td>
<td>48.1 (22.1)</td>
<td>0-80</td>
</tr>
</tbody>
</table>
Table 3. Correlations between cognitive measures and mNDI scores

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>0.98**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>0.48**</td>
<td>0.57**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>0.54**</td>
<td>0.53**</td>
<td>0.15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>0.46**</td>
<td>0.47**</td>
<td>0.25*</td>
<td>0.38**</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>6.</td>
<td>0.27**</td>
<td>0.28**</td>
<td>0.18*</td>
<td>0.24**</td>
<td>0.50**</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>0.31**</td>
<td>0.34**</td>
<td>0.11</td>
<td>0.34**</td>
<td>0.59**</td>
<td>0.40**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>-0.50**</td>
<td>-0.49**</td>
<td>-0.24**</td>
<td>-0.44**</td>
<td>-0.17*</td>
<td>-0.24**</td>
<td>-0.12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>-0.64**</td>
<td>-0.63**</td>
<td>-0.33**</td>
<td>-0.56**</td>
<td>-0.29**</td>
<td>-0.31**</td>
<td>-0.31**</td>
<td>0.69**</td>
<td></td>
</tr>
</tbody>
</table>

* p= 0.05, **p= 0.01

NDI = Neck Disability Index;
HADS-D = Hospital Anxiety and Depression Scale Depression Sub-scale;
TSK = Tampa Scale for Kinesiophobia; PCS = Pain Catastrophizing Scale;
PVAQ = Pain Vigilance and Awareness Questionnaire;
CPSS–pm = Chronic Pain Self-Efficacy Scale pain management sub-scale;
CPSS-pf = Chronic Pain Self-Efficacy Scale physical function sub-scale
5.3.1 Multiple regression analysis with disability (mNDI) as the dependent variable for all participants with chronic neck pain

Table four. demonstrates that demographics did not explain a statistically significant amount of the variance in disability. In the second step, pain intensity explained 21% of the variance in disability, whilst the cognitive factors significantly explained a further 33% of variance in the final step. Examination of the beta values revealed that nature of onset was significantly related to levels of disability, with patients with WAD reporting higher levels of disability. Furthermore, greater levels of pain intensity and catastrophizing and lower functional self-efficacy beliefs were significantly related to greater levels of disability.

Table 4. Regression analysis for all participants with CNP when disability (mNDI) was the dependent variable (n=149)

<table>
<thead>
<tr>
<th>Step</th>
<th>R²</th>
<th>R² Change</th>
<th>F Change</th>
<th>Standardised β</th>
<th>T</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demographics</td>
<td>0.04</td>
<td>0.04</td>
<td>1.40</td>
<td>0.06</td>
<td>0.86</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>0.01</td>
<td>0.03</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td>0.07</td>
<td>1.19</td>
</tr>
<tr>
<td>Pain duration</td>
<td></td>
<td></td>
<td></td>
<td>0.15</td>
<td>2.49*</td>
</tr>
<tr>
<td>Nature of onset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Pain intensity</td>
<td>0.25</td>
<td>0.21</td>
<td>38.32**</td>
<td>0.23</td>
<td>3.68**</td>
</tr>
<tr>
<td>3. Cognitive measures</td>
<td>0.58</td>
<td>0.33</td>
<td>20.32**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catastrophizing</td>
<td></td>
<td></td>
<td></td>
<td>0.29</td>
<td>3.66**</td>
</tr>
<tr>
<td>Pain-related fear</td>
<td></td>
<td></td>
<td></td>
<td>0.03</td>
<td>0.39</td>
</tr>
<tr>
<td>Pain Vigilance and awareness</td>
<td></td>
<td></td>
<td></td>
<td>-0.01</td>
<td>-0.17</td>
</tr>
<tr>
<td>SE Physical Function</td>
<td></td>
<td></td>
<td></td>
<td>-0.39</td>
<td>-4.38**</td>
</tr>
<tr>
<td>SE Pain management</td>
<td></td>
<td></td>
<td></td>
<td>-0.12</td>
<td>-1.46</td>
</tr>
</tbody>
</table>

Dependent Variable: Modified NDI %  

* p<0.05, **p<0.001
5.3.2 Multiple regression analysis with current pain intensity as the dependent variable for all participants with chronic neck pain

In the first step, demographics did not explain a significant proportion of the variance in current pain intensity. In the second step, the cognitive factors significantly explained an additional 16% of the variance in current pain intensity. Examination of the beta values for the final model (shown in Table 5.) revealed that greater levels of catastrophizing (β = 0.26, p<0.05) and lower functional self-efficacy beliefs (β= 0.29, p<0.05) were significantly related to greater levels of pain intensity.

Table 5: Regression analysis with current pain intensity as the dependent variable for all participants with chronic neck pain (n=149)

<table>
<thead>
<tr>
<th>Step</th>
<th>R²</th>
<th>R² Change</th>
<th>F Change</th>
<th>Standardised β</th>
<th>T</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demographics</td>
<td>0.02</td>
<td>0.02</td>
<td>0.73</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>0.14</td>
<td>1.60</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td>0.01</td>
<td>0.15</td>
</tr>
<tr>
<td>Pain duration</td>
<td></td>
<td></td>
<td></td>
<td>0.09</td>
<td>1.14</td>
</tr>
<tr>
<td>Nature of onset</td>
<td></td>
<td></td>
<td></td>
<td>0.06</td>
<td>0.73</td>
</tr>
<tr>
<td>2. Cognitive measures</td>
<td>0.18</td>
<td>0.16</td>
<td>5.11**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catastrophizing</td>
<td></td>
<td></td>
<td></td>
<td>0.26</td>
<td>2.18*</td>
</tr>
<tr>
<td>Pain-related fear</td>
<td></td>
<td></td>
<td></td>
<td>0.14</td>
<td>1.40</td>
</tr>
<tr>
<td>Pain vigilance and awareness</td>
<td></td>
<td></td>
<td></td>
<td>-0.15</td>
<td>-1.45</td>
</tr>
<tr>
<td>SE Physical function</td>
<td></td>
<td></td>
<td></td>
<td>-0.29</td>
<td>-2.44*</td>
</tr>
<tr>
<td>SE Pain management</td>
<td></td>
<td></td>
<td></td>
<td>0.03</td>
<td>0.26</td>
</tr>
</tbody>
</table>

Dependent Variable: Current pain intensity (question one of the NDI)

p=0.05, **p=0.001
5.3.3 Multiple regression analysis with depression (HADS-d) as the dependent variable for all participants with chronic neck pain

In the first two steps of the analysis, demographic factors and current pain intensity did not explain significant proportions of the variance in depression. In the third step of model, the cognitive factors significantly explained 34% of the variance in depression. The final model (shown in Table 6.) explained 39% of the variance in depression. Examination of the coefficients revealed that lower functional self-efficacy beliefs ($\beta=-0.43$, $p<0.005$) was the only cognitive factor significantly associated with greater levels of depression.

Table 6. Regression analysis for all participants with chronic neck pain when depression (HADS-d) was the dependent variable (n=149)

<table>
<thead>
<tr>
<th>Step</th>
<th>$R^2$</th>
<th>$R^2$ Change</th>
<th>$F$ Change</th>
<th>Standardised $\beta$</th>
<th>$T$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demographics</td>
<td>0.03</td>
<td>0.03</td>
<td>0.92</td>
<td>-0.07</td>
<td>-0.82</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>0.03</td>
<td>0.56</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td>0.03</td>
<td>0.36</td>
</tr>
<tr>
<td>Pain duration</td>
<td></td>
<td></td>
<td></td>
<td>-0.05</td>
<td>-0.71</td>
</tr>
<tr>
<td>Nature of onset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Pain intensity</td>
<td>0.05</td>
<td>0.02</td>
<td>3.44</td>
<td>-0.07</td>
<td>-0.89</td>
</tr>
<tr>
<td>3. Cognitive measures</td>
<td>0.39</td>
<td>0.34</td>
<td>14.39**</td>
<td>0.18</td>
<td>1.92</td>
</tr>
<tr>
<td>Catastrophizing</td>
<td></td>
<td></td>
<td></td>
<td>0.03</td>
<td>0.29</td>
</tr>
<tr>
<td>Pain-related fear</td>
<td></td>
<td></td>
<td></td>
<td>0.08</td>
<td>0.85</td>
</tr>
<tr>
<td>Pain Vigilance and Awareness</td>
<td></td>
<td></td>
<td></td>
<td>-0.43</td>
<td>-4.02**</td>
</tr>
<tr>
<td>SE Physical Function</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE Pain Management</td>
<td></td>
<td></td>
<td></td>
<td>-0.11</td>
<td>-1.06</td>
</tr>
</tbody>
</table>

Dependent Variable: HADS-d

* $p<0.05$, **$p<0.001$
5.4 Study two: A study exploring whether differences exist in the relationship between cognitive factors and levels of adjustment in participants with idiopathic CNP and CWAD

Study two explored whether the relation between the cognitive factors and levels of adjustment differed between those participants with idiopathic CNP and those with chronic whiplash associated disorder.

5.4.1 Between group differences

Independent sample t-tests revealed that there were no significant differences in levels of pain, disability or depression between the two groups. Moreover, there were no significant differences in the cognitive scores between patients with idiopathic CNP and those with CWAD. However, t-test revealed a significant difference in mean age between the groups (p<0.001). Specifically, the mean age of participants with idiopathic CNP was significantly higher than those with CWAD. Examination of χ² test revealed no significant differences in the proportion of males and females between the two groups.
5.4.2 Participants with idiopathic chronic neck pain

5.4.2.1 Participant Characteristics

Ninety-four participants reported idiopathic CNP. Forty-nine (52%) were female, the mean age was 51 years (range 16 to 85, SD=14.6) and the mean duration of neck pain was 48 months (range 3 to 480, SD=74.7). Table 7. shows the participant characteristics and Table 8. shows participants scores for the cognitive measures.
Table 7. Participants with idiopathic chronic neck pain characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>N (%)</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>51 (14.6)</td>
<td>16-85</td>
<td></td>
</tr>
<tr>
<td>Pain duration (Months)</td>
<td>48.4 (74.7)</td>
<td>3-480</td>
<td></td>
</tr>
<tr>
<td>Current pain intensity</td>
<td>1.8 (0.8)</td>
<td>0-4</td>
<td></td>
</tr>
<tr>
<td>Modified NDI %</td>
<td>33 (18.1)</td>
<td>0-88</td>
<td></td>
</tr>
<tr>
<td>Unmodified NDI%</td>
<td>36 (17.1)</td>
<td>0-84</td>
<td></td>
</tr>
<tr>
<td>Depression (HADS-d)</td>
<td>5.7 (3.8)</td>
<td>0-15</td>
<td></td>
</tr>
<tr>
<td>Sex:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>49 (53)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>45 (47)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full time</td>
<td>38 (40)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part time</td>
<td>18 (19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full time in the home</td>
<td>3 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>1 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Semi-retired</td>
<td>1 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>15 (16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>3 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed (ill health)</td>
<td>12 (13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/Living as married</td>
<td>62 (66)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>14 (15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>9 (10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>7 (7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnic Group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>88 (93)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian/Asian British</td>
<td>4 (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>1 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixed</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1 (1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 8. Scores for cognitive measures for participants with idiopathic CNP

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophizing (PCS)</td>
<td>19.5 (12.5)</td>
<td>0-49</td>
</tr>
<tr>
<td>Pain-related fear (TSK)</td>
<td>38.6 (10.8)</td>
<td>17-68</td>
</tr>
<tr>
<td>Pain Vigilance and Awareness (PVAQ)</td>
<td>41.8 (13.9)</td>
<td>10-76</td>
</tr>
<tr>
<td>Pain Management Self-efficacy (CPSS-pm)</td>
<td>22.2 (10.9)</td>
<td>0-40</td>
</tr>
<tr>
<td>Functional Self-efficacy (CPSS-pf)</td>
<td>48.2 (24.5)</td>
<td>0-80</td>
</tr>
</tbody>
</table>
5.4.2.2 Multiple regression analysis with disability (mNDI) as the dependent variable for participants with idiopathic Chronic Neck Pain

Demographics (age, sex and pain duration) did not explain a statistically significant proportion of the variance in disability. After accounting for the effects of demographics, pain intensity explained an additional 25% of the variance in disability ($p<0.001$). In step three, the cognitive factors accounted for an additional 30% of the variance in disability, with the final model (shown in Table 9) accounting for 58% of total variance. Examination of the beta values revealed that greater levels of pain intensity ($\beta=0.29$, $p<0.01$) and catastrophizing ($\beta=0.24$, $p<0.05$) and lower functional self-efficacy beliefs ($\beta=-0.34$, $p<0.001$) were significantly related to greater levels of disability.

Table 9. Regression analyses for participants with idiopathic chronic neck pain when disability (mNDI) was the dependent variable (n=94)

<table>
<thead>
<tr>
<th>Step</th>
<th>$R^2$</th>
<th>$R^2$ Change</th>
<th>$F$ Change</th>
<th>Standardised $\beta$</th>
<th>$T$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demographics</td>
<td>0.03</td>
<td>0.03</td>
<td>1.56</td>
<td>0.10</td>
<td>1.17</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>-0.05</td>
<td>-0.65</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td>0.12</td>
<td>0.12</td>
</tr>
<tr>
<td>Pain duration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Pain intensity</td>
<td>0.28</td>
<td>0.25</td>
<td>26.72**</td>
<td>0.29</td>
<td>3.40*</td>
</tr>
<tr>
<td>3. Cognitive measures</td>
<td>0.58</td>
<td>0.30</td>
<td>11.52**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catastrophizing</td>
<td></td>
<td></td>
<td></td>
<td>0.26</td>
<td>2.41*</td>
</tr>
<tr>
<td>Pain-related fear</td>
<td></td>
<td></td>
<td></td>
<td>0.01</td>
<td>0.15</td>
</tr>
<tr>
<td>Pain Vigilance and Awareness</td>
<td></td>
<td></td>
<td></td>
<td>0.13</td>
<td>1.42</td>
</tr>
<tr>
<td>SE Physical Function</td>
<td></td>
<td></td>
<td></td>
<td>-0.34</td>
<td>-2.95*</td>
</tr>
<tr>
<td>SE Pain Management</td>
<td></td>
<td></td>
<td></td>
<td>-0.10</td>
<td>-0.94</td>
</tr>
</tbody>
</table>

Dependent Variable: Modified NDI %

* $p<0.05$, **$p<0.001$
5.4.4.3 Multiple regression analysis with current pain intensity as the dependent variable for participants with idiopathic chronic neck pain

In the first step of the analysis, demographics did not explain a significant proportion of the variance in disability. In the second step the cognitive factors significantly explained 23% of the variance in current pain intensity. In the final model (shown in Table 10.), greater levels of catastrophizing ($\beta=0.37$, $p<0.01$) and lower levels of pain vigilance and awareness ($\beta=0.32$, $p<0.05$) were significantly related to greater pain intensity.

**Table 10: Regression analysis for participants with idiopathic chronic neck pain when current pain intensity was the dependent variable (n=94)**

<table>
<thead>
<tr>
<th>Step</th>
<th>$R^2$</th>
<th>$R^2$ Change</th>
<th>$F$ Change</th>
<th>Standardised $\beta$</th>
<th>$T$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demographics</td>
<td>0.04</td>
<td>0.04</td>
<td>1.31</td>
<td>0.24</td>
<td>2.25</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td>0.02</td>
<td>0.23</td>
</tr>
<tr>
<td>Pain duration</td>
<td></td>
<td></td>
<td></td>
<td>0.05</td>
<td>0.52</td>
</tr>
<tr>
<td>2. Cognitive measures</td>
<td>0.27</td>
<td>0.23</td>
<td>4.94**</td>
<td>0.37</td>
<td>2.98*</td>
</tr>
<tr>
<td>Catastrophizing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain-related fear</td>
<td>0.10</td>
<td>- 0.32</td>
<td>- 2.74*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain Vigilance and Awareness</td>
<td></td>
<td>- 0.24</td>
<td>- 1.57</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE Physical Function</td>
<td></td>
<td></td>
<td></td>
<td>- 0.66</td>
<td>- 0.40</td>
</tr>
<tr>
<td>SE Pain Management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dependent Variable: Current Pain Intensity (question one NDI)

* $p<0.05$, **$p<0.001$
5.4.4.4 Multiple regression analysis with depression as the dependent variable for participants with idiopathic chronic neck pain

In the first two steps of the analysis, demographics and current pain intensity did not explain significant proportions of the variance in depression. In the third step the cognitive factors significantly explained 32% of the variance in depression. The final model (shown in Table 11.) explained 37% of the variance in depression. Examination of the beta values revealed that only lower functional self-efficacy beliefs ($\beta=-0.35, \ p<0.05$) were significantly related to greater levels of depression.

Table 11. Regression analysis for participants with idiopathic chronic neck pain when depression (HADS-d) was the dependent variable (n=94)

<table>
<thead>
<tr>
<th>Step</th>
<th>$R^2$</th>
<th>$R^2$ Change</th>
<th>$F$ Change</th>
<th>Standardised $\beta$</th>
<th>$T$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demographics</td>
<td>0.02</td>
<td>0.02</td>
<td>0.70</td>
<td>-0.76</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>0.08</td>
<td>-0.76</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td>0.05</td>
<td>0.56</td>
</tr>
<tr>
<td>Pain duration</td>
<td></td>
<td></td>
<td></td>
<td>0.07</td>
<td>0.71</td>
</tr>
<tr>
<td>2. Pain intensity</td>
<td>0.05</td>
<td>0.03</td>
<td>2.83</td>
<td>0.05</td>
<td>0.67</td>
</tr>
<tr>
<td>3. Cognitive measures</td>
<td>0.37</td>
<td>0.32</td>
<td>7.99**</td>
<td>0.08</td>
<td>0.18</td>
</tr>
<tr>
<td>D C lassifying</td>
<td></td>
<td></td>
<td></td>
<td>0.02</td>
<td>1.54</td>
</tr>
<tr>
<td>Pain-related fear</td>
<td></td>
<td></td>
<td></td>
<td>0.17</td>
<td>1.42</td>
</tr>
<tr>
<td>Pain Vigilance and Awareness</td>
<td>0.35</td>
<td>-0.35</td>
<td>2.45*</td>
<td>-0.19</td>
<td>-1.41</td>
</tr>
<tr>
<td>SE Physical Function</td>
<td></td>
<td></td>
<td></td>
<td>-0.35</td>
<td>-2.45</td>
</tr>
<tr>
<td>SE Pain Management</td>
<td></td>
<td></td>
<td></td>
<td>-0.19</td>
<td>-1.41</td>
</tr>
</tbody>
</table>

Dependent Variable: HADS-d
* $p<0.05$, **$p<0.001$
5.4.3 Participants with chronic whiplash associated disorder

5.4.3.1 Participant characteristics

Fifty-five participants reported the onset of neck pain following a MVC. Sixty percent were female, mean age was 41 years (range 17 to 71, SD=12.6) and mean pain duration was 41.3 months (range 3 to 444, SD=89.6). Table 12. shows participants characteristics and Table 13. shows participants’ scores for the cognitive measures.
Table 12. Participant with CWAD characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>42 (12.6)</td>
<td>17-71</td>
<td></td>
</tr>
<tr>
<td>Pain duration (Months)</td>
<td>41.3 (89.7)</td>
<td>3-444</td>
<td></td>
</tr>
<tr>
<td>Current pain intensity</td>
<td>1.8 (0.9)</td>
<td>0-4</td>
<td></td>
</tr>
<tr>
<td>Modified NDI %</td>
<td>37 (16.1)</td>
<td>9-68</td>
<td></td>
</tr>
<tr>
<td>Unmodified NDI %</td>
<td>37 (15.5)</td>
<td>12-64</td>
<td></td>
</tr>
<tr>
<td>Depression (HADS-d)</td>
<td>5.3 (3.8)</td>
<td>0-16</td>
<td></td>
</tr>
<tr>
<td>Sex:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>33 (60)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22 (40)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupation:</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Full time</td>
<td>28 (51)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part time</td>
<td>8 (15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full time in the home</td>
<td>2 (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>3 (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>4 (7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>3 (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed (ill health)</td>
<td>7 (13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/Living as married</td>
<td>39 (71)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>9 (16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>7 (13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnic Group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>49 (89)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian/Asian British</td>
<td>5 (9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixed</td>
<td>1 (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 13. Scores for cognitive measures for participants with CWAD

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophizing (PCS)</td>
<td>17.3 (11.0)</td>
<td>0-37</td>
</tr>
<tr>
<td>Pain-related fear (TSK)</td>
<td>38.3 (8.3)</td>
<td>17-53</td>
</tr>
<tr>
<td>Pain Vigilance and Awareness (PVAQ)</td>
<td>41.2 (15.2)</td>
<td>12-68</td>
</tr>
<tr>
<td>Pain Management Self-efficacy (CPSS-pm)</td>
<td>23.1 (8.6)</td>
<td>6-40</td>
</tr>
<tr>
<td>Functional Self-efficacy (CPSS-pf)</td>
<td>48.0 (17.3)</td>
<td>3-72</td>
</tr>
</tbody>
</table>
5.4.3.2 Multiple regression analysis with disability (mNDI) as the dependent variable for participants with CWAD

In the first step of the analysis demographics explained 15% of the variance in disability, whilst in step two, pain intensity accounted for an additional 12% of the variance. In the final step, the cognitive factors explained a further 37% of the variance in disability \((p<0.001)\) beyond that explained by demographics and pain intensity. The final model (shown in Table 14.) explained 66% of the variance in disability. Examination of the beta values revealed that lower functional self-efficacy beliefs \((\beta=-0.47, p<0.01)\) and greater catastrophizing \((\beta=0.41, p<0.01)\) were significantly related to greater levels of disability.

Table 14. Regression analysis for participants with CWAD when disability (mNDI) was the dependent variable \((n=45)\)

<table>
<thead>
<tr>
<th>Step</th>
<th>R²</th>
<th>R² Change</th>
<th>F Change</th>
<th>Standardised β</th>
<th>T</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demographics</td>
<td>0.15</td>
<td>0.15</td>
<td>2.84</td>
<td>-0.01</td>
<td>-0.05</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>0.11</td>
<td>0.99</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td>0.08</td>
<td>0.75</td>
</tr>
<tr>
<td>Pain duration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Pain intensity</td>
<td>0.27</td>
<td>0.12</td>
<td>7.70**</td>
<td>0.21</td>
<td>2.04</td>
</tr>
<tr>
<td>3. Cognitive measures</td>
<td>0.66</td>
<td>0.39</td>
<td>9.42**</td>
<td>0.41</td>
<td>2.87**</td>
</tr>
<tr>
<td>Catastrophizing</td>
<td></td>
<td></td>
<td></td>
<td>0.18</td>
<td>1.12</td>
</tr>
<tr>
<td>Pain-related fear</td>
<td></td>
<td></td>
<td></td>
<td>-0.39</td>
<td>-2.42</td>
</tr>
<tr>
<td>Pain Vigilance and Awareness</td>
<td></td>
<td></td>
<td></td>
<td>-0.47</td>
<td>-3.43**</td>
</tr>
<tr>
<td>SE Physical Function</td>
<td></td>
<td></td>
<td></td>
<td>-0.05</td>
<td>-0.34</td>
</tr>
<tr>
<td>SE Pain Management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dependent Variable: Modified NDI %
* \(p<0.05\), **\(p<0.001\)
5.4.3.3 Multiple regression analysis with current pain intensity as the dependent variable

It can be seen from Table 15. that neither the cognitive factors nor demographics explained a significant proportion of the variance in current pain intensity. None of the variables entered in the final regression model displayed significant beta values.

Table 15. Regression analysis for participants with CWAD when current pain intensity was the dependent variable (n=45)

<table>
<thead>
<tr>
<th>Step</th>
<th>R²</th>
<th>R² Change</th>
<th>F Change</th>
<th>Standardised β</th>
<th>T</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demographics</td>
<td>0.09</td>
<td>0.09</td>
<td>1.63</td>
<td>-0.16</td>
<td>-0.87</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>-0.02</td>
<td>0.15</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td>0.21</td>
<td>1.35</td>
</tr>
<tr>
<td>Pain duration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Cognitive measures</th>
<th>0.24</th>
<th>0.15</th>
<th>1.72</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophizing</td>
<td></td>
<td>-0.04</td>
<td>-0.17</td>
</tr>
<tr>
<td>Pain-related fear</td>
<td>0.12</td>
<td></td>
<td>0.51</td>
</tr>
<tr>
<td>Pain Vigilance and Awareness</td>
<td>0.20</td>
<td></td>
<td>0.87</td>
</tr>
<tr>
<td>SE Physical Function</td>
<td>-0.29</td>
<td>-1.25</td>
<td></td>
</tr>
<tr>
<td>SE Pain Management</td>
<td>0.22</td>
<td></td>
<td>1.12</td>
</tr>
</tbody>
</table>

Dependent Variable: Current Pain Intensity (question one NDI)
*p<0.05, **p<0.001
5.4.3.4 Multiple regression analysis with depression as the dependent variable for participants with CWAD

In the first two steps of the analysis, demographics and current pain intensity did not explain significant proportions of the variance in depression. In the third step of model, the cognitive factors significantly explained 46% of the variance in depression. The final model (shown in Table 16.) explained 52% of the total variance. Examination of the beta values revealed that only lower functional self-efficacy beliefs ($\beta=-0.62, p<0.001$) were significantly related to greater levels of depression.

Table 16. Regression analysis for participants with CWAD when depression (HADS-d) was the dependent variable (n=45)

<table>
<thead>
<tr>
<th>Step</th>
<th>$R^2$</th>
<th>$R^2$ Change</th>
<th>$F$ Change</th>
<th>Standardised $\beta$</th>
<th>$T$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demographics</td>
<td>0.05</td>
<td>0.05</td>
<td>0.88</td>
<td>0.24</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>-0.04</td>
<td>0.24</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td>-0.07</td>
<td>-0.51</td>
</tr>
<tr>
<td>Pain duration</td>
<td></td>
<td></td>
<td></td>
<td>-0.11</td>
<td>-0.82</td>
</tr>
<tr>
<td>2. Pain intensity</td>
<td>0.06</td>
<td>0.01</td>
<td>0.35</td>
<td>-0.14</td>
<td>-1.17</td>
</tr>
<tr>
<td>3. Cognitive measures</td>
<td>0.52</td>
<td>0.46</td>
<td>8.07**</td>
<td>-0.34</td>
<td>2.00</td>
</tr>
<tr>
<td>Catastrophizing</td>
<td></td>
<td></td>
<td></td>
<td>0.08</td>
<td>0.43</td>
</tr>
<tr>
<td>Pain-related fear</td>
<td></td>
<td></td>
<td></td>
<td>-0.14</td>
<td>-0.75</td>
</tr>
<tr>
<td>Pain Vigilance and Awareness</td>
<td></td>
<td></td>
<td></td>
<td>-0.62</td>
<td>-3.81**</td>
</tr>
<tr>
<td>SE Physical Function</td>
<td></td>
<td></td>
<td></td>
<td>-0.06</td>
<td>0.34</td>
</tr>
<tr>
<td>SE Pain Management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dependent Variable: HADS-d
* $p<0.05$, **$p<0.001$
5.5 Summary of results

5.5.1 All participants with chronic neck pain

Nature of onset, pain intensity, catastrophizing and functional self efficacy beliefs were all significantly related to levels of disability. Catastrophizing and functional self-efficacy beliefs were significantly associated with levels of pain intensity, whilst only functional self-efficacy beliefs were associated with levels of depression.

5.5.2 Differences between participants with idiopathic CNP and CWAD.

Pain intensity was associated with levels of disability in patients with idiopathic CNP but not those with CWAD. However, catastrophizing and functional self-efficacy beliefs were significantly associated with levels of disability in both groups. Similarly, in both groups only functional self-efficacy beliefs were significantly associated with levels of depression. In contrast, catastrophizing and pain vigilance and awareness were associated with levels of pain intensity in those participants with idiopathic CNP, whilst none of the cognitive factors displayed a significant association with levels of pain intensity in those with CWAD.
6.0 Discussion

The aim of study one was to determine the extent to which the predictive FAM variables and self-efficacy beliefs were related to levels of adjustment in patients with CNP. Moreover, study two aimed to determine whether the relationship between levels of adjustment and the cognitive factors differed between those patients with idiopathic CNP and those with CWAD.

6.1 Study one: The relationship between the cognitive factors and levels of adjustment in participants with chronic neck pain

6.1.1 The relationship between the cognitive factors and levels of disability in all participants with chronic neck pain

Age, sex and pain duration were not significantly associated with levels of disability in the study one. In contrast, higher pain intensity displayed a strong association with disability, significantly explaining 21% of the variance. This is consistent with other chronic pain studies, which have reported that pain intensity accounts for between 17-31% of the variance in disability\textsuperscript{16,57,78}. In contrast to these findings, some studies have reported that pain plays a relatively minor role in explaining disability in chronic pain populations. For example, a study of 104 patients with CLBP referred to a chronic pain rehabilitation centre, reported that pain-related fear was more strongly related to disability than pain intensity itself\textsuperscript{56}.
It is worth noting that the study by Crombez et al\textsuperscript{56} was conducted in a pain clinic environment, whereas the current study, along with those of Woby et al\textsuperscript{57} and Ayre and Tyson\textsuperscript{78} were carried out in physiotherapy departments. These findings possibly intimate that patients referred to physiotherapy may differ from those referred to alternative forms of treatment. Specifically, it would seem that pain intensity is more strongly associated with levels of disability in those patients referred to physiotherapy than those referred to specialist pain management programmes. This is possibly due to differences in the characteristics of individuals treated in pain clinic environments, as compared to those treated with physiotherapy.

Patients who require pain clinic treatment may be those who report greater levels of disability or who have failed to make significant improvements with other interventions, such as physiotherapy. Plausibly, this may be as factors other than pain intensity are the primary determinants of disability in these patients. Indeed, it is feasible that it is those patients with greatest cognitive risk factors who fail to improve significantly with physiotherapy\textsuperscript{52} and ultimately require pain clinic treatment. Consequently, patients treated in pain clinic settings may be those who exhibit the greatest levels of disability and cognitive risk factors, whereas physiotherapy environments contain patients with a greater variety of disability levels and cognitive risk factors.

The findings of the current study suggest that pain intensity may be an important consideration when treating patients with CNP and disability.
Reducing pain intensity may bring about important reductions in disability.
Indeed, previous studies of physiotherapy interventions for patients with CNP have demonstrated that treatments which reduce pain are also effective in reducing levels of disability\(^9^9-10^2\). It is feasible that improvements in disability observed in these studies were, at least in part, underpinned by reductions in pain intensity. In view of these findings, it would seem prudent when treating patients with CNP to include interventions which have been shown to reduce levels of pain intensity. This may in turn reduce levels of disability amongst these patients.

Reducing pain intensity may be one mechanism to reduce levels of disability, however, the results of the current thesis suggest that levels of pain intensity do not fully account for levels of disability. Indeed, even after accounting for the effects of demographics and pain intensity, the cognitive factors displayed the strongest association with levels of disability. Specifically, greater levels of catastrophizing and lower functional self-efficacy beliefs were most strongly associated with greater levels of disability. The significant relationship observed between catastrophizing and disability in the current study provides partial support for the Fear Avoidance Model\(^2^4\) in patients with CNP. According to this model, participants with higher levels of catastrophizing and pain-related fear are likely to decrease or avoid activity because they are fearful of damaging their neck or exacerbating their pain. Accordingly, it is feasible that participants in the current study who displayed greater levels of catastrophizing experienced greater disability because they disengaged from domestic, work and social
activities due to the perceived negative consequences of participating in these activities.

As well as proposing that prolonged avoidance of activity will result in greater levels of disability, the FAM also posits that avoidance will result in a deconditioning effect, which will, in turn, lead to even greater levels of disability. Interestingly, a previous study that investigated the relationship between catastrophizing and functional capacity in patients with chronic fatigue syndrome and chronic pain reported that greater catastrophizing was significantly correlated with lower performance on a number of measures of aerobic capacity. It is possible that similar associations may be observed between levels of catastrophizing and functional capacity in patients with CNP. Moreover, such decreases in functional capacity may help to explain the associations observed between catastrophizing and disability.

In partial support of the above notion, previous studies have reported that patients with CNP display increased fatigability of the sternocleidomastoid and scalene muscles and decreased strength of the neck flexors, extensors and rotators when compared to age matched, healthy control subjects. Moreover, previous studies have demonstrated treatment programmes comprising of aerobic, endurance and strengthening exercise result in decreases in pain and disability in participants with CNP. It is possible that such programmes were effective as they reverse some of the effects of deconditioning observed in patients with CNP. However, future studies are
required to explore whether the relationship between catastrophizing and disability is mediated by decreases in cervical muscle strength and endurance.

An alternative explanation for the association between catastrophizing and disability is offered by a previous study of chronic pain patients that demonstrated that participants with greater levels of pain-related fear experienced greater levels of attentional interference\(^{56}\). Although the study did not consider the effects of catastrophizing per se, given the significant associations observed between catastrophizing and pain-related fear observed in this study, and in previous work\(^{29}\), it is feasible that catastrophizing is also significantly related to levels of attentional interference.

Attentional interference might result in a reduced ability to concentrate, which, in turn, may result in inferior performance, especially in tasks requiring high levels of cognitive effort and concentration. Interestingly, several items of the disability measure employed in this study (the mNDI) assess cognitively demanding tasks, such as reading, work, concentration and driving. It is therefore possible that attentional interference might significantly impact on performance in these activities and may underpin the relationship between levels of catastrophizing and disability observed in this study. However, this suggestion is speculative and future studies are required to investigate the meditational relationship between levels of catastrophizing, attentional interference and disability in patients with CNP.
That catastrophizing displayed a significant relationship with levels of disability is consistent with previous studies, which have reported a positive relationship between catastrophizing and disability in cross-sectional studies of participants with sub-acute\textsuperscript{51} and chronic neck pain\textsuperscript{35,49,106}. Moreover, Nederhand and colleagues\textsuperscript{50} reported that higher baseline levels of catastrophizing were also associated with ongoing pain and disability at six month follow up. In addition to the findings from these cross-sectional and longitudinal studies, elevated levels of catastrophizing have been also associated with a failure to make a clinically significant improvement in disability\textsuperscript{52} and a lack of patient perceived recovery\textsuperscript{53} in patients with CNP who were undergoing physiotherapy treatment.

In conjunction with the findings of the current thesis, the studies discussed previously appear to suggest that raised levels of catastrophizing act as a significant barrier to recovery in patients with CNP. Therefore, it is feasible that strategies which reduce catastrophizing may result in significant reductions in disability, particularly in those who do not respond well to conventional physiotherapy treatments. In partial support of this notion, Sullivan and colleagues\textsuperscript{107} demonstrated in a non-randomised comparison trial of patients with CWAD that a physiotherapist-led intervention, underscored by structured goal setting and cognitive re-appraisal exercises, was more effective than conventional physiotherapy treatment in reducing catastrophizing and work disability. It can therefore be surmised that such treatment approaches may also be effective in reducing levels of catastrophizing in patients with other forms of CNP, however future randomised controlled trials are required to
adequately explore whether this type of intervention is more efficacious than conventional physiotherapy treatments in isolation.

In contrast to previous studies\textsuperscript{50,64,66-68,106}, the current study did not find a strong association between pain-related fear and disability when other pertinent cognitive factors were considered. It is noteworthy that those studies observing a positive association between pain-related fear and disability did not consider the influence of self-efficacy beliefs. As in the current study, previous studies of patients which have investigated self-efficacy beliefs alongside pain-related fear have reported that self-efficacy tends to emerge as the stronger predictor of disability\textsuperscript{29,78,79}.

Interestingly however, Woby et al\textsuperscript{37} reported that self-efficacy beliefs mediated the relationship between pain-related fear and disability in a study of 102 participants with CLBP referred for physiotherapy treatment. It is feasible that a similar mediation effect may have occurred in participants in the current study. This may account for the significant correlation observed between pain-related fear and disability, whilst no such relation was apparent in the regression analysis. Consequently, although the findings of this thesis suggest that targeting pain-related fear may not be an effective method of attenuating disability, it is feasible that reducing pain-related fear may be an effective method of enhancing self-efficacy beliefs, which, in turn, may reduce levels of disability. However, further studies are required to explore whether such a meditational relationship exists between levels of pain-related fear, self-efficacy and disability.
An alternative explanation for the disparity in findings between the current study and previous work may be differences in study design. Several of the studies discussed previously have explored the transition from acute to chronic pain\textsuperscript{50,106} or examined participants with sub-acute neck pain\textsuperscript{51}. Moreover, two of the above studies explored non-clinical populations; one explored computer workers recruited by telephone\textsuperscript{64} and the other recruited participants from an insurance company database of persons claiming compensation following a MVC\textsuperscript{106}. Conversely, the current study explored the relationship between pain-related fear and disability in a cohort of patients with CNP who were referred for physiotherapy treatment. Therefore, it is possible that the relationship between pain-related fear and disability differs according to the stage of chronicity and treatment context.

Finally, it is feasible that the current study reported differing findings with regards to the relationship between pain-related fear and disability due to the different measure of pain-related fear employed. In the current study, pain-related fear was measured using the TSK. However, some previous studies reporting a positive association between levels of pain-related fear and disability have employed the Fear Avoidance Beliefs Questionnaire (FABQ)\textsuperscript{66-68}. It is possible that the TSK and FABQ assess different aspects of pain-related fear. In support of this notion, Cleland and co-workers\textsuperscript{65} examined the relation between disability and pain-related fear, as assessed by both the TSK and FABQ, in a cohort of 78 participants with CNP. Interestingly, only the FABQ work sub-scale was uniquely related to levels of disability. This may suggest
that in patients with CNP, fear of movement/(re)injury (as assessed by the TSK) is associated with disability to a lesser extent than fears specifically related to work. However, future studies are required to assess whether fear avoidance beliefs about work remain significantly related to levels of disability when considered alongside self-efficacy beliefs, as, as discussed previously, the current findings suggest that functional self-efficacy beliefs exert the strongest influence over levels of disability in patients with CNP.

That study one found that functional self-efficacy beliefs were strongly related to levels of disability agrees with previous work in patients with neck pain. Kyhlbäck and colleagues\textsuperscript{84} reported that lower self-efficacy beliefs in patients with acute neck pain were significantly associated with greater disability at one year follow up. Moreover, Söderlund and Lindberg\textsuperscript{85} reported that self-efficacy beliefs were significant determinants of disability in a cross sectional cohort of patients with CWAD. Furthermore, the findings of the current study also support studies of patients with other chronic pain conditions, which have reported a consistent relationship between lower self-efficacy beliefs and greater levels of disability\textsuperscript{29,78,108}.

There are several possible explanations for the relationship observed between lower functional self-efficacy beliefs and greater levels of disability in patients with CNP. It is plausible that at onset of symptoms, patients are unable to engage in their usual activities because of more severe neck pain. This may result in a reduction in their confidence to successfully complete functional tasks, meaning that even once the acute symptoms subside, patients do not
attempt to re-engage in the activity. Alternatively, self-efficacy beliefs may be reduced as participants repeatedly fail in attempts to carry out functional activities, therefore losing confidence in successfully completing these tasks and subsequently disengaging from them. Such loss of confidence might then generalise to different contexts, resulting in a disengagement from activities which the participants had previously been able to successfully complete.

In view of the findings of this study it would seem that decreasing levels of catastrophizing and enhancing functional self-efficacy beliefs may result in important reductions in levels of disability. Previous studies of participants with CLBP have demonstrated that effective methods of modifying cognitive factors and reducing disability are graded exposure and graded activity\textsuperscript{109,110}. Interestingly, both of these treatment modalities require the patient to identify activities which they are currently not engaging in, with a view to increasing participation. Graded exposure aims to do this through psychological education sessions and gradually exposing patients to specific activities that they previously avoided. This enables disconfirmation of catastrophic thoughts and return to functional activity\textsuperscript{110}. In contrast, graded activity requires participants to identify specific treatment goals and then work towards these goals at specific activity quotas, usually starting at 70-80\% of maximum capacity. Activity quotas are then steadily increased over time until the goal is achieved\textsuperscript{110}.

In view of the studies discussed above, it is plausible that a key component of treatment in patients with chronic pain conditions is the identification of
treatment goals that are important to the individual. Working towards these goals in a structured manner, either through graded activity or graded exposure appears to be an effective means by which to reduce disability and modify cognitive factors. Interestingly, when a previous study of participants with CNP compared graded activity to a conventional physiotherapy intervention, no significant differences were observed between the groups in terms of pain or disability, with both treatments improving levels of function\textsuperscript{111}. However, no previous studies have examined the efficacy of combining a conventional physiotherapy regime with treatment designed to expose participants to specific activities that they have ceased to engage in. It is possible that the two interventions reduce disability by different mechanisms and therefore treatment efficacy may be increased by combining these two approaches. Consequently, future studies should delineate whether the addition of treatment specifically aiming to return participants to desired activities enhances outcome in patients with CNP.

In contrast to previous work\textsuperscript{69}, the current study did not support a significant relationship between pain vigilance and awareness and disability. It is noteworthy that previous studies exploring this relationship have been conducted in cohorts of patients with heterogeneous chronic pain conditions. Moreover, these studies have been conducted in chronic pain management centres, rather than physiotherapy departments, as in the current study. It is feasible that the relationship between pain vigilance and awareness and disability differs amongst different chronic pain conditions and in different treatment contexts. Alternatively, it may be that previous studies have not
assessed the influence of pain vigilance and awareness alongside other cognitive factors, meaning that the significance of this relationship has been overstated. Nevertheless, the current findings suggest that targeting the modification of pain vigilance and awareness in isolation is unlikely to be an effective method of reducing disability in participants with CNP.

In addition to the above, the current study did not support a significant relationship between pain self-efficacy beliefs and levels of disability. To the author’s knowledge, this is the first study to explore this relationship in patients with CNP, however, previous studies have explored this relationship in other chronic pain conditions. In contrast to the current findings, previous studies have reported a significant relationship between pain self-efficacy beliefs and levels of disability\(^{80,82,83,112}\). However, it should be noted that important methodological differences exist between the current study and previous work. Firstly, Buckelew and associates\(^{80}\) explored the relationship between disability and pain self-efficacy beliefs separately to functional self-efficacy beliefs. It is possible that there is significant conceptual overlap between these constructs, and that when considered together, functional self-efficacy beliefs exert the stronger influence over disability.

In a similar manner to the above study, Arnstein et al\(^{83}\) used a composite measure of functional and pain management self-efficacy beliefs, meaning that it was not possible to delineate which specific aspect of self-efficacy beliefs was strongly related to levels of disability. Moreover, Turner et al\(^{82}\) and Brister et al\(^{112}\) appear to have used a composite measure of the pain management and
symptoms sub-scales of the Arthritis Self-efficacy Scale (from which the CPSS is derived), with only two of the five pain management items included in their scale, with the remaining six items coming from the symptoms sub-scale. Consequently, the results of these studies are not directly comparable with the findings of the current trial. In view of the lack of previous evidence supporting a relationship, and given the findings of the current study, it would appear that modifying pain management self-efficacy beliefs is unlikely to be advantageous in reducing levels of disability in patients with CNP.
6.1.2 The relationship between the cognitive factors and levels of pain intensity in all participants with chronic neck pain

After accounting for the effects of demographics, the cognitive factors displayed a significant association with levels of pain intensity, accounting for 16% of the variance in current pain intensity. Specifically, greater levels of catastrophizing and lower functional self-efficacy beliefs were associated with greater levels of pain intensity. These findings are consistent with previous work, which have shown a significant relationship between greater levels of catastrophizing and greater pain intensity in patients with CNP\textsuperscript{39,46}. In contrast, Kivioja and co-workers\textsuperscript{47} reported that catastrophizing scores, as assessed in the emergency room immediately after a whiplash injury, were not predictive of the presence of neck pain at one year follow up. However, it is noteworthy that Kivioja and colleagues did not assess pain intensity as such, but rather assessed whether pain was present or not in a simple dichotomous (pain present: yes/no) outcome. It is feasible that catastrophizing is related to the magnitude of pain experienced by individuals with neck pain rather than the presence of pain per se.

A possible mechanism which may underpin the association between raised levels of catastrophizing and greater pain intensity is provided by studies employing neuro imaging procedures. Seminowicz and Davis\textsuperscript{33} performed functional magnetic resonance imaging scans on a cohort of 22 healthy participants and observed a significant association between catastrophizing and activation of specific brain regions associated with the anticipation of pain,
attention to pain, emotional and affective aspects of pain and motor control. Moreover, similar findings were observed by Gracely and colleagues\textsuperscript{34} in a study of patients with fibromyalgia. It is feasible that similar changes in cortical activation may have occurred in the participants in the current study, accounting for the greater levels of pain intensity observed in participants who reported greater catastrophizing. However, further studies are required to delineate whether such changes in cortical activation occur in patients with CNP.

Reduced functional self-efficacy beliefs were also significantly related to current pain intensity in the current study. It is plausible that participants with reduced functional self-efficacy beliefs reduced their participation in physical activity, due to a lack of confidence in being able to successfully complete the task. Consequently, they may have experienced a reduction in cervical muscle strength and endurance, which has been postulated to result in painful musculo-skeletal disorders, even in the absence of serious physical pathology\textsuperscript{113}. Indeed, previous studies have demonstrated that patients with CNP do indeed display reductions in specific muscle strength\textsuperscript{105} and endurance\textsuperscript{104}. Reduced strength and endurance of the cervical musculature may result in more rapid fatigue during physical activity, causing an increase in pain intensity and disability. Treatments intended to reduce CNP should therefore include strategies aimed at enhancing self-efficacy beliefs, which may lead to participants re-engaging in physical activity. As discussed previously, treatments which involve progressive goal setting might be effective methods of enhancing self-efficacy beliefs\textsuperscript{59,114}. Gradually re-engaging in physical activity might result in increases in strength and stamina of the cervical musculature,
resulting in lower pain intensity. Moreover, previous studies have demonstrated that strength and endurance training of the cervical muscles results in lower pain intensity at one and three year follow up\textsuperscript{103}.

The current study did not find a significant relationship between pain intensity and levels of pain-related fear, pain vigilance and awareness or pain-management self-efficacy beliefs. This is in contrast to a previous study, which demonstrated a significant relationship between pain-related fear and pain intensity in patients with neck pain\textsuperscript{65}. However, it should be noted that only 29.5\% of the participants in Cleland’s study had experienced neck pain for three months or more. It is feasible that pain-related fear displays a stronger association with pain intensity in the acute and sub-acute stages of injury than in patients with chronic neck pain. Alternatively, the disparity in findings may be due to the fact that Cleland and associates did not consider other cognitive constructs alongside pain-related fear. Previous studies in patients with CLBP have reported an association between pain-related fear and pain intensity\textsuperscript{115,116}, however, when other cognitive measures have been considered alongside pain-related fear, its influence over levels of pain is no longer significant\textsuperscript{29}. It is possible that similar associations are true of patients with CNP; i.e. pain-related fear is not a strong determinant of levels of pain intensity when considered alongside other cognitive factors, such as catastrophizing or functional self-efficacy beliefs.

No previous studies have considered the relationship between pain vigilance and awareness and levels of pain intensity in participants with CNP. Indeed,
there is generally a paucity of data pertaining to this relationship in participants with chronic pain conditions. Study one of this thesis suggests that pain vigilance and awareness was not strongly associated with pain intensity in patients with CNP. However, it should be noted that Crombez and colleagues reported that pain vigilance and awareness was more prevalent amongst CLBP and fibromyalgia patients who reported greater pain intensity. It is feasible that pain vigilance and awareness assumes greater importance in patients who report higher levels of pain. However, the findings of study one do not support a strong association between pain vigilance and awareness and pain intensity, suggesting that targeting this factor may not be an efficacious method of decreasing pain intensity in patients with CNP.

The non-significant association observed between pain self-efficacy beliefs and pain intensity is in contrast to a study of patients with temporomandibular pain, which supported a significant relationship between these variables. However, it is noteworthy that Brister and associates employed a compound measure, assessing functional, pain management and other symptom management self-efficacy beliefs. It is therefore not possible to delineate which specific aspect of self-efficacy was responsible for the observed association. Moreover, an earlier study of patients with rheumatoid arthritis explored the influence of functional, pain management and other self-efficacy beliefs separately. As with the current study, Lefebvre and colleagues reported that functional self-efficacy beliefs, but not pain management beliefs were significantly related to pain intensity.
In contrast to the findings discussed above, Buckelew and co-workers suggested that all three aspects of self-efficacy beliefs were uniquely related to pain intensity in patients with fibromyalgia. However, given the disparity between the studies discussed above, it is feasible that the relationship between pain management self-efficacy beliefs and pain intensity differs significantly between chronic pain disorders. Furthermore, given that fibromyalgia patients have been shown to exhibit greater levels of pain-related fear, negative affect and catastrophizing than patients with CLBP, it is feasible that self-efficacy beliefs are also significantly different to other chronic pain conditions. This may underscore why different findings were observed in the participants in the study of Buckelew and colleagues, as compared to the findings of either Lefebvre or the current study. In view of this, the current study suggests that attempts to enhance pain management self-efficacy beliefs are unlikely to result in significant improvements in pain severity.
6.1.3 The relation between the cognitive factors and levels of depression in all participants with chronic neck pain

Demographics were not significantly associated with levels of depression. Moreover, current pain intensity did not demonstrate a significant association with depression, although this only narrowly failed to reach significance ($R^2=0.02$, $P=0.07$). However, even if this relationship had reached significance the findings of the current study would suggest that the association between pain intensity and depression is relatively weak, with, at best, only a small proportion of the variance in depression accounted for by pain intensity (2%) in patients with CNP. This finding is in contrast to previous studies of participants with chronic pain conditions, where pain intensity has emerged as a strong predictor of depression. For example, in a large, population based study, Currie and Wang\textsuperscript{117} reported that greater pain intensity was significantly related to co-existing major depressive symptoms. Moreover, in an earlier study, Arnstein and colleagues\textsuperscript{83} also reported a significant relationship between pain and disability in patients with chronic pain conditions.

A possible explanation for this disparity may be that the levels of depression reported in the previous studies differed considerably to those in the current study. Specifically, Currie and Wang\textsuperscript{117} explored predictors of major depression, whilst participants in the study of Arnstein et al\textsuperscript{83} reported moderate levels of depression. Conversely, in the current study, mean HADS-d score was 3.8, which is not considered to be representative of clinical levels of depression\textsuperscript{87}. Interestingly, Asghari et al\textsuperscript{118} explored the association between
pain and depression in a cohort of participants with heterogeneous chronic pain conditions who reported mild to moderate levels of depression. As in this study, Asghari and colleagues reported that pain intensity accounted for a relatively small (7%) proportion of the total variance in depression. Together, these findings imply that the relationship between pain intensity and depression may differ between cohorts of patients with different severity of depressive symptoms. Specifically, in patients who report mild to moderate depression, pain intensity appears to play a relatively minor role. However, in cohorts of patients with major depressive symptomology, pain intensity appears to be a stronger determinant of levels of depression.

That reported levels of depression differed so greatly between the present study and previous studies is likely to be due to the different methodology employed and treatment environments in these studies. Currie and Wang\(^\text{117}\) performed a large epidemiological study in the general population, whilst Arnstein and co-workers recruited patients from a pain management clinic. Participants in the current study were recruited from patients referred for physiotherapy treatment and it is likely that this group differs significantly from both the general population and from pain clinic populations. It is plausible that individuals with major depressive illness are either not referred for physiotherapy treatment, decline to attend or chose not to participate in the current study. Consequently, participants in the present study did not report high levels of depression, which may account for the differences with previous studies.
After accounting for the effects of demographics and pain intensity, the cognitive factors were associated with a further 34% of the variance in depression. Functional self-efficacy beliefs were the only cognitive factor uniquely associated with depression. Specifically lower levels of self-efficacy were associated with higher levels of depression. No previous studies have explored the association between self-efficacy beliefs and levels of depression in patients with CNP, however, the findings of the current thesis are consistent with those of previous studies of patients with chronic pain conditions. Arnstein and co-workers reported that even after controlling for the effects of pain intensity, self-efficacy beliefs remained a strong predictor of levels of depression in patients with chronic pain conditions. Similarly, Asghari et al reported that self-efficacy beliefs were significant determinants of levels of depression in a further cohort of patients with chronic pain conditions.

The current study did not support the relationship between catastrophizing, pain-related fear, pain vigilance and awareness and depression purported by the FAM. This is in contrast to studies of other chronic pain conditions, which have reported significant associations between depression and catastrophizing and depression and pain-related fear. However, it is noteworthy that the previous studies did not examine the influence of self-efficacy beliefs alongside the relationship between depression and the FAM variables. As discussed previously, the relationship between disability and pain-related fear appears to be less evident when considered alongside self-efficacy beliefs. It is feasible that a similar relationship exists between the
FAM variables and depression, whereby self-efficacy mediates the relationship between pain-related fear and catastrophizing and levels of depression.

It is noteworthy however that the current study is the first to explore the relationship between cognitive factors and levels of depression in patients with CNP. The findings suggest that the elevated levels of depression observed in the participants may not have been the consequence of pain per se, but rather because participants had lost confidence in engaging in physical tasks. On the basis of this, enhancing participants’ self-efficacy beliefs might result in important reductions in depressive symptomology in patients with CNP and mild-moderate depressive symptoms. Strategies which may enhance self-efficacy beliefs were outlined previously on page 111.
6.1.4 Summary of the relationship between the cognitive factors and levels of adjustment in all participants with chronic neck pain

As hypothesised, this study found significant associations between the cognitive factors and levels of adjustment amongst participants with CNP. Specifically, greater levels catastrophizing and lower functional self-efficacy beliefs were strongly related to greater levels of disability and pain intensity. Additionally, lower functional self-efficacy beliefs were also significantly associated with greater levels of depression. On the basis of this, interventions which specifically aim to reduce catastrophizing and enhance functional self-efficacy beliefs might bring about significant improvements in levels of adjustment.
6.2 Study two: Does the relationship between the cognitive factors and levels of adjustment differ between participants with idiopathic chronic neck pain and participants with chronic whiplash associated disorder?

Analyses were performed in order to explore whether the relationship between the FAM, self-efficacy beliefs and levels of adjustment differed between those participants with idiopathic CNP and those with CWAD. Where results did not differ significantly between the groups or from those reported in study one, these findings will not be discussed in detail to avoid repetition.

6.2.1 Between group differences in participant characteristics.

Between-group comparisons revealed no significant differences in the scores for either the measures of adjustment or the cognitive measures. Consequently, it is unlikely that any differences observed between the groups were due to between group variations in levels of pain, disability, depression or cognitive factors. Participants with idiopathic CNP were significantly older than those with CWAD, however, the effects of age were controlled for in all analyses prior to assessing the effects of the cognitive measures. Therefore, it is unlikely that the difference in mean age affected the outcome of analyses examining the relationship between the cognitive measures and levels of adjustment.
6.2.2 Differences in the relationship between cognitive factors and levels of disability between patients with idiopathic CNP and CWAD

The relationship between pain intensity and levels of disability was smaller in those patients with CWAD as compared to idiopathic CNP. Interestingly however, there were no significant differences in mean pain scores between the groups (1.8 for both idiopathic CNP and CWAD), suggesting that this relationship was not due to participants with idiopathic CNP experiencing greater levels of pain intensity. Nevertheless, pain explained a significant proportion of variance in disability in both groups.

After controlling for the effects of pain intensity, the cognitive factors were strongly related to levels of disability in both groups. Moreover, greater levels of catastrophizing and reduced self-efficacy beliefs were the only variables uniquely associated with levels of disability in both participants with idiopathic CNP and those with CWAD. Possible mechanisms underpinning these relationships were discussed earlier on pages 106-110 and pages 112-114. The current study therefore suggests that similar cognitive variables influence levels of disability in patients with CNP, regardless of the mechanism of onset. On the basis of this, similar strategies may be effective in reducing levels of disability in both groups, as discussed earlier on pages 111-112.
6.2.3 Differences in the relationship between cognitive factors and levels of pain intensity between patients with idiopathic CNP and CWAD

Significant differences emerged between the relationship between cognitive factors and pain intensity between participants with idiopathic CNP and those with CWAD. Greater levels of catastrophizing and lower levels of pain vigilance and awareness were significantly associated with greater pain intensity in those with idiopathic CNP. In contrast, none of the cognitive factors were significantly associated with pain intensity in the multivariate model in those participants with CWAD. A possible explanation for this disparity may be that different neuro-physiological mechanisms may determine levels of pain intensity in different types of neck pain. As discussed on pages 115-117, previous studies have suggested that cognitive factors may influence pain intensity via the influence which catastrophizing exerts on activation of specific brain regions associated with pain perception\textsuperscript{33,34}.

However, other authors have argued that spinal cord neuron hypersensitivity is a key neuro-physiological mechanism determining pain intensity in those patients with CWAD\textsuperscript{120,121}. Indeed, Banic and co-workers\textsuperscript{120} provided empirical support to this hypothesis, demonstrating that patients with CWAD exhibit reduced pain withdrawal reflex threshold (as compared to healthy controls), both in the cervical region and at sites distant to the initial injury. Moreover, Scott et al\textsuperscript{121} examined pressure pain threshold and heat and cold pain threshold in both patients with CWAD and idiopathic CNP. Although both groups demonstrated decreased pain thresholds in the cervical region, only
participants with CWAD displayed reduced pain thresholds at sites distant to the neck. Together, these studies suggest that spinal cord hypersensitivity is a feature of CWAD, but not idiopathic CNP. Consequently, it is plausible that neuroplastic changes occurring at spinal cord level in those with CWAD alter the afferent nociceptive input to higher cortical centres, thus negating the influence of catastrophizing on levels of cortical activation. However, this hypothesis is speculative and further studies are required to explore whether such a relationship exists between spinal cord hypersensitivity, cortical activation, catastrophizing and pain intensity.

It should also be noted that conflicting findings have previously been reported regarding the relation between catastrophizing and pain in patients with CWAD. In partial agreement with the current study, Kivioja and colleagues reported that catastrophizing at onset of WAD was unrelated to the persistence of pain at one year. Contrastingly, Söderlund and co-workers reported a significant relation between baseline catastrophizing and pain intensity at six month follow up. Furthermore, Sullivan et al. reported that levels of catastrophizing were significantly associated with greater pain intensity in patients with CWAD who were referred for treatment in a pain clinic.

An alternative explanation for the inconsistent findings discussed above, as well as the differences observed between idiopathic CNP and CWAD in the current study, may be that the association between catastrophizing and pain intensity in patients with CWAD may be moderated by other psychological variables. Partial support is leant to this notion by a previous study of patients with CWAD.
allocated patients to eight sub-groups, based on dichotomised (high/low) scores on measures of pain intensity, depression and catastrophizing\textsuperscript{119}. Interestingly, catastrophizing had the greatest effect on measures of health and well-being when pain and depression scores were low. Conversely, when either pain or depression was high, the effect of catastrophizing on the measures of function and quality of life was diminished. It is plausible that depression may moderate the relation between catastrophizing and pain intensity in a similar manner; that is, catastrophizing may significantly influence levels of pain intensity only when depression is low. However, this suggestion is speculative and future studies are required to assess whether the relation between pain intensity and catastrophizing is differentially affected by patients’ level of depression.

Alternatively, it is possible that cognitive factors other than those examined in this study are more important determinants of levels of pain intensity in participants with CWAD. For example, in a well designed follow up study, Sterling and colleagues\textsuperscript{63} demonstrated that post traumatic stress symptoms (PTSS) were significant determinants of ongoing pain and disability in patients with CWAD. Participants who developed PTSS did so due to the traumatic nature of onset of neck pain associated with MVC. However, participants with idiopathic CNP are likely to be at a lower risk of developing PTSS, as their neck pain was not preceded by a traumatic incident. On the basis of this, it is plausible that PTSS are the most important cognitive determinant of pain intensity in patients with CWAD, whereas catastrophizing and pain vigilance and awareness are more strongly associated with pain in those with idiopathic CNP.
The association observed between greater pain vigilance and awareness and lower pain intensity in participants with idiopathic CNP was contrary to that reported in a previous study, which reported that attention to pain was positively associated with pain intensity in patients with CLBP\textsuperscript{115}. It is possible that the relationship between pain and levels of pain vigilance and awareness differs between specific clinical populations and different clinical settings, which may account for the disparity in findings with those of Roelofs et al\textsuperscript{115}. Plausibly, patients with CNP who closely monitor their pain intensity might be more competent at pacing their activity in comparison to patients who do not monitor pain intensity as closely. Consequently, these patients are able to complete similar amounts of activity, but without experiencing increases in pain intensity. However, there is currently a paucity of data exploring whether pain intensity is differentially affected by levels of activity pacing in patients with CNP. In light of these findings, further investigation is warranted to assess whether the relationship between levels of pain vigilance and awareness and pain intensity is mediated by activity pacing.

In contrast, it should also be noted that a positive trend was noted between pain vigilance and awareness and pain intensity in patients with CWAD, although this association did not reach statistical significance ($p=0.77$). It was hypothesised that similar associations would be observed in participants with idiopathic CNP and CWAD, and that the direction of the relationship between pain vigilance and awareness and pain differed between the groups was unexpected. However, as previously mentioned, the association in the CWAD
group did not even approach statistical significance and it is possible that this unusual trend is due to the fact that a relatively small sample size was included in the CWAD sub-analyses (n=55).

Whilst a smaller sample size is acceptable where larger effect sizes are observed for the model\textsuperscript{125}, the CWAD pain intensity model explained only a moderate proportion of variance in pain intensity\textsuperscript{126}. Consequently, a larger sample size would be required for strong conclusions to be drawn for this particular analysis. Whilst statistical under-powering of the pain intensity analysis likely explains the observed relationship between pain vigilance awareness and pain intensity, it also means that other findings for the CWAD pain intensity analyses should be interpreted with caution. Further studies recruiting larger sample sizes are therefore required to further explore the precise associations between pain vigilance and awareness and pain intensity in patients with CWAD.

Nevertheless, the current study would appear to suggest that cognitive factors display a weaker association with levels of pain intensity in patients with CWAD, as compared to those with idiopathic CNP. Based on the current findings, targeting the modification of cognitive factors appears to be unlikely to significantly influence levels of pain intensity in patients with CWAD. Consequently, other treatment strategies are likely to assume greater importance in modifying pain intensity in this particular clinical group. In contrast, targeting the reduction of catastrophizing and enhancing vigilance and
awareness to pain may be an effective method of reducing pain intensity in participants with idiopathic CNP.
6.2.4 Differences in the relationship between cognitive factors and levels of depression between patients with idiopathic CNP and CWAD

Findings in the depression analyses did not differ significantly between those with idiopathic CNP and those with CWAD. Namely, reduced functional self-efficacy beliefs were the only variable uniquely associated with greater levels of depression in the final analyses. Potential mechanisms underpinning the relationship between functional self-efficacy beliefs and depression were discussed earlier in section 6.1.3 (p122-125) and will not be discussed again to avoid repetition. On the basis the current findings, enhancing functional self-efficacy beliefs may be an effective method of reducing levels of depression in both patients with idiopathic CNP and those with CWAD.
6.2.5 Summary of the differences in the relationship between cognitive factors and levels of adjustment between patients with idiopathic CNP and CWAD

As hypothesised, the association between the cognitive factors and levels of disability and depression did not differ markedly between the groups. Increased levels of catastrophizing and reduced self-efficacy beliefs were significantly associated with greater disability in both groups. Moreover, greater levels of depression were also associated with lower functional self-efficacy beliefs in both participants with idiopathic CNP and those with CWAD.

In contrast, the hypothesis that cognitive factors would be equally strongly associated with pain intensity in both groups was not supported. Increased catastrophizing and reduced pain vigilance and awareness were related to greater levels of pain intensity in patients with idiopathic CNP, but none of the cognitive factors displayed a strong association with pain intensity in participants with CWAD. On the basis of these findings, reducing catastrophizing and enhancing functional self-efficacy results may be an effective method of improving levels of disability and depression, regardless of the nature of onset of CNP. Contrastingly, targeting catastrophizing and pain vigilance and awareness may improve levels of pain intensity in those with idiopathic CNP, but appears unlikely to significantly affect pain in participants with CWAD.
6.3 Limitations

This study has some limitations that should be noted. The study required participants to complete a questionnaire, therefore meaning that an ability to read and write English was essential. This resulted in a predominately white sample (90%), which is not fully representative of the local population, where only 81% of the population are white\textsuperscript{122}. Moreover, participants were recruited from areas reporting high levels of material deprivation\textsuperscript{123,124}, meaning that it is unclear whether the current findings will generalise to other, more affluent populations.

No physiological measures were taken in the current study and consequently the importance of cognitive factors may have been over-stated. Other factors, such as reductions in cervical muscle strength and endurance\textsuperscript{104,105}, have been postulated to contribute to neck pain and disability. It is unclear whether the strength of the relationship between cognitive factors and levels of adjustment observed in this study would be as robust if such factors were considered alongside cognitive variables. That said, a previous study of patients with CLBP which examined both physical and cognitive measures reported that catastrophizing retained a significant association with pain intensity and disability, even after the effects of physical impairment were controlled for\textsuperscript{27}. In view of this, it is the present author’s contention that the relationship between cognitive factors and adjustment would remain significant, even when physiological factors were considered. However, future studies are required to
explore this association after the effects of physical factors have been controlled for.

It should also be noted that smaller sample sizes were included in the sub-analyses in study two. As noted in section 4.1, different authors advocate different methodology when calculating required sample sizes\textsuperscript{96,125}. Ninety-four participants were included in the idiopathic CNP analyses, which given the large effect sizes observed for the models\textsuperscript{126}, is likely to be adequate to draw conclusions from the data. However, only 55 participants were included in the CWAD analyses, with nine independent variables entered into the model. This may mean that the strength of the conclusions that can be drawn from the CWAD analyses is somewhat limited.

Nevertheless, strong effect sizes were observed for the disability and depression models, meaning that these results are likely to be robust. In contrast, the pain intensity analysis explained a lower proportion of variance in outcome, meaning that this analysis is likely to be under-powered and that the conclusions must therefore be interpreted with caution. Future studies should aim to replicate study two whilst recruiting a larger sample size, in order to further explore the association between cognitive factors and levels of pain intensity amongst participants with CWAD. Moreover, as discussed in section 4.5.2 (p 74), alternative types of regression analyses, (e.g. backwards regression) should be considered in order to maximise the statistical power of the models.
Finally, the cross-sectional nature of this study means that the relation between cognitive factors and levels of disability, pain and depression cannot be interpreted as causative. Indeed, it is feasible that greater levels of disability, pain and depression result in changes in cognitive factors, rather than vice versa. However, previous longitudinal studies have shown that participants who were free of pain at baseline, yet still reported greater catastrophizing and pain-related fear, were significantly more likely to report disability at six month follow up\textsuperscript{26,31}. These findings suggest that cognitive factors contribute to the development of disability in patients with chronic pain conditions, rather than vice versa. Nevertheless, longitudinal studies of patients with CNP are required to conclusively establish whether cognitive factors display a causative relationship with levels of adjustment.
6.4 Studies one and two clinical implications

In light of the findings of studies one and two of this thesis, several important clinical implications can be drawn.

1. In patients with CNP, targeting cognitive factors may result in significant reductions in pain, disability and depression. Specific efforts should be made to reduce catastrophizing and enhance functional self-efficacy beliefs.

2. Targeting cognitive factors may significantly influence levels of adjustment, regardless of whether the patient is experiencing idiopathic CNP or CWAD. However, modification of cognitive factors may influence pain intensity to a lesser extent in patients with CWAD than those with idiopathic CNP.
7.0 Study three: Does adding a cognitive behavioural based intervention to physiotherapy improve treatment outcome? A randomised controlled trial

7.1 Introduction

Studies one and two of this thesis highlighted that cognitive factors were significantly related to levels of adjustment in patients with CNP who were referred for physiotherapy treatment. This finding implies that modifying these cognitive factors may bring about favourable changes in levels of adjustment in patients with CNP. On the basis of this, it would appear to be important to identify treatments which are able to successfully modify these cognitive factors. Moreover, it is important to establish whether such treatments are more efficacious than conventional physiotherapy alone. Previous studies have demonstrated that physiotherapy in combination with CBT is more effective than either exercise or CBT alone in patients with other chronic pain conditions. However, access to specialist CBT services within the NHS is often limited, meaning that combined physiotherapy and CBT rehabilitation is often not available to patients with CNP. This highlights the need for more accessible rehabilitation programmes which are able to successfully modify cognitive risk factors.

Interestingly, previous studies which have explored the efficacy of physiotherapy based programmes which explicitly target the modification of
cognitive factors have reported promising results. For example, Sullivan and colleagues\textsuperscript{107} performed a non-randomised comparison trial comparing a usual physiotherapy to physiotherapy plus treatment designed to reduce catastrophizing in patients with CWAD. Treatment consisted of cognitive re-appraisal exercises and functional goal setting and resulted in significantly greater reductions in levels of work disability than usual physiotherapy alone. Whilst this study demonstrates that targeting cognitive factors may enhance treatment outcome, it should be noted that the study intervention was compared to a historical cohort group who underwent physiotherapy rehabilitation, rather than a concurrently randomised control sample. Moreover, the primary outcome measure was work disability, meaning that the effect of the intervention of other aspects of disability is unclear. Further studies of this intervention using randomised methodology and examining other aspects of disability would strengthen the conclusions that can be drawn from this study.

Some of the methodological concerns outlined above were addressed in a large (n=315), well designed randomised control trial of participants with chronic neck or back pain. In this study, Klaber-Moffett and co-workers\textsuperscript{128} compared the efficacy of an exercise-based intervention to a “solution finding approach”, which was underpinned by cognitive behavioural principles. Patients allocated to the solution finding approach received two or three treatment sessions, in which the trial physiotherapists helped the patient to identify their main problems, work out solutions and set goals realistic goals for returning to functional activity. No statistical differences in disability were observed between the groups, suggesting that physiotherapy based interventions which are
underpinned by a cognitive behavioural approach are at least as effective as other physiotherapy interventions.

However, it is noteworthy that in the above study, participants who were randomised to receive the goal-setting intervention did not receive this in conjunction with the exercise programme. Many previous studies have demonstrated that exercise is an effective method of reducing pain and disability in patients with CNP, and it is feasible that combining exercise with functional goal setting and other treatments designed to address cognitive factors, may be more effective than either treatment in isolation. Moreover, the physiotherapists who delivered the solution finding intervention had only received two days training in solution finding techniques. It is feasible that greater reductions in disability may have been observed if the solution finding treatments were delivered by therapists who were experienced in this type of intervention.

A further, robust randomised controlled trial of 212 participants with CLBP compared a physiotherapist-led pain management intervention to two different physiotherapy treatments. The first intervention consisted of spinal mobilisation techniques and individualised exercise programmes and the second consisted of a spinal stabilisation exercise programme. Moreover, the study benefitted from the inclusion of a full economic evaluation of the relative cost-effectiveness of the three treatment groups. The pain management intervention aimed to modify specific cognitive factors, through educational sessions and a structured exercise programme. The authors reported that although all treatments
included in the trial were equally efficacious in reducing pain and disability, patients who received the pain-management intervention required significantly fewer secondary care referrals, investigations and in-patient procedures than the other two groups. This resulted in the pain-management intervention being considerably more cost effective than either individual physiotherapy or spinal stabilisation exercises\textsuperscript{130}.

Interestingly, Woby and colleagues\textsuperscript{59} examined the cognitive processes which underpin reductions in disability following participation in a physiotherapist-led pain management programme. Changes in cognitive factors were indeed found to be related to changes in levels of pain, disability and depression in patients with CLBP who had undergone rehabilitation. Specifically, reductions in pain-related fear and increases in functional self-efficacy beliefs were significantly associated with improvements in levels of adjustment. This suggests that treatments which modify cognitive factors result in reductions in pain, disability and depression. Moreover, the study of Woby and colleagues appears to demonstrate that physiotherapists are able to deliver interventions which are capable of bringing about important changes in cognitive variables.

On the basis of the aforementioned work, it is conceivable that interventions similar to those described previously may be an effective method of targeting cognitive factors and therefore maximising treatment efficacy in patients with CNP. However, in order to establish whether adding such interventions to conventional physiotherapy treatment improves patient outcome, it is necessary to perform a randomised controlled trial in patients with CNP. Therefore, the
aim of study three was to compare the efficacy of an exercise intervention to the same exercise intervention delivered in combination with treatment which explicitly aimed to reduce catastrophizing and enhance functional self-efficacy beliefs.

A literature search was performed in January 2008 to identify previous studies which have explored either exercise-based treatments or physiotherapist-led interventions which aimed to modify cognitive factors in an effort to reduce pain and disability. The search terms “physiotherapy” or “physical therapy” or “exercise” and “neck pain” were entered into medical subject headings (MeSH) and exploded. The search was then undertaken using the MeSH terms to ensure that all appropriate terms were included in the search. The search was repeated every six months to ensure that any new relevant publications were not excluded. The final search was undertaken in January 2011, after which final preparation of the thesis was undertaken.

Articles which included any of the search terms outlined above in the title or key words were identified and abstracts were obtained. The abstracts were then reviewed and any articles which reported the findings of randomised controlled trials comparing the effectiveness of exercise or other physiotherapeutic modality to another intervention were identified. These articles were then obtained in full and critically appraised. In instances where the abstract could not be reviewed, the full article was obtained and reviewed so that relevant studies were not excluded. A manual search of the reference lists of each
article was then undertaken to ensure that any articles which had not appeared in the original search were identified.

The following section will therefore review the evidence for physiotherapy-based treatments of CNP and outline the development of both the cognitive-behavioural orientated and control interventions.
7.2 Development of the interventions

7.3 Development of the control intervention

In order to develop an effective control intervention for the study, a literature review was undertaken using the search terms “neck pain” “physiotherapy” “physical therapy” “exercise” “exercise therapy” and “treatment*” to identify previous studies which had explored the efficacy of commonly applied physiotherapy interventions. The literature search was undertaken in September 2007 and no restrictions were placed on the age of articles included review. The focus of the search was to identify effective, exercise based interventions, as the both of the treatment groups in study three were to receive this intervention. As the cognitive-behavioural orientated intervention aimed to encourage self management of CNP, it was considered that including “passive” treatments, such as manual therapy or electrotherapy would be at odds with this management philosophy. However, if studies were identified which conclusively demonstrated additional benefit of adding specific treatment modalities to an exercise programme, that modality was considered for inclusion in the study.

Potential studies were identified and the abstracts obtained. As the review aimed to delineate the efficacy of exercise interventions, as well as the relative efficacy of different exercise interventions, full manuscripts were obtained if the study compared two forms of exercise therapy or compared exercise therapy to another form of physiotherapy. A manual search of the reference lists of the articles reviewed was also undertaken to identify any other studies missed by
the initial search. The articles were critically appraised by the author and by a team of experienced physiotherapists (one consultant physiotherapist, two clinical specialist physiotherapists and one senior physiotherapist). The articles were then discussed and the intervention developed based on the consensus drawn from the literature.

The following section discusses the previous studies which have compared the efficacy of exercise-based treatments to other physiotherapy treatments. Moreover, studies comparing the efficacy of different forms of exercise are also discussed. Studies comparing exercise interventions to treatments based around cognitive behavioural principles are discussed in section 7.4.1 (p171) and therefore are not discussed in this section.
7.3.1. Should physiotherapy treatment of CNP include manual therapy?

Several studies have compared the efficacy of exercise based treatments to manual therapy (mainly spinal mobilisation or manipulation). For example, Korthals-de Bos and colleagues\(^ {131}\) compared a physiotherapy programme, consisting of relaxation, stretching, functional exercises and manual traction to manual therapy (specifically spinal mobilisation) or usual GP care. The authors reported that patients receiving manual therapy recovered more quickly and reported small, but statistically significant differences in pain reduction at 52 week follow up. Similarly, Hoving and colleagues\(^ {132}\) performed a randomised controlled trial comparing the same three interventions. Again, patients receiving manual therapy recovered more quickly (at seven week follow up) and reported small, but statistically significant differences in pain reduction at one year follow up. No significant differences were observed in changes in disability between the three groups at one year follow up, with all groups reporting reductions in disability.

Although the two studies discussed above were adequately powered and employed sound methodology, it should be noted that the inclusion criterion for these studies was neck pain for two weeks or more. Therefore, it is likely that many of the patients included in the study were experiencing acute or sub-acute neck pain. Clinical guidelines suggest that acute and chronic pain conditions require different management approaches\(^ {133,134}\) and it is possible that patients with acute or sub-acute neck pain respond differently to those patients with
Therefore, it is unclear whether the aforementioned studies would have reported the same findings if only patients with CNP been included.

On the above note, Bronfort and colleagues\textsuperscript{135} reported on the effects of three different treatment regimes in patients with CNP. One-hundred and ninety-one participants were recruited and randomised to one of three treatment interventions. One group performed exercises using high-tech cervical strengthening equipment (MedX cervical extension and rotation machine), the second group received low tech strengthening exercises and spinal manipulative therapy and the final group received spinal manipulative therapy alone. Additionally, all groups performed a home strengthening exercise programme using rubber resistance band.

No significant differences were observed between the three groups on completion of 11 weeks of treatment, however, at 12 month follow up both the exercise alone and exercise plus spinal manipulation therapy groups experienced significantly greater reductions in pain than spinal manipulation therapy alone. Moreover, when these patients were followed up two years after commencing treatment, the two groups which received supervised exercise as part of the treatment maintained their superior outcome over spinal manipulation therapy alone\textsuperscript{100}. It should be noted however, that the above studies recruited participants via newspaper advertisements in North America. It is unclear whether the this study population is comparable to that commonly treated in the context of the United Kingdom National Health Service, as individuals who volunteer to participate in such research studies may be more
highly motivated than other populations. It is therefore possible that different results may be observed in different treatment contexts.

In a further cross-over trial of females aged 25-53 who had experienced neck pain for at least six months, Ylinen and colleagues compared two treatment interventions. One group received four weeks of manual therapy, whilst the other group received four weeks of home stretching exercises. After four weeks, treatment allocation was switched for a further four weeks, so both groups received both treatments. No significant differences were observed in levels of pain or disability at either four or twelve weeks after commencing treatment\textsuperscript{136}. This finding also appears to suggest that manual therapy does not bring about greater or more rapid reductions in chronic neck pain and disability when only patients with CNP are considered. However, caution should be employed when interpreting these results, due to the non-randomised nature of the trial, the lack of longer term follow up and the fact that only female participants aged 25-53 were included. Feasibly, male participants and older or younger participants may respond differently to those included in this trial.

The notion that adding manual therapy to exercise does not expedite recovery is supported by further studies. For example, Jordan and colleagues\textsuperscript{137} compared the effectiveness of adding three different types of treatment to a standardised home exercise programme consisting of cervical stretching and strengthening exercises and a brief educational “neck school”. In addition, one group received intense exercise using a neck strengthening weights machine, a second received a physiotherapy regime consisting of manual therapy,
electrotherapy and heat treatment. The final group received manual therapy according to chiropractic principles. The study employed sound methodology and recruited 119 participants, although no sample size calculation was included, meaning that it is unclear if the study was appropriately powered. At four and twelve month follow up all groups had made significant improvements in pain and function, however, there were no significant differences between the groups. Moreover, all improvements were maintained at 12 month follow up.

Similarly, Dziedzic and co-workers\textsuperscript{138} carried out a randomised controlled trial comparing common physiotherapy interventions: exercise alone, exercise plus manual therapy and exercise plus pulsed short wave diathermy (PSWD). This study has the advantages of not only employing robust methodology and recruiting a large, appropriately powered sample, but it was also carried out in the UK NHS, the population of interest in the current study. The study reported that, not only did the addition of manual therapy or PSWD add no additional benefit in terms of reductions in disability, patients who received exercise alone reported fewer GP consultations in the following six months, suggesting that adding passive treatments may discourage a self-management approach of CNP.

On the basis of the studies discussed previously, it would appear that the addition of manual therapy to a home exercise programme does not incur additional benefit in patients with CNP. Moreover, adding manual therapy may be associated with greater healthcare costs and discourage a self-management approach. As self-management of CNP is a key facet of the approach to be
employed in this study, no manual therapy treatments were included in the control intervention.
7.3.2 Should physiotherapy treatment of CNP include electrotherapy?

Several studies have compared exercise interventions to other physiotherapeutic treatments. Chiu and co-workers\textsuperscript{99} performed a randomised controlled trial comparing the efficacy of a well defined neck strengthening programme to infra-red irradiation treatment. The study employed sound methodology and was appropriately powered to detect a clinically meaningful difference in treatment. The authors reported that six weeks after commencing treatment, patients who were randomised to receive exercise reported significantly larger decreases in pain and disability. Moreover, at six month follow up, those patients who had received exercise reported lower pain intensity, and had maintained improvements in disability, although this was no longer significantly different to the infra-red treatment group.

In a similar, well designed study, Chiu and colleagues\textsuperscript{139} again compared the efficacy of exercise and infra-red irradiation, this time also assessing the effectiveness of transcutaneous electrical nerve stimulation (TENS). Both the exercise and TENS groups reported significantly larger decreases in pain than the infra red group at both six weeks and six months after commencing treatment. There was a trend toward larger decreases in pain in the exercise group, although this did not reach statistical significance. Moreover, although all three groups reported significant reductions in disability six weeks after starting treatment, significantly larger reductions were observed in the TENS and exercise groups. Furthermore, at six month follow up, significantly larger reductions in disability were observed in the exercise group as compared to the
infra red group. However, there were no longer any significant differences between the infra red group and the TENS group.

As discussed previously, Dziedzic and co-workers\textsuperscript{138} performed a randomised controlled trial comparing exercise alone, exercise plus manual therapy and exercise plus pulsed shortwave diathermy. All three groups reported significant reductions in levels of disability at follow up, however, no significant differences were observed between the groups. This suggests that the addition of PSWD to an exercise programme does not result in superior outcomes for patients with CNP.

The studies discussed previously demonstrate that exercise is more efficacious than infra red radiation in reducing levels of pain intensity and disability. Moreover, exercise results in greater long-term reductions in disability than TENS. Furthermore, adding PSWD to an exercise programme does not appear to incur additional benefit. On this basis, adding electrotherapy interventions to exercise does not appear to be justified in patients with CNP. Consequently, TENS and PSWD were not included in the control intervention in the current study.
7.3.3 Efficacy of different exercise regimens

7.3.3.1 Cervical strengthening and endurance exercises

Although many previous studies have demonstrated the efficacy of exercise for the treatment of CNP, many of these studies have employed different exercise regimes. In order to develop the most efficacious intervention as the control intervention in the current study, the following section will discuss the efficacy of different exercise approaches and intensities.

Jordan et al\textsuperscript{137} performed a randomised controlled trial assessing the efficacy of three interventions in patients with CNP. Patients in all three groups completed a home exercise programme consisting of cervical strengthening exercises with rubber resistance band, set at 60\% of maximum isometric contraction. In addition, one group was treated with intensive physiotherapy, consisting of additional cervical and upper limb strengthening, aerobic exercise and stretching. The second group received passive physiotherapy treatments, such as mobilisations and electrotherapy, whilst the final group received manipulation of the cervical spine.

When the patients were followed up four and twelve months later, no significant differences were observed between the groups. All three groups reported statistically significant reductions in levels of pain, as measured by a compound measure of current, average and worst pain. All three interventions were found to be similarly efficacious in reducing levels of disability, with mean reductions
of three points (on a 30 point scale) reported at 12 month follow up in all three groups.

It is apparent from this study that cervical strengthening exercises, in combination with one of the three other treatments, are an effective means by which to reduce pain and disability. Unfortunately, the choice of outcome measures employed by Jordan and colleagues makes direct comparison of the efficacy of their intervention with those reported in other studies difficult. Specifically, most studies have reported average or worst pain levels separately, rather than combining them as per Jordan and colleagues. Moreover, the disability measure employed by Jordan et al is not commonly employed in other CNP studies.

In a further study, Ylinen and colleagues performed a RCT comparing three different exercise interventions in female patients with CNP. All patients received education, psychological support and manual therapy as deemed appropriate by the treating clinician. One group was also given stretching exercises, whilst the second group was treated with cervical muscle endurance exercises. The final group performed cervical and upper limb strengthening exercise to 80% of their maximum capacity, using rubber resistance bands. Those patients who were randomised to receive endurance or strengthening exercises exhibited significantly greater reductions in pain and disability than those treated with stretching exercises alone. Moreover, greater improvements in neck muscle strength were observed in the strengthening group than the endurance or stretching groups. Although this study suggests that
strengthening or endurance exercise programmes may be superior to stretching
exercises alone, it should be noted that only female office workers aged 25-53
were included in this study. It is therefore unclear whether males, women
outside of this age range or females from other professions respond in the
same manner to these treatments.

In a further follow up study, the group initially randomised to receive the
stretching intervention were then treated with the same strengthening
intervention employed previously\textsuperscript{140}. Interestingly, when these patients were
followed up twelve months after completing the strengthening intervention, their
pain and disability had decreased by a similar magnitude to the group who
originally received strengthening exercise intervention. Furthermore, when the
groups who initially treated with strengthening and endurance exercises were
followed up three years post treatment, improvements in pain and disability had
been maintained\textsuperscript{102}.

Other studies have also explored the efficacy of strengthening exercises for
patients with CNP. Chiu and co-workers employed an intervention consisting of
exercises to activate the deep cervical flexors and strengthen the cervical
flexors and extensors by using weights and pulleys in two separate randomised
controlled trials\textsuperscript{99,139}. Interestingly, in these studies, initial training intensity was
set at 30\% of peak isometric strength and then gradually increased. Although
this intervention resulted in significantly greater reductions in pain intensity than
the control intervention (infra-red irradiation), the magnitude of the reduction
was rather less than in the studies of Ylinen et al\textsuperscript{101,102,140}. 

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Specifically, Chiu and colleagues\(^{99,139}\) reported mean reductions of 1.5 on an 11 point numeric verbal pain scale at six month follow up in their two trials. Contrastingly, Ylinen and colleagues\(^{101}\) reported reductions of 40mm on a visual analogue scale at 12 month follow up. Although it is possible that this difference in the magnitude of change may be related to the different follow up periods, it is unlikely that the participants in the study of Ylinen were merely regressing to the mean, as participants who were randomised to receive stretching alone did not experience such great reductions in pain. It is also possible that differences in the change in pain intensity can be accounted for by the different measures employed in the two studies. However, the magnitude of the difference in change in pain between the studies would suggest that greater reductions in pain were observed in the studies of Ylinen and co-workers. Unfortunately, the two studies employed different measures of disability, meaning that direct comparison of the efficacy of the interventions in reducing levels of disability was not possible.

In a further study, Bronfort and colleagues demonstrated that manual therapy in combination with strengthening of the cervical muscles was efficacious in reducing levels of neck pain\(^{135}\). However, in this study, participants were not instructed to exercise at a specific exercise intensity, rather starting off with lighter weights and gradually increasing resistance. Patients in both groups who received the strengthening interventions reported clinically significant reductions in levels of pain intensity at one year follow up. However, these were of a lower magnitude than those observed by Ylinen and co-workers\(^{101}\).
Contrasting, similar changes in neck disability index score were observed in the studies of Bronfort and Ylinen, with both groups reporting clinically significant reductions in disability.

The aforementioned studies appear to suggest that both cervical strengthening and endurance exercises are effective methods of reducing pain intensity and disability in patients with CNP. However, strengthening treatment regimens seem to be most effective when the intensity of the exercise is set at a greater level. Specifically, regimes which required patients to exercise to 80% of their maximum strength resulted in greater reductions in pain intensity than those where patients exercised at lower intensities.

7.3.3.2 Upper limb strengthening exercise

Some studies have explored the efficacy of strengthening exercises of the upper limbs in reducing levels of neck pain. Anderson and co-workers\textsuperscript{141} performed a randomised controlled trial where participants received either strength training of the arms, at 70% of maximum intensity, or a general fitness programme and counselling. Although sound methodology was employed in this study and participants recruited from numerous centres, it should be noted that a relatively small sample size was recruited to this study (mean participants per group = 16). In spite of this, significant differences were observed between the groups. Those patients who received fitness training did not experience significant reductions in pain intensity, whilst those who underwent strength
training reported significant reductions in worst pain (reduction on VAS=35mm) and general pain (reduction on VAS=20mm).

In an earlier study, Waling and colleagues\textsuperscript{129} compared the efficacy of three exercise interventions to a control group, consisting of stress management. The first group received strengthening exercises for the upper limbs. Participants were asked to perform 10-12 maximal concentric contractions of four upper limb exercises using air resistance machines. The second group performed upper limb endurance exercises (arm cycling and rubber chest expanders), whilst the third group performed “body awareness” co-ordination exercises. Following completion of treatment, participants randomised to the strength or endurance groups reported significantly greater reductions in pain than the control group. However, the magnitude of these changes was of a lower order than reported in the studies discussed previously (reduction in VAS=1–1.5). It is noteworthy that the Waling’s follow up period was shorter than reported in other trials (up to four weeks following completion of treatment). It is possible that greater reductions in disability may have been observed if the participants had completed the exercise programmes for a longer period, as in other studies\textsuperscript{101,102}.

These studies suggest that upper limb strength or endurance exercises may be an effective method of reducing pain intensity in patients with CNP. However, the magnitude of reductions in pain reported in some studies suggest that upper limb strengthening in isolation may not be as efficacious as when it is performed in conjunction with cervical strengthening.
7.3.3.3 Other exercise approaches

A further exercise-based approach often employed by physiotherapists is the McKenzie method, also known as mechanical diagnosis and therapy. The McKenzie method involves an assessment, whereby the patient repeats specific cervical movements. The therapist then notes which movements reduce or abolish pain, or cause pain to move toward the centre of the body. The patient is then required to perform this direction specific exercise frequently throughout the day.

A previous study compared the efficacy McKenzie exercises to a functional goal setting programme and problem solving approach\textsuperscript{128}. At twelve month follow up, patients who received McKenzie treatment reported significant reductions in disability although there was no significant difference between McKenzie treatment and the goal setting approach. The reductions in disability were of a similar magnitude to those reported in the studies exploring strength and endurance exercises discussed earlier. Moreover, an earlier study compared the efficacy of McKenzie treatment to a general stretching and strengthening exercise programme and a control group, who received low intensity ultrasound\textsuperscript{142}. All three groups reported significant improvements in levels of pain and disability, however, there were no significant differences in outcome between the general exercise group and the McKenzie group.

As no clear evidence of superiority of the McKenzie approach over other exercise regimes was identified, and given that this approach requires
additional post-graduate training, McKenzie based treatments were not included as part of the control intervention in this study.

### 7.3.3.4 Summary of studies examining the efficacy of different exercise regimes.

From the studies discussed earlier, it appears that the most efficacious exercise treatments for reducing pain and disability in patients with CNP are those which combine stretching exercises with either strengthening or endurance exercises of the cervical and upper limb musculature. Moreover, treatments which involved participants performing strengthening exercises at a greater intensity, typically around 80% of their maximum isometric strength, reported superior reductions in pain to studies where participants exercised at lower intensities.

### 7.3.4 Selection of the training regime

On the basis of the studies outlined previously, either endurance or strengthening interventions appear to be equally efficacious in treating CNP. Interestingly however, Nikander and colleagues\(^ {143} \) performed a secondary analysis of an earlier randomised controlled trial\(^ {101} \). In this secondary analysis, the authors explored whether a dose-response relationship existed between amount of exercise completed and reductions in pain and disability in patients completing the strengthening and endurance exercise programmes. Time
spent performing general activity and time spent performing specific neck training exercises was recorded and converted to metabolic equivalents (METs).

Reductions in pain and disability corresponded positively with the amount of specific neck training performed, but not levels of general activity. Furthermore, type of training was not directly related to reduction in pain and disability. However, the greatest improvements were observed in those patients who completed more than 35 MET hours per month, with all of these patients reducing their pain by a minimum of 20mm on a VAS. Interestingly, all of the patients who completed more than 35 MET hours per month belonged to the strength training group. The authors postulated that this was due to the higher intensity of the strength training, which was performed at 80% of maximum strength. In order to meet 35 MET hours per month of exercise, strength training participants had to complete 40 minute work outs. Contrastingly, to meet the same training level, the endurance group were required to exercise for 60 minutes.

On the basis of the above study, it appears that comparable results can be achieved with a shorter training period with strengthening exercises as compared to endurance exercises. In an attempt to enhance treatment compliance by making the exercise intervention as short as possible, a strengthening exercise programme was selected. It was postulated that this would offer participants the best opportunities achieve maximum reductions in pain and disability in the shortest possible training time.
7.3.4.1 Selection of the exercises

The exercises selected for the trial were based on those employed by Ylinen et al\textsuperscript{101}, as this study reported the greatest reduction in levels of pain at 12 months and 3 years\textsuperscript{102}. Exercise intensity and repetitions were set according to sports medicine principles, according to the American College of Sports Medicine (ACSM) guidelines\textsuperscript{144}. The control intervention developed for the trial was named the Progressive Neck Exercise Programme (PNEP).

7.3.4.2 Strengthening exercises

7.3.4.3 Cervical exercise intensity

When performing strengthening exercises, participants completed one set of twelve repetitions at high intensity. The patients used rubber resistance band (Thera-band inc., Ohio, USA) to perform the cervical and upper limb exercises. It was not feasible to issue each patient with a dynamometer to calculate a specific percentage of their one repetition maximum to exercise. However, Thera-band resistance bands offer increased resistance in a linear relationship to the amount of elongation they undergo. That is, the more a band is stretched, the more resistance it offers. The highest strength of band was used for all patients.
Accordingly, participants were instructed that each time they performed their strengthening exercises they should initially perform five low-resistance warm up exercises. They were then instructed to perform the exercise maximally, to calculate the maximum extension of the band they could achieve, whilst still performing the exercise correctly. Participants then completed a further twelve repetitions of each exercise, where they stretched the band to approximately 75% of the maximum distance they could achieve. Participants were instructed that they should feel temporary muscle fatigue after completing the exercises, but not so that they experienced a lasting increase in their pain. According to ACSM guidelines, exercising at this intensity is adequate to bring about improvements in strength.

7.3.4.4 Cervical exercise technique

Patients performed isometric cervical strengthening exercises, in accordance with the protocol of Ylinen et al\textsuperscript{101}. Participants performed the exercises in a seated position, with the band securely fastened between a door and doorframe. Participants were instructed to keep their head in a static position, whilst moving the body in-order to isometrically load the muscles. Participants exercised the cervical flexors by leaning forwards, side flexors by flexing the trunk sideways to the left and right and extensors by leaning backwards. The exercises are shown in appendix two.
Additionally, the participants also performed one set of 12 repetitions of deep cervical flexor exercises, according to the protocol laid down by Chiu et al\textsuperscript{99}. Participants were instructed to lie in a supine position, with a pillow behind the occiput. They then flattened the cervical lordosis, tucking the chin in by performing a slight nodding motion of the head.

7.3.4.5 Upper limb exercise intensity

Patients also performed one set of twelve repetitions for all upper limb exercises. The treating physiotherapist selected the initial intensity of the exercise by trying the patient with different strengths of resistance band until the maximum intensity was found by where the participant could perform the exercise, whilst maintaining good exercise technique. Tension was then released from the band so that the exercises were performed at approximately 75% of maximum resistance. The band was then progressed as deemed appropriate by the physiotherapist.

7.3.4.6 Upper limb exercise technique

Participants performed shoulder shrugs, biceps curls and upright rows of the right and left arms. The exercises are shown in appendix two.
7.3.4.7 Stretching exercises

Participants performed stretching exercises of the cervical spine. Stretches were performed into flexion, extension, left and right side flexion, left and right rotation and retraction. The participants used their arms to apply gentle overpressure to the movements. In line with ACSM guidelines, stretches were held for 20 seconds and three repetitions of each exercise were performed. The exercises are shown in appendix two.
7.3.5 Final Progressive neck exercise programme (PNEP) regime

Following an initial assessment, patients randomised to PNEP received a further 40 minute appointment during which they were taught the PNEP stretching and strengthening exercises, as described in section 7.2.1. The patients were also advised that there was no serious problem with their neck, that pain did not mean that they were damaging their neck further and that people who keep active despite pain tend to experience lower levels of neck pain related disability. Physiotherapists were allowed to advise the patients to return to activity, but the use of specific, structured goal setting was not permitted. In addition, the participants were advised to take regular aerobic exercise for 30 minutes, five times per week and were given an educational booklet to re-enforcing the advice given by the physiotherapist.

The educational booklet was developed in line with current evidence regarding the management of chronic neck pain by a team of senior clinicians (one consultant physiotherapist, two clinical specialist physiotherapists and two senior physiotherapists). The booklet explained that neck pain was unlikely to be due to serious pathology, outlined the role of the role of de-conditioning and inactivity in the persistence of CNP and outlined strategies for managing CNP. The booklet contained brief summaries of the topics covered on each IBMT session (see section 7.2.4.1, p162-167). A copy of the booklet can be found in appendix three.
The participants then received three further 20 minute follow up appointments, during which the physiotherapist ensured that the patients was continuing to exercise to sufficient intensity and progressed upper limb resistance band as appropriate. Patients were advised to continue to exercise for a minimum of one year in-order to gain maximum benefit from the programme.
7.4 Development of the study intervention

The main focus of the study intervention was to reduce levels of catastrophizing and enhance functional self-efficacy beliefs. Furthermore, as this was a physiotherapy-based trial, it was important that the study intervention was able to be delivered by physiotherapists (i.e. did not require input from other health professionals, such as clinical psychologists). Therefore, only studies where the interventions were delivered entirely by physiotherapists were considered when designing the study intervention.

7.4.1 Studies investigating physiotherapy-based cognitive interventions

Woby and colleagues\textsuperscript{59} reported the efficacy of Interactive Behavioural Modification Therapy (IBMT), in reducing disability and modifying certain cognitive factors in patients with CLBP. Interactive behavioural modification was a physiotherapist-led programme, which was underpinned by cognitive behavioural principles and aimed to enhance functional self-efficacy beliefs and reduce levels of catastrophizing and pain-related fear. Their programme involved participants undergoing a programme of interactive educational sessions, aerobic and stretching exercises and functional goal setting. Following treatment, participants reported significant reductions in disability, catastrophizing and pain-related fear, while functional self-efficacy beliefs were significantly enhanced. Furthermore, reductions in pain-related fear and improvements in self-efficacy beliefs were significantly related to reductions in
levels of disability. However, it should be noted that Woby et al did not include a usual care or no treatment comparison group. As the participants received a total of 17.5 hours of treatment, it is possible that the improvements observed were due to Hawthorne or non-specific treatment effects, rather than the specific content of the programme.

However, the limitation of the study of Woby discussed above was partially addressed by Critchley and co-workers. Critchley and colleagues performed a randomised controlled trial comparing the efficacy of a physiotherapy pain management programme to usual physiotherapy or a spinal stabilisation exercise programme in patients with CLBP. The physiotherapy pain management programme was underpinned by cognitive behavioural principles and consisted of structured education sessions aimed at reducing fear of movement and encouraging active self management of LBP. Sessions covered modern knowledge of CLBP (e.g. hurt does not equate to harm), functional goal setting, encouragement of self management and the utilisation of positive coping strategies. However, the article did not provide an in depth breakdown of the exact content of each treatment session. In addition to the cognitive behavioural orientated component of the programme, participants also completed an aerobic exercise programme. Although no significant differences were observed in levels of pain or disability between the groups at 18 month follow up, all groups made significant improvements in pain and disability. However, the physiotherapy pain management programme was considerably more cost effective and resulted in significantly fewer future healthcare consultations than the other two physiotherapy regimes.
In a further study, Klaber-Moffett and colleagues\textsuperscript{128} carried out a randomised control trial of patients with CNP or CLBP. They compared the efficacy of a solution finding approach to a programme of treatment according to McKenzie exercise principles. Both groups reported significant reductions in pain and disability, although, there were no significant differences between the groups in reductions in disability. However, participants receiving the solution finding approach received fewer appointments than in the McKenzie group.

The solution finding approach employed in this trial was once more underpinned by cognitive behavioural principles. The treating physiotherapist helped the participant to identify pain related problems and collaboratively develop solutions to allow patients to overcome these problems. Therapists participating in the trial were given training in this approach and a trial manual to guide treatment. However, the exact treatment techniques employed by these therapists is not apparent.

It is also noteworthy that the physiotherapists delivering the intervention were experienced in the delivery of McKenzie treatments, having completed postgraduate training, as well as a completing a training day with the study team. On the other hand, the physiotherapists were not familiar with the solution finding approach and only received two days training in these techniques. Indeed, Klaber-Moffett et al acknowledge in their discussion that psychological questioning and goal setting were not well implemented in the solution finding approach, whereas the trial physiotherapists were more confident in delivering
the McKenzie treatments. It is therefore plausible that superior results may have been observed in the solution finding approach treatment group if it had been performed by therapists with greater experience of delivering this type of intervention. Moreover, the participants receiving the solution finding approach did not receive an exercise programme for their neck or back pain. Given the plethora of evidence supporting the utility of exercise in treating chronic spinal pain, it is feasible that combining exercise with the solution finding approach may have enhanced the efficacy of the intervention.

On this note, Sullivan and colleagues\textsuperscript{107} performed a non-randomised comparison trial of patients with CNP following a motor vehicle collision. One group received conventional physiotherapy alone, whilst a second group also received treatment involving cognitive re-appraisal exercises and functional goal setting. Those participants who received the cognitive intervention reported significantly lower levels of work disability following treatment. This study appears to lend some support to the notion that adding treatments aimed at addressing cognitive factors enhances outcome in patients with chronic pain. However, the non-random nature of the trial and focus specifically on work disability limits the conclusions that can be drawn from this study.

The trials discussed above suggest that physiotherapy pain management programmes are at least as effective as other forms of physiotherapy and may be considerably more cost effective in patients with CLBP. A common theme across all of these interventions is the incorporation of specific, structured goal setting and interactive, educational sessions, which are underpinned by
cognitive behavioural principles. Studies one and two of this thesis highlighted that raised levels of catastrophizing and reduced functional self-efficacy beliefs were significantly related to levels of pain and disability. The aforementioned studies imply that cognitive behavioural orientated treatments and functional goal setting techniques may be effective methods of modifying these cognitive factors and therefore bringing about important reductions in pain and disability. On the basis of this, the study intervention was developed with these techniques as key components of treatment.
7.4.2 Final Interactive Behavioural Modification Therapy Regime

The study intervention was based around the “Interactive Behavioural Modification Therapy” (IBMT) techniques described by Woby et al\textsuperscript{59}. This intervention was chosen for a number of reasons. Firstly, Woby and colleagues previously demonstrated that physiotherapists experienced in delivering IBMT interventions were able to successfully bring about reductions in catastrophizing and enhance functional self-efficacy beliefs. Moreover, modifying these cognitive factors with IBMT treatment was shown to be significantly related to reductions in levels of disability. Finally, clinicians in the participating physiotherapy departments were experienced in delivering IBMT treatments. This helped to minimize problems experienced in previous trials, where the trial physiotherapists were not familiar with cognitive behavioural approaches and thus may have delivered sub-optimal treatment interventions (e.g. Klaber-Moffett et al\textsuperscript{128}).

The precise structure and content of the programme was developed by a steering group of senior and clinical specialist physiotherapists, who were experienced in both delivering IBMT treatments and treating patients with CNP and other chronic pain conditions. Firstly, all of the participating clinicians appraised the aforementioned studies and highlighted what they felt were key components of treatment. The group then met and discussed programme content until an outline format of the programme was developed. The author then developed a detailed outline of the programme, which was then presented to the steering group. The group members each made suggestions as to how
the content could be optimised and consensus was reached regarding each point. The programme overview was then adapted to reflect these changes and once more presented to the steering group. The final programme was then agreed upon by all members of the group.

A four session, group based format, was decided on, with each session lasting approximately two hours. The programme aimed to reduce catastrophizing by addressing negative or unhelpful beliefs held by patients through a series of interactive education sessions. Moreover, patients were required to set functional goals to return to activities that they had ceased to engage in. This aimed to reduce catastrophizing by allowing dis-confirmatory experiences to occur and to enhance functional self-efficacy beliefs by means of personal mastery experiences\textsuperscript{74}. In addition, the participants also completed the same PNEP exercise regime described previously in section 7.2.1.6, p151-154).

7.4.2.1 Content of the interactive behavioural modification programme

The following section outlines the topics covered in each IBMT session. All sessions were designed to be highly interactive and specific to the needs of the participants in that session. Sessions did not take the form of a “neck school” education session, but rather therapists facilitated patients to participate in each session and address specific concerns about their condition. It should also be noted that IBMT involves performing condition-specific exercise. Therefore, the IBMT intervention in this study incorporated the same best-evidence exercise
programme described previously (i.e. the progressive neck exercise programme).

7.4.2.2 Week one

At the beginning of the first session, participants' personal expectations and concerns about participation in the programme were discussed. This was done to ensure that participants had realistic expectations about outcomes of treatment and the likely timescale for improvements in neck pain and function. The therapists then outlined the structure and function of the spine, emphasising the robustness of the spinal column. Furthermore, participants were asked about any diagnoses they had been given or any conditions they felt that may account for their neck pain. Different diagnoses of the neck were then discussed, with an emphasis on explaining medical terminology in lay terms. Moreover, it was clarified to patients that imaging of the neck correlates poorly to levels of pain and disability and that CNP is multi-factorial, rather than the result of a lesion in one specific tissue.

The differences between acute and chronic pain conditions were then discussed, with participants asked to describe the quality of the two different pain states. This was undertaken to highlight that although acute pain is often the result of tissue damage, chronic pain rarely represents ongoing tissue trauma. Subsequently, alternative mechanisms for persistence of symptoms beyond the expected time for tissue healing were offered. Firstly, the chronic
pam cycle was discussed. This posits that following the onset of pain, activity levels decrease, leading to joint stiffness, muscle weakness and a loss of aerobic fitness. In turn, this leads to an increase in pain, especially during activity. Moreover, this can lead to further reductions in activity, emotional changes (such as low mood, frustration or anger) and sleep disturbances, which are hypothesised to worsen pain.

A simplified model of the pain-gate theory was then explained, in order to account for the relation between emotions, sleep and levels of pain. Moreover, the pain-gate model was also used to explain how exercise can modify pain intensity. Finally, a brief explanation was given of sensitisation of the nervous system, which can account for ongoing pain in the absence of significant spinal pathology.

The participants then performed the PNEP exercises in a group environment and goal setting concepts were introduced and homework issued. Homework involved participants identifying on a pro-forma all of the activities which they had ceased to engage in, or were not able to do to the full extent they desired. Participants were also asked to score on zero to five scales how important it was for them to return to this activity and how confident they currently were in engaging in the activity. This information was collected to allow the therapists to establish which activities the patients valued most and which they were most lacking in confidence in, in order to tailor goals to patient needs.
7.4.2.3 Week two

At the beginning of the second session the therapists discussed with participants any problems they may have experienced whilst performing or after performing the exercises and their progress over the preceding week. Furthermore, how often the stretching and strengthening exercises were performed and reasons for low exercise compliance were discussed. The therapists also addressed any concerns that the participants may have had relating to the exercises.

The interactive educational session outlined how different factors can affect neck pain. The session aim was to recognise that not only physical factors influence levels of pain. Rather, the therapists facilitated the participants so that they recognised that their thoughts, emotions, beliefs and behaviours can all influence levels of pain and function. Strategies to help manage these varying factors were then discussed. The participants then performed the PNEP exercises, with the therapists ensuring that the exercises were performed using the correct technique and to the correct intensity.

Finally, each participant set a functional goal to work towards of the coming week. Goals could be to do with work, chores, physical activity or social pastimes. Therapists ensured that all goals were set according to SMART principles. That is, goals were specific, measurable, realistic, achievable and timed.
7.4.2.4 Week three

At the beginning of the session, the goals set at the end of week two and compliance with PNEP exercises were reviewed. The therapists assisted the participants in problem solving any difficulties that they may have encountered whilst performing their goals or barriers to them re-engaging in that activity.

The first part of the interactive educational session involved participants listing all of the activities that they consider to be part of their “normal” life. They were then asked to state which activities they continued to do, which they had decreased their participation in and which they had stopped all together. The activities were listed in two columns to reflect activities that were related to work or chores (termed “have to” activities) and those that were related to enjoyable, sporting or social activities (termed “want to” activities). This was done to illustrate that individuals with chronic pain frequently continue with “have to” activities, whilst ceasing many of their “want to” activities. Reasons for this imbalance were examined and it was highlighted that equal importance should be placed on “have to” and “want to” activities. Moreover, the consequences of avoiding “want to” activities, such as negative mood, further physical de-conditioning and loss of ones sense of self were outlined.

The second part of the educational session covered activity pacing. The negative consequences of following a “boom and bust” pattern of activity were debated and guidelines for increasing activity over a longer period were offered.
The participants then performed the PNEP regime and set goals for the coming week.

7.4.2.5 Week four

Firstly, goals and exercises were reviewed as per week three. Management strategies to employ in case of a flare up were then considered, with particular emphasis placed on keeping active, avoiding prolonged rest and controlling pain, by using medication or by other modalities (for example, using a hot pack). Additionally, participants received information on commonly prescribed medications, including their mechanism of action, indications and side-effects. However, medication reviews were not performed and patients were advised to discuss with their general practitioner if they felt that they required their medications changing.

Finally, long term maintenance of CNP was discussed. Participants were advised to continue to perform the PNEP exercises for at least one year in order to gain maximum effect. Moreover, participants were also advised to take aerobic exercise for half an hour five times per week, as part of a healthy lifestyle. Participants were encouraged to continue to use a goal setting approach to fully return to all of their valued activities and a long-term plan was discussed with the therapist. The PNEP exercises were then performed.
8.0 Study three aims and hypotheses

8.1 Aims

8.1.1 Primary aim

The primary aim was to investigate whether IBMT resulted in significantly greater mean decreases in levels of disability six months after randomisation in patients with CNP.

8.1.2 Secondary aims

The secondary aims of the study were as follows:

- To determine whether IBMT resulted in significantly greater mean decreases in levels of pain six months after randomisation.
- To determine whether IBMT resulted in significantly greater mean changes in cognitive factors six months after randomisation.
- To determine whether IBMT resulted in significant differences in the proportion of patients making clinically important reductions in pain and disability.
- To determine whether IBMT resulted in significant differences in rates of future primary and secondary care consultations.
- To determine whether IBMT resulted in significant differences in levels of participant satisfaction and participant perceived recovery.
8.2 Hypotheses

8.2.1 Primary hypothesis

Both treatment groups included exercise-based interventions which have previously been shown to be effective in reducing disability in patients with CNP. It was therefore anticipated that both groups would make reductions in disability at six month follow up. However, study one of this thesis suggested that a significant association may exist between cognitive factors and levels of disability. It was therefore hypothesised that specifically targeting these factors might result in larger reductions in levels of disability. On this basis the primary hypothesis was as follows:

Both groups will experience reductions in disability following treatment. Patients receiving IBMT will experience greater reductions in disability at six month follow up than those receiving PNEP.

8.2.2 Secondary hypotheses

Since IBMT treatment specifically targets the modification of cognitive factors, it was hypothesised that this would result in greater changes in the cognitive measures than in the PNEP group. As study one of this thesis also suggested that cognitive factors may also influence levels of pain intensity, it was therefore
hypothesised that specifically targeting cognitive factors may also result in larger decreases in pain intensity. Moreover, it was hypothesised that should participants make larger reductions in pain and disability, this would be reflected in a greater proportion of participants perceiving an improvement in their condition and therefore greater treatment satisfaction.

Since one of the aims of IBMT is to encourage self management of CNP, it was also hypothesised that this might result in fewer future consultations with general practitioners’ and subsequently fewer onward referrals to secondary care. Finally, if the hypothesised improvements in treatment outcome were realised, this should be manifested in a greater proportion of participants making a clinically important reduction in pain and disability. On the basis of the above, secondary hypotheses were as follows:

- Participants receiving IBMT will demonstrate significantly greater changes on the cognitive measures.
- Participants receiving IBMT will demonstrate significantly greater reductions in pain intensity
- Participants receiving IBMT will report higher treatment satisfaction and perceive greater improvements in their condition.
- Participants receiving IBMT will require fewer primary and secondary care consultations.
- A significantly greater proportion of participants receiving IBMT will demonstrate clinically important reductions in pain and disability.
9.0 Methods

9.1 Participants

All patients with chronic neck pain referred to the physiotherapy departments of North Manchester General Hospital, Fairfield General Hospital, The Royal Oldham Hospital and the Cornerstones Primary Care Centre between July 2008 and August 2009 were invited to participate in the study. Study two of this thesis suggested that some differences exist in the relationship between the cognitive factors and levels of pain and disability between patients with idiopathic CNP and CWAD. However, cognitive factors were found to be strongly related to levels of adjustment in both groups, therefore patients with both idiopathic CNP and CWAD were recruited into the study. Moreover, from a pragmatic viewpoint, it would not be possible to recruit the required sample size by recruiting patients with either only idiopathic CNP or only CWAD to the study.

Potential participants were mailed an information leaflet, explaining the aims of the study and the content of the interventions, a consent form and a study questionnaire. Patients who agreed to participate in the study were asked to return the questionnaire and consent form in a pre-paid envelope. Participants were then contacted by telephone to arrange an assessment with a physiotherapist who had received training in the trial protocol. Patients were able to contact the author by telephone or email to discuss any questions or concerns they had regarding the trial before deciding whether to participate or not. Those patients who did not wish to participate in the study were advised to
contact the physiotherapy department to arrange an appointment, as per usual protocol. Non-participants received standard physiotherapy care.

Participants were assessed by a trial physiotherapist, who excluded patients from the study if they meet any of the exclusion criteria (see section 9.3.2, p173). Patients were free to withdraw from the study without giving an explanation at any time.

9.2 Sample size

As disability was the main outcome measure of interest, the required sample size was calculated to detect an additional 10% change in NPQ scores between the two groups. This figure was decided upon as Sim and colleagues\textsuperscript{148} suggested that a minimally clinically important difference in NPQ equates to a 25% reduction in baseline score. Previous, large physiotherapy based studies in the UK\textsuperscript{138,149} employing the NPQ as their primary outcome have reported mean baseline NPQ scores of between 31 and 38. Based on these scores, a 25% reduction in NPQ score would equate to a 7.8 and 9.5% mean reduction in NPQ as a being a minimally important clinical difference. Therefore a conservative between group difference of 10% at six month follow up was decided on. Based on this figure and a standard deviation of 11.6\textsuperscript{149} a sample size of 21 participants per group was required to give a power level of 80% with an alpha level of five.
To allow for a 25% loss to follow up it was decided to recruit 28 participants to each group. Recruitment rates to previous NHS-based physiotherapy studies of patients with chronic pain have been shown to be range from 11% to 48%\textsuperscript{138,150}. Taking the most conservative of these figures (11%) it was anticipated that a total of 509 patient referrals would be required to allow for adequate recruitment to the trial (See Figure 3).

**Figure 3. Sample size requirement**

```
Invited to Participate  
(n = 509)

Randomized  
Recruitment anticipated being 11% of referrals  
(n = 56)

Allocated to IBMT  
(n = 28)

Allocated to PNEP  
(n = 28)
```
9.3.1 Inclusion criteria

All patients aged 17 or over with neck pain of at least three months duration and who were able to read and write English were eligible for inclusion in the study.

9.3.2 Exclusion criteria

As the study population of interest was patients with non-specific CNP (i.e. no serious cause for symptoms was apparent), patients who presented with red flags (see p60) or who had other symptoms suggestive of serious pathology (e.g.; carcinoma, spondyloarthropathy or other inflammatory disorder) were also excluded. These patients were excluded as red flags may indicate serious underlying pathology and therefore require urgent medical investigation. Moreover, the exercise and condition management approaches employed in the current study are unsuitable treatment approaches for patients with serious pathologies.

Finally, patients with a diagnosed serious psychiatric disorder (e.g. bipolar disorder, schizophrenia or dementia) were also excluded. This was as guidelines suggest that patients with serious psychiatric disorders should not be included in group-based treatments incorporating cognitive behavioural principles, as these patients may respond differently to treatment and require specialist psychological management\textsuperscript{145}. Moreover, previous authors have highlighted that significant ethical considerations are associated with obtaining
informed consent to participate in research from patients with certain mental health disorders.\textsuperscript{146}

\textbf{9.4 Assessment}

In order to ensure that inclusion and exclusion criteria were met, all patients received a standardised assessment. The assessment was developed in line with national guidelines\textsuperscript{147} and in conjunction with a team of senior clinicians who were experienced in the assessment of patients with CNP (one consultant physiotherapist, two clinical specialist physiotherapists and two senior physiotherapists). The assessing physiotherapist took a detailed history of the patients’ symptoms and performed a standardised physical examination. The assessing physiotherapist examined range of movement of the cervical spine, upper limb myotomes, dermatomes and reflexes and examined for objective signs of vertebro-basilar artery insufficiency (VBI). To test for VBI, participants were seated and asked to extend their neck to the end of range of movement and maintain this position for 30 seconds. The participants were then asked to rotate their head maximally to the left, and then to the right, holding at the extreme of movement for 30 seconds each time. Any signs of VBI (e.g. dizziness, visual disturbance, “drop attacks”, dysphagia or dysarthria) were noted and the participants with symptoms suggestive of VBI were advised to avoid sustained postures which brought on these symptoms. Finally, the physiotherapist palpated the cervical spine and visually examined the patients’ neck for signs of deformity or other abnormality.
Findings from the assessment were then logged onto a standardised pro-forma (shown in appendix four) to indicate if the inclusion/exclusion criteria were met. Patients were considered to be unsuitable for inclusion following assessment if they met any of the following criteria:

**Radiculopathy:**
- Pain referring from the neck to below the elbow
- Muscular weakness in a myotomal pattern
- Diminished reflexes compared to the unaffected arm
- Paraesthesia in a dermatomal distribution (patients with confirmed peripheral neuropathies or carpal tunnel syndrome were included in the trial if paraesthesia remained unchanged since the onset of neck pain)

**Myelopathy:**
- Positive Babinski sign
- Upper limb weakness
- Increased upper or lower limb tone of new onset
- Disturbance of gait
- Clumsiness of the hands
- Bilateral upper limb pain
- Hyper-reflexia
- Paraesthesia
Vertebro-Basilar Insufficiency

- Symptoms of nausea, nystagmous, dysphagia, dysarthria, dizziness, visual disturbance or drop attack on sustained end of range cervical extension or rotation.

Fracture:

- History of traumatic onset in combination with severe bony tenderness and/or severe restriction of cervical range of movement without previous radiological investigation.

Inflammatory arthropathy:

- Confirmed previous diagnosis.
- Greater than two hours of early morning stiffness.
- Multiple joint symptoms.
- Symptoms considerably worsened by rest, eased by exercise.
Upper cervical instability:

– Positive Lhermitte’s sign
– Radiological evidence of instability
– NB: In cases where participants reported symptoms suspicious of upper cervical instability (feeling of instability/subluxation, referral of symptoms into all four limbs on movement) further testing for upper cervical instability was to be performed. However, no cases of suspected upper cervical instability were identified during the trial.
9.5 Randomisation

Having undergone assessment, participants who were suitable for inclusion were randomised to receive either PNEP or IBMT. To ensure random treatment allocation, a computer-generated random allocation table was produced and treatment allocation transposed to printed cards, which were then sealed in opaque envelopes. The assessing physiotherapist then opened the next sequentially numbered envelope and the participant was randomised to receive the treatment indicated inside. Separate random number tables were produced for each of the three physiotherapy departments taking part in the trial, so that equal numbers of participants from each department were randomised to each intervention.

9.6 Interventions

Following randomisation, the participants received either PNEP or IBMT as described previously. In addition, participants in both groups received an educational booklet outlining causes of CNP and management strategies. The educational literature can be found in appendix three. The treating physiotherapist recorded the number of treatment sessions received, as well as any additional treatments offered on a standardised pro-forma, which can be found in appendix five.
9.7 Treatment adherence

In order to assess adherence to the exercise programme, participants’ were issued with an exercise diary. In the diary, they were asked to record the number of occasions that they had performed their strengthening and flexibility exercises each week over the four week treatment period. The exercise diary can be found in appendix six.

9.8 Blinding

9.8.1 Participant blinding

Due to the nature of the interventions (one-to-one PNEP or group based IBMT) it was not be possible to blind participants to which treatment they received.

9.8.2 Blinding of treating clinicians

As clinicians actively delivered the interventions, it was not be possible to blind them to which treatment the participant was receiving. However, clinicians were blinded to treatment allocation until randomisation in an effort to avoid clinicians’ treatment preference influencing participation in the study.
9.8.3 Blinding of researchers

All questionnaires used in this study were self-report and therefore did not require staff to administer them. Each potential participant was allocated a study code, which was recorded on the front of each questionnaire. No further information by which the participant could be identified was included on the questionnaires. Initial questionnaires were returned by post and data was inputted on to a spreadsheet (Excel for Windows, Microsoft Inc, Seattle, USA) by the author. When a participant was randomised, the treating physiotherapist recorded treatment allocation, which was then transposed as either a 1 or a 0 onto the spreadsheet. Data were then transferred to a medical statistics package (SPSS for Windows version 14, Chicago, Illinois, USA) and statistical analyses were then carried out by the author, who was blinded to treatment allocation.

9.9 Adverse events reporting

Adverse events were reported in two ways. Firstly, usual procedures of the NHS trust in which the study was being undertaken (the Pennine Acute Hospitals NHS Trust) were followed. Specifically, incident report forms were completed and sent to the clinical risk management department. Secondly, a pro-forma (shown in appendix seven) was completed outlining the nature of the adverse event. The pro-forma was then sent to the author and the nature of the incident recorded.
9.10 Ethical approval

Ethical approval was granted by the Salford and Trafford Local Research Ethics Committee, ref:07/H1004/218. Ethical approval was also provided by the Pennine Acute Hospitals NHS Trust Research and Development department.
9.11 Outcome measures

The self report measures completed by participants are outlined below.

9.11.1 Demographics

Data were collected regarding participants’ age, sex, pain duration, work status, ethnicity and martial status. Additionally, data were collected regarding participants’ treatment preference. A brief description of the two interventions was given and participants were then asked to highlight whether they would prefer to receive IBMT, PNEP or whether they did not have a treatment preference. It was made clear to patients that their treatment preference would not influence the treatment that they received, which would be decided by random allocation.
9.11.2 Primary outcome measure

The primary outcome measure was change in disability at six months, as assessed by the Northwick Park Neck Pain Questionnaire (NPQ)\textsuperscript{151}. The NPQ is a nine item measure of pain and disability related to neck pain. Each question is scored from zero to four and the scores summed and converted to a percentage, with higher scores representing greater disability. The NPQ has been shown to have good short term repeatability and internal consistency\textsuperscript{151}.

The NPQ was chosen for study three of this thesis in preference to the NDI (as in studies one and two) for two main reasons: Firstly, since studies one and two were commenced, several large, United Kingdom National Health Service based trials of physiotherapy interventions for CNP have been published in well respected, peer reviewed journals\textsuperscript{128,138,149}. To enable like-for-like comparison with these studies, the decision was made to change the outcome measure employed in study three to the NPQ. This allowed findings of the trials to be compared more readily to previous trials to assess whether the treatments delivered in the current thesis were of comparable efficacy to other NHS based physiotherapy interventions. Secondly, both the NDI and NPQ have been shown to be psychometrically sound and be equally sensitive to change\textsuperscript{152}, suggesting that the robustness of the results of the current thesis were not be affected by the change of outcome measure.
9.11.3 Secondary outcome measures

The secondary outcome measures were changes in pain intensity, pain-related fear, catastrophizing, pain vigilance and awareness and functional self-efficacy beliefs six months after commencing treatment. Additionally, data assessing global assessment of change in neck pain status, change in general health and satisfaction with physiotherapy treatment were collected at six month follow up. The specific measures used are outlined below. Several of these measures have been described in detail previously in study one. In these instances, the measures are not described again to avoid repetition and reference to the relevant section is given for each measure.

9.11.3.1 Current pain intensity (Numeric Rating Scale; NRS\textsuperscript{48})

Participants were asked to rate their pain on an eleven point NRS, anchored 0 (no pain at all) and 10 (worst imaginable pain). The NRS is a validated measure of pain intensity in chronic pain populations and has been shown to be psychometrically robust\textsuperscript{48}. The NRS was chosen as the measure of pain intensity as it is easy to complete and allowed comparison to other recent NHS based trials\textsuperscript{138}. 

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9.11.3.2 Pain Catastrophizing Scale (PCS; see p70)

9.11.3.3 Tampa Scale for Kinesiophobia (TSK; see p70)

9.11.3.4 Chronic Pain Vigilance and Awareness Scale (PVAQ; see p71)

9.11.3.5 Chronic Pain Self-Efficacy Scale – Physical Function Sub Scale (CPSS-pf; see p72)

9.11.3.6 Global assessment of change

Global assessment of change was measured in order to compare the proportion of patients who perceived that their condition had improved. Sim and colleagues suggest that patient perceived improvement is an important outcome indicator and should be measured alongside specific functional measures in patients with CNP\textsuperscript{151}. Patients’ global assessment of change was measured with a five point rating scale\textsuperscript{151}. The scale was anchored “much better” and “much worse” and assessed patients’ perceived improvement in their neck pain.
9.11.3.7 Patient satisfaction

As well as the clinical outcome measures outlined previously, treatment satisfaction was also measured to ensure that the two treatments met patient expectations of treatment. Patient satisfaction was measured with a five point scale, anchored “very satisfied” and “very dissatisfied”.

9.11.3.8 Future healthcare consultations

Reducing healthcare usage has important financial and societal implications. If two treatments are of equal efficacy in terms of clinical outcomes but one treatment results in lower healthcare utilisation, it is likely to be preferable to offer that treatment. Therefore, the treating physiotherapists recorded any additional treatment sessions that were offered. Moreover, at six month follow up, participants recorded the number of consultations they had had with a range of healthcare professionals following completion of physiotherapy treatment.
9.12 Statistical analysis

All analyses were carried out on an intention-to-treat basis. In cases where follow up data were not available, the last value was carried forward (i.e. it was assumed that no changes had occurred in that participant’s levels of pain, disability or cognitive factors). Two types of analyses were performed. Firstly, group-level analyses were performed to establish whether significant between-group differences emerged. Secondly, analyses of Minimal Clinically Important Changes were performed to establish the proportion of participants in each group who made meaningful changes in pain and disability. The following section outlines these analyses in more detail.

9.12.1 Primary analysis

Levene and Shapiro-Wilk tests were performed to ensure homogeneity of variance and normal distribution of the data. Moreover, data were plotted in histogram and box plot form and visually inspected to confirm the findings of the above tests. Independent t-tests were then used to determine whether mean change in disability score at six months post treatment differed significantly between the two groups. Analysis was performed on an intention-to-treat basis. Missing data were imputed using a last known value carried forward method, as advocated by Hollis and Campbell. Consequently, participants not providing data at six month follow up were presumed to have made no change as baseline values were carried forward.
9.12.2 Secondary analyses: Pain and cognitive factors

Additional independent $t$-tests were performed on the secondary outcome measures to determine whether significant differences emerged between the two groups with respect to changes in pain (numeric rating scale) and the change scores on the cognitive measures (PCS, TSK, PVAQ and CPSS-pf).

9.12.3 Minimal Clinically Important Changes (MCIC)

In addition to the between group comparisons outlined above, the proportion of participants making a minimal clinically important change (MCIC) in each group was also calculated. Minimal clinically important change is the smallest change on an outcome measure that is considered by a patient or clinician to be of clinical significance\textsuperscript{148}. As changes on an outcome measure smaller than the MCIC are not likely to be perceived by a patient as meaningful, calculating the proportion of patients making a MCIC gives a useful indicator of the proportion of patients who have obtained a meaningful benefit from a treatment intervention. As previously outlined, previous literature has demonstrated that not all patients with neck pain respond in the same manner to physiotherapy treatments\textsuperscript{52,53}. On the basis of this, it is plausible that some patients may benefit to a greater extent from certain treatments, however this may not be apparent from group level analysis. It was beyond the scope of the current thesis to recruit a sufficiently large sample to perform exploratory sub-group analysis, however, performing MCIC analyses enabled a useful comparison as
to whether significantly more patients improve following certain treatments. From a clinical perspective, this is likely to be a useful outcome measure when selecting which treatments are most likely to benefit patients.

In the current study, the proportion of participants making a minimal clinically important change (MCIC) in pain and disability was calculated and Chi squared tests performed to establish whether significant differences existed between the two groups. The MCIC level for disability was set as a 25% reduction in baseline NPQ score, as per the criteria of Sim and colleagues\(^{148}\). The MCIC in pain was a classed as a two point reduction on an eleven point NRS. This was based on the criteria of Kovacs and co-workers\(^{153}\), who suggested a 1.5 point reduction on an 11 point NRS as the MCIC in pain. As it was not possible for patients to make half point reductions in pain, a stricter, two point criteria was set. Finally, the number of patients who would need to be treated to ensure a superior outcome in one patient was then calculated for both disability and pain.

**9.12.4 Patient perceived outcomes**

For patient perceived improvement in neck pain, participants were dichotomised into two groups: “improved” (patient rating as better or much better) or not improved (no change, worse or much worse). A Chi squared test was then performed to assess whether significant between group differences existed. Where no data were provided for patient perceived improvement, data were imputed as no change in neck pain.
For patient satisfaction, outcomes were again dichotomised. Participants who indicated that they were very satisfied or satisfied were classed as being “satisfied with treatment”. Those indicating that they were neither satisfied nor dissatisfied, dissatisfied or very dissatisfied were classed as “not satisfied with treatment”. In instances where participants did not provide data for satisfaction with treatment, data were imputed as neither satisfied nor dis-satisfied with treatment.

### 9.12.5 Future healthcare consultations

Total primary care, secondary care and independent sector care appointments were calculated for each category and independent *t*-tests performed to establish whether significant differences existed between the groups.

### 9.12.6 Sensitivity analysis

Previous authors have suggested that in cases where data is missing, some form of data imputation should be performed. In the primary analyses, intention-to-treat analysis was performed, whereby in cases where data were missing, the last value was carried forward. However, in order to confirm that this method did not unduly bias the results, three sensitivity analyses were also performed for the pain and disability analyses. There is currently no consensus in the literature as to precisely which sensitivity analyses should be performed.
Therefore, in the first analysis, missing follow up data were imputed presuming that participants' pain and disability had worsened by 10%. The analyses were then performed again, this time presuming that the participants with missing data had improved by 10%. Finally, the analyses were performed using only participants who provided follow up data.

9.13 Follow up

Participants were asked to complete the self-report measures outlined on pages 195-198 six months after entering the study. Questionnaires were posted with a pre-paid return envelope six months after randomisation. Participants who did not return the questionnaire after three weeks were contacted by telephone to ensure that they had received the questionnaire and request that they completed and returned it. Figure 4. (p208) shows a flow diagram of the study protocol.
Referrals are triaged and all patients with CNP meeting inclusion criteria are identified.

Study invitation letter, study information, consent form and questionnaire posted to potential participants.

Patients willing to participate in the study sign and return the consent form and questionnaire.

Participants taught level one (range of movement) exercises and undergo randomisation.

Patients who meet exclusion criteria on assessment are excluded from the trial and receive treatment as usual.

Patients not wishing to participate contact the physiotherapy department to arrange treatment usual.

Participants contacted by telephone and assessment arranged.

Follow up questionnaire posted to participants six months post randomisation.

Telephone reminder three weeks after questionnaire was posted to ensure that the participant has received the questionnaire.

PNEP

IBMT
9.14 Treatment fidelity

To ensure that trial assessment and treatment protocols were followed appropriately, 10% of assessment and treatment sessions were randomly selected and observed by the author. A pro-forma was produced to document whether correct protocols were followed in the assessments (shown in appendix eight). A further pro-forma (shown in appendix nine) was used to document whether PNEP exercises were demonstrated appropriately and whether patients' exercise technique was corrected. A final pro-forma (shown in appendix ten) was produced to document whether all educational topics were covered in the IBMT group sessions, whether IBMT principles (interactive questioning and challenging unhelpful beliefs) were applied appropriately and whether goal setting principles were applied correctly (i.e. homework issued at the end of the first session and goal setting and reviews on subsequent sessions).
10.0 Results

10.1 Baseline characteristics

Six-hundred and sixty five patients were invited to participate in the study, of which 107 agreed to do so (16%). Of those agreeing to take part, 57 met the inclusion criteria. Twenty eight were randomised to receive PNEP and 29 were randomised to receive IBMT. Figure 5. (p211) summarises recruitment rates into the trial, group allocation and follow up rates, whilst figure 6. (p211) shows reasons for exclusion from the trial. Thirty four (59.5%) of participants expressed a preference for PNEP, six (10.5%) for IBMT and 17 (30%) expressed no preference. There were seven participants in each group who reported that pain had started following a MVC (i.e. they were experiencing Chronic Whiplash Associated Disorder).
Figure 5. Study three participant recruitment and treatment allocation

Invited to participate (n=665)

Did not return questionnaire (n=558)

Agreed to participate (n=107)

Excluded (n=50)
See figure 6.

Assessed

Suitable for inclusion (n=57)

Randomised

PNEP (n=28)
Provided follow up data (n=14)

IBMT (n=29)
Provided follow up data (n=23)

Figure 6. Reasons for participant exclusion from study three

Did not attend assessment=11
Radiculopathy=9
Vertebral-basilar artery insufficiency=7
Not randomised due to administrative error=5
Rheumatological disorder=5
Neck pain not participants primary complaint=4
Duration less than three months=4
Recovered=3
Osteoporotic fracture=1
Poor spoken English=1
There were no significant differences in mean age, pain duration or male:female ratio between the two groups. Moreover, levels of disability, pain and the cognitive measures did not differ significantly between the groups. Table 17. shows mean baseline data values. There was a statistically significant difference between the groups in the proportion of participants providing six month follow up data ($p=0.03$). Specifically, fourteen participants who received PNEP provided follow up data, whilst 23 provided data from the IBMT group. There were no differences in sex or pain duration between those returning the questionnaire and those who did not. However, non-responders were significantly younger than those who provided follow up data (mean age 39 v. 52).

**Table 17. Baseline measures**

<table>
<thead>
<tr>
<th>Measure</th>
<th>PNEP</th>
<th>IBMT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>45.8</td>
<td>49.2</td>
</tr>
<tr>
<td>Sex (%) Male</td>
<td>50</td>
<td>59</td>
</tr>
<tr>
<td>Female</td>
<td>50</td>
<td>41</td>
</tr>
<tr>
<td>Pain duration (years)</td>
<td>3.9</td>
<td>4.8</td>
</tr>
<tr>
<td>Disability (NPQ%)</td>
<td>36.7</td>
<td>36.8</td>
</tr>
<tr>
<td>Pain intensity (NRS)</td>
<td>5.4</td>
<td>5.9</td>
</tr>
<tr>
<td>Pain-related fear (TSK)</td>
<td>33.6</td>
<td>36.7</td>
</tr>
<tr>
<td>Catastrophizing (PCS)</td>
<td>17.2</td>
<td>17.8</td>
</tr>
<tr>
<td>Functional self-efficacy</td>
<td>63.0</td>
<td>63.4</td>
</tr>
<tr>
<td>(CPSS-pf)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain vigilance and awareness (PVAQ)</td>
<td>43.3</td>
<td>39.5</td>
</tr>
</tbody>
</table>

NPQ = Northwick Park Neck Pain Questionnaire; NRS = Numeric Rating Scale; TSK = Tampa Scale for Kinesiophobia; PCS = Pain Catastrophizing Scale; CPSS-pf = Chronic Pain Self-efficacy Scale – physical function sub-scale; PVAQ = pain vigilance and Awareness Questionnaire
10.2 Interventions

Of the 28 participants randomised to receive PNEP, data on the number of sessions received were available for 21 participants. Data for the remaining participants were not available due to breach of the trial protocol in some instances, where data were not recorded on the treatment received pro forma. Of those participants where data were available, 11 (52%) attended all sessions, whilst 17 (81%) attend at least two of the four PNEP sessions. Of those randomised to receive IBMT, data were available for 28 of the 29 participants. Of these 15 (56%) attended all sessions, with 24 (86%) attending at least two of the four sessions.

Amongst participants randomised PNEP alone, one participant withdrew from the study. No reasons were given for withdrawal by this participant. In the IBMT group, one patient withdrew, because they were unable to get the time off work to attend the group. Furthermore, two participants randomised to receive IBMT were unable to attend the group. However, these patients did not withdraw and were treated on a one to one basis as per the IBMT protocol (interactive education and goal setting). There were no significant differences in the number of withdrawals between groups. The mean number of participants in each IBMT group was 3.5 (range=2-6).
10.3 Exercise compliance

Only 13 participants returned the exercise diary (IBMT n=8; PNEP n=5). Moreover, the exercise diaries were mostly completed by those participants who attended all or the majority of treatment sessions. Amongst participants who returned the exercise diaries, compliance with the exercises was good. The mean number of times the participants performed the exercises per week was 6.8 for the flexibility exercises, 3.7 the neck strengthening exercises and 4.3 for the upper limb strengthening exercises.

10.4 Adverse events

No adverse events related to treatment were reported in either group. One patient in the PNEP group was subsequently diagnosed with multiple sclerosis, however, their condition was not adversely affected by participation in the trial.

10.5 Treatment fidelity

Six assessments were observed and data recorded. In all instances assessments were carried out in line with trial protocol. Thirteen PNEP sessions were observed. In each instance, the exercise programme was demonstrated correctly and patients’ technique was corrected so that they performed the exercises appropriately. Finally, five IBMT group sessions were
observed. As with PNEP, all exercises were taught appropriately. Moreover, all topics were covered and IBMT principles (interactive questioning and challenging unhelpful beliefs) were employed appropriately. Treatment protocol was followed with goal setting principles, with homework issued on the first session and goal reviews on subsequent sessions. However, it is noteworthy that some participants were unable to identify functional goals to work towards, as they had persisted with all desired activities, despite their neck pain.

10.6 Tests of normality of the data

Both Levene and Shapiro-Wilk tests were non-significant, suggesting homogeneity of variance and normal normally distribution of the data. Visual inspection confirmed normal distribution and heterogeneity of the data. Parametric tests were therefore performed for where data were of interval level.
10.7 Primary outcome: disability

10.7.1 Group level analysis

Participants who received PNEP reported a mean reduction in NPQ score of 7.2%, whilst those receiving IBMT reported a mean reduction of 10.2%. However, there was no significant difference in the change NPQ score between the groups (Table 18., p201).

10.7.2 Minimal clinically important change

In the PNEP group, seven patients experienced a MCIC in disability, whilst 20 did not. In the IBMT group, 17 experienced a MCIC in disability, whilst 12 did not. Chi squared test revealed that this difference reached statistical significance (Table 19., p201). The number needed to treat to ensure that one additional patient made a MCIC in disability was three when patients received IBMT rather than PNEP.
10.8 Secondary outcomes

10.8.1 Pain intensity

10.8.1.1 Group level analysis

Participants receiving PNEP reported a mean decrease in pain of one NRS point, whilst those receiving IBMT reported a mean decrease of 2.2 points (Table 18. page 201). The difference between the groups (1.2) was statistically significant ($p=0.04$).

10.8.1.2 Minimal clinically important change

In the PNEP group seven patients experienced a MCIC in pain, whilst 20 did not. Conversely, in the IBMT group 16 participants experienced a MCIC in pain, whilst 13 did not. Chi squared test revealed that this difference reached statistical significance (Table 19. page 201). The number needed to treat to ensure one additional patient made a MCIC in pain intensity was four when patients received IBMT rather than PNEP.
10.8.2 Cognitive measures

Table 18. (p 220) shows the changes in the scores on the cognitive measures. Greater increases functional self-efficacy beliefs were observed in the IBMT group, however the difference did not reach statistical significance ($p=0.19$). Decreases in catastrophizing and pain vigilance and awareness were observed in both groups, but no significant differences were observed between groups. Finally, significantly larger reductions in pain-related fear were observed in the IBMT group than in PNEP ($p<0.05$).

10.8.3 Healthcare utilisation

Thirty-three participants provided data pertaining to healthcare usage in the six months since commencing physiotherapy treatment. Rates of additional healthcare utilisation were low across the whole sample, with no significant differences between the groups.

Five participants consulted their GP about their neck pain (two PNEP, three IBMT), however there were no referrals to rheumatology, orthopaedics or spinal surgery in either of the groups. Three participants in the PNEP group received extra treatment sessions from the trial physiotherapist, compared to one in the IBMT group. However, two patients in the IBMT group paid for private physiotherapy, compared to only one in the PNEP group.
No participants received osteopathic or chiropractic treatment, one underwent acupuncture (IBMT) and one had other alternative healthcare (PNEP).
### Table 18. Changes in outcome measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>PNEP post treatment mean</th>
<th>IBMT post treatment mean</th>
<th>PNEP change</th>
<th>IBMT change</th>
<th>Difference</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disability (NPQ%)</td>
<td>29.5</td>
<td>26.5</td>
<td>–7.2</td>
<td>–10.2</td>
<td>3.0</td>
<td>0.45</td>
</tr>
<tr>
<td>Pain intensity (NRS)</td>
<td>4.4</td>
<td>3.7</td>
<td>–1.0</td>
<td>–2.2</td>
<td>1.2</td>
<td>0.04*</td>
</tr>
<tr>
<td>Pain-related fear (TSK)</td>
<td>33.8</td>
<td>32.0</td>
<td>0.2</td>
<td>–4.7</td>
<td>4.9</td>
<td>0.03*</td>
</tr>
<tr>
<td>Catastrophizing (PCS)</td>
<td>11.4</td>
<td>11.8</td>
<td>–4.5</td>
<td>–6.1</td>
<td>1.6</td>
<td>0.56</td>
</tr>
<tr>
<td>Functional self-efficacy (CPSS-pf)</td>
<td>64.0</td>
<td>66.3</td>
<td>1.0</td>
<td>3.2</td>
<td>2.2</td>
<td>0.19</td>
</tr>
<tr>
<td>Pain vigilance and awareness (PVAQ)</td>
<td>38.4</td>
<td>36.7</td>
<td>–4.9</td>
<td>–3.6</td>
<td>1.3</td>
<td>0.34</td>
</tr>
</tbody>
</table>

* = Significant between group difference (p<0.05)

### Table 19. Minimal Clinically Important Changes

<table>
<thead>
<tr>
<th>Measure</th>
<th>MCIC PNEP (%)</th>
<th>MCIC IBMT (%)</th>
<th>Difference (%)</th>
<th>P Value</th>
<th>NNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disability (NPQ%)</td>
<td>7 (25)</td>
<td>17 (59)</td>
<td>34</td>
<td>0.02*</td>
<td>3</td>
</tr>
<tr>
<td>Pain intensity (NRS)</td>
<td>7 (25)</td>
<td>16 (55)</td>
<td>30</td>
<td>0.03*</td>
<td>4</td>
</tr>
</tbody>
</table>

* = Significant between group difference (p<0.05)

NPQ = Northwick Park Neck Pain Questionnaire; NRS = Numeric Rating Scale; TSK = Tampa Scale for Kinesiophobia; PCS = Pain Catastrophizing Scale; CPSS-pf = Chronic Pain Self-efficacy Scale – physical function sub-scale; PVAQ = pain vigilance and Awareness Questionnaire
10.9 Patient perceived outcomes

10.9.1 Patient satisfaction

Amongst the whole study population, 47% were very satisfied with treatment, 14% satisfied, 39% neither satisfied nor dissatisfied and 2% dissatisfied. After dichotomising the outcome, Chi squared test revealed a significant difference between the groups. More participants receiving IBMT reported satisfaction with treatment than in the PNEP group (22 satisfied in the IBMT group versus 12 in the PNEP group).

10.9.2 Patient perceived improvement

Following dichotomisation of outcome, 20 patients receiving IBMT (69%) reported that their symptoms had improved, compared to 10 (36%) in the PNEP group. Chi squared testing revealed that this difference was statistically significant.
10.10 Sensitivity Analyses

Results for the sensitivity analyses are shown in table 20 (p224).

10.10.1 Missing data assumed to be 10% worse

There were no significant differences from the primary analyses. Reduction in pain remained significantly greater in the IBMT group, whilst the mean difference in reduction in disability did not reach statistically significant levels.

10.10.2 Missing data assumed to be 10% better

As in the main analysis, there were no significant differences between mean reductions in disability. In contrast to the primary analysis, there was no significant difference in mean reduction in pain intensity, although it is noteworthy that this only narrowly failed to reach statistical significance ($p=0.06$).

10.10.3 Complete data only

When only complete data were used in the analyses, no significant differences were observed between the groups in terms of changes in disability. In contrast
to the main analysis, no significant differences were observed between the groups in changes in pain intensity.
Table 20. Sensitivity analyses

<table>
<thead>
<tr>
<th>Measure</th>
<th>Assuming 10% deterioration</th>
<th>Assuming 10% improvement</th>
<th>Complete data only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PNEP</td>
<td>IBMT</td>
<td>Difference</td>
</tr>
<tr>
<td>Disability (NPQ%)</td>
<td>-5.8</td>
<td>-9.5</td>
<td>-3.8</td>
</tr>
<tr>
<td>Pain Intensity (NRS)</td>
<td>-0.4</td>
<td>-2.0</td>
<td>-1.6</td>
</tr>
</tbody>
</table>

* = Significant between group difference (p<0.05)

NPQ = Northwick Park Neck Pain Questionnaire; NRS = Numeric Rating Scale; TSK = Tampa Scale for Kinesiophobia; PCS = Pain Catastrophizing Scale; CPSS-pf = Chronic Pain Self-efficacy Scale – physical function sub-scale; PVAQ = pain vigilance and Awareness Questionnaire
11.0 Discussion

Preliminary analysis of the data demonstrated that there were no significant differences between the groups in baseline values for age, sex, pain duration, pain intensity, disability or any of the cognitive measures. This suggests that randomisation was successful and any between group differences observed in this study could not be accounted for by differences in baseline data.

In comparison to previous large UK NHS-based physiotherapy studies of patients with CNP, participants in the current study were of similar age, reported similar levels of pain intensity\(^\text{138,149}\) and pain related-fear\(^\text{128,149}\). Levels of disability were comparable with the studies of Dziedzic and colleagues\(^\text{138}\) and Klaber Moffett et al in their 2004 study\(^\text{149}\). However, participants in Klaber Moffett’s 2006 study\(^\text{128}\) reported higher levels of disability than in the current study or the studies mentioned previously. This suggests that the participants in the 2006 Klaber Moffett study may have been somewhat more disabled than other populations of patients with CNP, rather than those in the current study differing from other NHS based samples.

With regards to treatment compliance, the majority of participants in both groups attended at least two of the four treatment sessions, suggesting that most participants would have had sufficient opportunity to learn the correct exercise technique. Moreover, treatment fidelity assessments suggested that the trial assessment and treatment protocols were followed appropriately. Unfortunately, it was not possible to accurately assess compliance with the
exercises, as exercise diaries were returned by only 13 of the 57 participants. Amongst those who did return the diaries, exercise compliance was good, however, this may be due to reporting bias, with only those patients with good compliance returning the diaries.
11.1 Changes in disability following treatment

In the primary analysis, participants in both groups reported reductions in levels of disability. However, in contrast to the study three hypothesis, there was no statistically significant difference between the groups. These findings were supported by the sensitivity analyses, whereby all three analyses produced the same conclusion as the primary analysis.

From this finding, it could be concluded that IBMT does not incur any additional improvements in disability beyond that offered by PNEP. However, when minimum clinically important changes (MCIC) in disability were compared between the groups, significant differences emerged. In the PNEP group, 25% of patients made a clinically important reduction in disability, compared to 59% in the IBMT group. Taken at face value these findings seem contradictory to the primary analysis. However, the disparity between these two statistical analyses may be in part explained by the fact that the primary analysis was powered to detect an additional between group difference of 10%. Many of the participants reported relatively low levels of disability, despite the presence of neck pain. In these patients it may not have been possible to make an additional 10% decrease in disability beyond that incurred with PNEP alone.

In contrast, the MCIC in disability is classed as a 25% reduction in baseline levels of disability\textsuperscript{148}, meaning that it was possible for all participants to meet the criteria for a MCIC in disability. Therefore, where group level analysis measured mean changes across the whole treatment group, the proportion
making a MCIC represents the number of patients who where likely to have obtained a clinically meaningful improvement in their symptoms. In view of this, there may have been a ceiling effect in terms of possible improvement in disability in the primary analysis, whereas no such limit existed in the MCIC analysis. In this respect, it could therefore be argued that MCIC is a more clinically meaningful measure of treatment response. This notion is supported by the fact that, in the IBMT group, a significantly greater proportion of participants perceived that their condition had improved and significantly more participants were satisfied with treatment. This suggests that participants also perceived superior treatment outcomes when treated with IBMT.

A possible explanation for the disparity in these findings may be that not all patients with CNP respond to treatment in the same manner. Hill and colleagues demonstrated that patients who displayed greater catastrophizing at baseline did not respond well to conventional physiotherapy treatments. Although the current study did not find significant differences in reductions in catastrophizing, IBMT was associated with greater reductions in pain-related fear. It is feasible that greater levels of pain-related fear are also significant barriers to recovery in patients with CNP. Patients with greater pain-related fear may not benefit from conventional physiotherapy interventions as they may fear exacerbating their symptoms or causing physical damage and consequently do not perform the exercises regularly or re-engage in functional activity.

As IBMT addresses specific concerns about neck pain and exposes participants to feared activities in a gradual, structured manner, it is plausible that it was
these processes which underpinned decreases in pain-related fear. On the other hand, patients treated with PNEP alone who exhibited higher levels of pain-related fear were not exposed to specific, feared activities and did not receive the same level of input to address their fears. Consequently, more highly-fearful participants may have obtained greater benefit from IBMT than PNEP, accounting for the greater proportion of participants making a MCIC in disability.

Contrastingly, participants with lower levels of pain-related fear may have obtained equal benefit from either intervention. Logically, participants who do not display high cognitive risk factors are unlikely to obtain further benefit from an intervention targeting risk factors that they do not exhibit. This may have resulted in the superior benefits of IBMT in a sub-group of fearful patients not being apparent when all participants were considered, meaning that group level differences in reductions in disability did not reach statistical significance.

It is also possible that a similar effect may have existed with regards to levels of catastrophizing. Although the difference in between group change in catastrophizing did not reach statistical significance, a non-significantly larger reduction in catastrophizing was observed in the IBMT group. It is plausible that the postulated fearful sub-group discussed earlier may also have made significantly greater decreases in catastrophizing. However, this effect was not apparent when all participants were considered. However, this suggestion is speculative and further research is required to compare whether IBMT results in
greater reductions in catastrophizing in a sub-group of patients with higher baseline cognitive risk factors.

Interestingly, a cross-sectional study of patients with CLBP treated in a physiotherapy environment reported that pain-related fear was not significantly related to levels of disability when other cognitive factors were considered\textsuperscript{28}. However, studies exploring the efficacy of IBMT in a high cognitive risk factor sub-group of patients with CLBP by the same research team have reported that reductions in pain-related fear were indeed significantly related to reductions in disability\textsuperscript{57,59}.

It is feasible that similar associations exist in patients with chronic neck pain, namely that reductions in pain-related fear are the strongest cognitive determinant of reductions in disability. Alternatively, it is plausible that interactions between cognitive factors account for changes in levels of disability, rather than one specific cognitive factor solely accounting for treatment effects. Potentially, changes in pain-related fear may moderate the effects of catastrophizing on reducing disability in patients with CNP. Specifically, reductions in catastrophizing may result in larger decreases in disability when they are accompanied by reductions in pain-related fear. Whilst both PNEP and IBMT reduced catastrophizing to some extent, only IBMT resulted in significant reductions in levels of pain-related fear. This may underpin the greater proportion of participants who reported clinically significant improvements in disability in the IBMT group. However, further research is warranted to establish whether reductions in pain-related fear moderate the effects of
changes in catastrophizing in decreasing disability in patients with CNP. Moreover, future studies are required to investigate whether the superior results observed with IBMT in this study were indeed underpinned by a sub-group of participants who do not benefit from conventional physiotherapy interventions but improve when treated with IBMT.

Study one of this thesis reported that reduced functional self-efficacy beliefs displayed the strongest association with disability. On this basis, IBMT attempted to maximally enhance self-efficacy in an effort to bring about greater reductions in disability. However, only small increases in self-efficacy were found in both IBMT and PNEP, suggesting that neither intervention had a large impact on self-efficacy beliefs. However, it should be noted that participants in study three reported significantly higher functional self-efficacy beliefs than those in study one. Moreover, participants in a previous study, which demonstrated the efficacy of IBMT in patients with CLBP, exhibited lower baseline self-efficacy beliefs and greater increases in self-efficacy following treatment than in the current study. Given the high baseline levels of self-efficacy reported by participants in study three, there was a much smaller scope for enhancing these beliefs. Consequently, one of the mechanisms by which IBMT was hypothesised to offer additional benefit over PNEP was reduced. It is feasible that larger treatment effects may have been observed with IBMT in a population of participants with lower self-efficacy beliefs. Furthermore, treatment outcome may be optimised by specifically selecting patients for IBMT treatment based on low self-efficacy beliefs, as previously reported by Woby et al\textsuperscript{57,59}. 
It is unclear why self-efficacy levels differed so greatly between the two studies, given the similarities between demographic factors and other cognitive factors in the two studies. However, it is possible that participants with low self-efficacy beliefs declined to participate in study three as it was made clear in the description of the interventions that IBMT treatment involved re-engaging in activities which participants had withdrawn from. Feasibly, low self-efficacy beliefs may have meant that potential participants felt that they would not be able to adequately complete the IBMT intervention, causing them to decline to participate altogether. However, this suggestion is speculative and future studies should aim to collect cognitive data from non-participants to enable comparison between those agreeing to participate and those who do not.

Alternatively, variables other than changes in cognitive factors may explain the greater proportion of participants making a MCIC in disability when treated with IBMT. Feasibly, improved exercise compliance may be one of the factors underpinning the superior improvements observed in this group. Indeed, greater exercise compliance has previously been shown to be related to superior outcome in patients with CNP\textsuperscript{143}. Moreover, Sluijs and colleagues\textsuperscript{155} demonstrated that exercise compliance was significantly enhanced when patients felt that their condition was thoroughly reviewed on a regular basis. As interactive education, problem solving and goal reviews are integral components of IBMT treatment, these factors may have led patients to have a greater understanding of the rationale behind performing the exercises and may have increased treatment compliance.
Alternatively, the group based environment of IBMT treatment may have been a factor in improving exercise compliance, with several aspects accounting for superior treatment outcomes. Firstly, the group environment allowed participants to share in other participants’ positive outcomes, which may have provided positive feedback and encouraged compliance with treatment. Increased frequency of exercise may have then led to greater gains in strength and flexibility. In turn, this may have translated into greater reductions in pain intensity and a greater ability to perform functional activities. Unfortunately however, due to the low return rate of exercise diaries, it was not possible to explore whether between group differences were underpinned by treatment compliance.

Secondly, the goal reviews and problem solving were carried out in a group environment, where all participants were encouraged to contribute. This may have allowed participants to learn vicariously through observing other participants’ positive and negative experiences in trying to return to functional activities. This may have increased the opportunity for participants to observe which strategies were likely to improve function and which were likely to be detrimental. As a result of this, more participants may have been able to employ strategies which allowed them to make clinically important reductions in disability.

Finally, the group environment may have enabled greater social interaction amongst participants. Penttinen and colleagues\textsuperscript{156} demonstrated that social
interaction between participants significantly enhanced the efficacy of a “back school” intervention in a randomised controlled trial of patients with non-specific CLBP. As PNEP was delivered on a one-to-one basis, opportunities for social interaction between participants with similar chronic pain conditions were limited. Contrastingly, IBMT was delivered in small groups and it is feasible that greater social interaction partially accounted for the greater proportion of participants experiencing a clinically important improvement in disability in this group.

It should also be noted that significantly superior pain outcomes were observed in the IBMT group. It is possible that the greater proportion of participants making a MCIC in disability in the IBMT group can be accounted for by greater reductions in pain in this group. Feasibly, greater reductions in pain intensity may have meant that participants were more willing to re-engage in functional activities and therefore experienced lower levels of disability. Indeed, Woby and co-workers\textsuperscript{59} demonstrated that reductions in pain intensity were significantly related to changes in levels of disability following IBMT in patients with CLBP. It is likely that a similar relationship exists between reductions in pain intensity and disability in the current study. Potential explanations for the between group differences observed in pain intensity are discussed in detail in section 11.4 (p240).

Finally, it is also possible that the greater proportion of participants improving in the IBMT group may be accounted for by the fact that there were a significantly higher number of participants in the PNEP group who did not provide six month
follow up data. Consequently, a greater proportion of data were carried forward, meaning that those participants were classed as not making a MCIC in disability. Although it is unlikely that all patients who did not provide data had improved, the missing data means that conclusions from the MCIC analyses must be made with caution. Moreover, further studies are required to test the proposed hypothesis that some patients benefit to a greater extent from IBMT treatment. Such studies would be required to recruit an adequate sample size to enable sub-group analysis, based on baseline cognitive scores.

In light of the above, and that no significant between-group differences were observed in the disability analysis, it must be concluded that study three failed to clearly demonstrate the superiority of IBMT over PNEP in reducing levels of disability. Whilst the MCIC analyses suggested that more patients may benefit from IBMT treatment, it is feasible that for many patients, PNEP alone is as effective in reducing levels of disability.
11.2 Comparison to previous trials exploring changes in disability

Participants in the current study reported comparable reductions in disability to other trials which have employed similar cervical strengthening interventions\textsuperscript{101,135,142}. Moreover, the current trial reported superior reductions in disability at six month follow up to those reported by Chiu and colleagues (2004), which utilised a less intense training intervention. The current trial therefore is in agreement with previous trials in demonstrating that strengthening exercises can be an efficacious method of treating CNP and that higher intensity exercise programmes appear to be more effective than lower intensity regimes. It is worthy of note however that several of these trials used the Neck Disability Index (NDI), rather than the Northwick Park Neck Pain Questionnaire (NPQ), as used in this trial. Nevertheless, whilst direct comparison of results is not possible, both the NPQ and NDI are derived from the Oswestry Disability Index and both are converted to a percentage, therefore some comparison of results is possible.

When the results of the current trial were compared to large-scale NHS trials of patients with CNP, contrasting results were found. The current study reported greater decreases in disability than both treatment groups explored by Klaber Moffett and colleagues\textsuperscript{149}. Interestingly, Klaber Moffett compared a brief physiotherapy intervention to usual physiotherapy practice, whereby the treating clinician decided upon the appropriate treatment modality. In the usual treatment group, only 20.8% of patients were treated with a home exercise
programme and only 38.4% received advice regarding their condition. In contrast, exercise and advice were key components of treatment in both of the treatment groups in the current study.

This highlights that treatments underpinned by exercise and advice, such as those employed in the current study, appear to be more efficacious in treating neck pain than more passive forms of physiotherapy, such as electrotherapy or manual therapy. This is possibly as passive modalities do not adequately address significant barriers to recovery, such as cognitive factors, resulting in inferior clinical outcome. Alternatively, exercise-based treatments may bring about greater physiological changes in factors such as strength and flexibility which are unlikely to be affected by passive modalities. As discussed previously, improved physical conditioning may translate to a greater ability to perform physical activities and result in greater improvements in disability.

When the current findings are compared to those of Dziedzic and co-workers\textsuperscript{138}, similar reductions in disability were found. This is unsurprising as treatments in the study of Dziedzic were also underpinned by exercise, written and verbal advice and patient re-assurance that there was no serious problem with their neck. However, in contrast to the current study, the physiotherapists in Dziedzic trial were allowed to prescribe exercises at their discretion. It is therefore unclear which specific exercises were most commonly employed, prohibiting direct comparison of the exercise interventions.
The final large-scale NHS based trial of treatments for neck pain compared a McKenzie exercise programme to a “solution finding approach”\textsuperscript{128}. The reductions reported in the IBMT group in the current study were comparable to those observed in both groups in the study of Klaber Moffett and associates. However, the reductions in the PNEP group appear to be of a smaller magnitude, although it is unclear whether these differences would have reached statistical significance. It is possible that greater reductions may have been observed by Klaber Moffett and colleagues as participants in their study reported higher baseline levels of disability. Nikander and colleagues\textsuperscript{143} reported that the most severely affected patients benefit most from neck training interventions. Therefore, it is plausible that the lower baseline levels of disability reported in our study accounted for the inferior results observed in the PNEP group, as compared to the interventions employed by Klaber Moffett and colleagues\textsuperscript{128}.

In summary, the mean changes in disability in both treatment groups of the current study were broadly comparable to those observed in previous NHS based studies. Moreover, the interventions employed in this study resulted in greater decreases in disability than those reported in routine NHS care or a brief physiotherapy intervention\textsuperscript{149}. This highlights that treatment of CNP should be underpinned by structured exercise programmes, reassurance regarding prognosis and advice encouraging self management of pain.
11.3 Summary of changes in disability following treatment

The primary analysis did not demonstrate a significant difference between the groups in change in disability. In contrast, a significantly larger proportion of patients made a clinically important reduction in disability when treated with IBMT. Although it is not possible to definitively conclude from the current study that adding IBMT to PNEP results in greater reductions in disability, it appears that participants were more likely to make clinically meaningful improvements when treated with IBMT. However, these findings must be interpreted with caution, due to the high levels of missing data in the analyses. Nevertheless, as the current thesis does provide some suggestion that patients may be more likely to improve when treated with IBMT, future studies are warranted to establish whether matching patients to specific treatments maximises reductions in disability.
11.4 Changes in pain following treatment

As hypothesised, between group comparison revealed a statistically significant difference in change in pain intensity of 1.2 NRS points in favour of IBMT. The minimum clinically meaningful change in pain intensity in patients with neck pain has been reported to be 1.5 points on an 11 point NRS\textsuperscript{153}. According to this criterion, the mean reduction in pain in those patients treated with PNEP (1.0) is not of clinical significance. Contrastingly, those treated with IBMT exhibited a mean reduction of 2.2 points, above the threshold for a MCIC in pain. Additionally, 55% of participants receiving IBMT made a clinically important (two point reduction on the NRS) reduction in pain, in comparison to only 25% in the PNEP alone group.

The current findings therefore suggest that employing IBMT treatment techniques results in clinically important reductions in pain intensity beyond those observed with PNEP. Moreover, number needed to treat analysis suggested that for every four patients treated with IBMT, one additional patient would experience a clinically meaningful reduction in pain intensity. This suggests that employing IBMT treatment for patients with CNP may result in superior outcome for significant numbers of patients, were it to be offered more widely. However, given the relatively small sample size included in this study and the high percentage of missing data, further studies are required before definite recommendations to offer IBMT can be made.
When the sensitivity analyses were examined, similar results were observed in the 10% worse analysis as in the primary analysis. In contrast, when participants with missing data were assumed to have improved by 10%, the difference between mean reduction in pain intensity failed to reach statistical significance. However, it is noteworthy that there was still a 1.1 point mean difference in pain reduction between the groups and that this only narrowly failed to reach statistical significance ($p=0.06$). This still suggests a strong trend towards the superiority of IBMT, even when all participants with missing data were assumed to have improved. In contrast, in the final sensitivity analysis, where only participants who provided complete data were considered, no significant differences in pain were observed between the groups. However, the complete data analysis should be interpreted with caution for a number of reasons. Firstly, significantly lower numbers of participants who received PNEP provided follow up data compared to those who received IBMT. Secondly, participants who provided follow up data reported larger improvements than when the sample as a whole was considered. This suggests that there may have been a response bias, in that participants who experienced a positive treatment outcome may have been more likely to provide follow up data than those who did not.

On this basis, Hollis and Campbell\cite{98} suggested that excluding patients with missing data from analyses altogether can lead to falsely overstating the efficacy of a treatment. Moreover, they suggest that intention-to-treat analysis with some form of data imputation is more likely to more closely represent the true data value than complete data only analysis. In view of this, the analyses
with data imputation were likely to be a more accurate reflection of the data than the complete data only analyses. Nevertheless, whilst the sensitivity analyses generally support the findings of the main analyses, the complete data only analysis would appear to suggest that missing data may have contributed to the between group differences. On the basis of the high proportion of missing data, some caution must be exercised when interpreting the data.

Study one of this thesis suggested that catastrophizing and functional self-efficacy beliefs were strongly linked to levels of pain intensity in patients with CNP. Moreover, it was hypothesised that IBMT treatment would result in greater changes in these cognitive factors, which would translate into greater reductions in pain intensity. Although superior improvements in pain intensity were observed with IBMT, significantly greater changes in catastrophizing and self-efficacy were not observed. This suggests that the greater changes in pain intensity observed with IBMT were not underpinned by greater changes in either catastrophizing or self-efficacy beliefs. However, as discussed earlier, significantly greater reductions in pain-related fear were observed in patients treated with IBMT.

It is feasible that these greater reductions in pain-related fear underpinned the superior pain outcomes observed in the IBMT group. Conceivably, greater levels of pain-related fear may have meant that some participants were unwilling to perform the PNEP exercise programme or were not willing to work to the higher intensities associated with greater improvements in pain intensity. However, reducing pain-related fear may have encouraged better
compliance with the exercise programme, thus leading to greater decreases in pain intensity. Moreover, reducing pain-related fear may have enabled participants to re-engage in activities they previously avoided. In turn, this may have led to restoration of normal cervical musculature function, dysfunction of which has been implicated in the aetiology of chronic neck pain\textsuperscript{104,105}.

In support of this notion, Elfving and colleagues\textsuperscript{157} demonstrated that in patients with CLBP, both catastrophizing and pain-related fear were negatively related to activity participation and intensity. Moreover, Vlaeyen and collaborators\textsuperscript{24} demonstrated that pain-related fear was associated with decreased lifting capacity in patients with CLBP. It is feasible that similar associations between pain-related fear and activity engagement exist in patients with CNP. Furthermore, reducing pain-related fear may reduce barriers to activity participation and therefore facilitate successful rehabilitation.

It is also likely that improvements in pain intensity in both groups were, at least in part, underpinned by physiological changes in the musculature and other soft tissues of the cervical spine. Previous studies of patients with CNP have demonstrated that reduced muscle strength\textsuperscript{106} and endurance\textsuperscript{104} are associated with neck pain, when compared to pain free populations. Moreover, strengthening regimes similar to the one employed in this study have been shown to be associated with improvements in neck muscle strength and concomitant reductions in pain\textsuperscript{101,102,140}. Moreover, greater training intensity has been shown to be related to greater clinical improvement, with a direct relationship between time spent training and pain relief obtained\textsuperscript{143}. Although
the current study did not measure cervical muscle strength, it is feasible that similar increases in strength were observed in the current participants, which may have underpinned the reductions in disability observed in both groups.

Furthermore, in view of the dose-response relationship highlighted by Nikander and colleagues\textsuperscript{143}, it is distinctly possible that exercise compliance was a significant factor in explaining the differences observed between the groups. It is plausible that the superior results observed in the IBMT group were due to improved treatment compliance, rather than greater modification of cognitive factors. As discussed earlier (p232), treatment compliance has been shown to be improved when patients feel that they are regularly reviewed. Since detailed, weekly reviews were integral to IBMT, participants may have felt that they were being reviewed more thoroughly and thus treatment compliance may have been enhanced. Moreover, it is feasible that the improved social interactions involved in group based treatments, as outlined on page 229, may have also significantly contributed to enhancing pain outcomes in the IBMT group.

Additionally, the superior results observed with IBMT may be partially accounted for by the effects of individual therapist interactions. The IBMT groups were delivered by an experienced physiotherapist who had extensive experience of delivering both IBMT and exercise group interventions. In contrast, the PNEP intervention was delivered by a number of therapists, although all had a minimum of five years post graduate experience. Consequently, it is likely that communication skills and therapeutic relationships
with patients differed between therapists. The therapeutic relationship established between patient and physiotherapist is known to significantly affect compliance with exercise\textsuperscript{155}, and patient outcome\textsuperscript{158}. Although trial fidelity assessments ensured that exercise technique was taught correctly to participants, the extent to which the therapists engaged with participants and established a therapeutic relationship may have differed and therefore affected exercise compliance and treatment outcome.

Unfortunately, due to the low return rate of the exercise diaries, it was not possible to compare treatment compliance between the two groups and explore the validity of the hypotheses suggested above. Future studies are required to assess the role of exercise compliance in patients with CNP in more detail. Moreover, potential factors which may influence compliance, such as the exercise setting, understanding of the treatment rationale and therapist-patient relationships should also be considered. Strategies to maximise participant return of exercise diaries, such as electronic methods, telephone interviews or face-to-face follow up interviews should also be considered.
11.5 Comparison to previous studies exploring changes in neck pain intensity

In comparison to previous studies exploring the efficacy of physiotherapy interventions in reducing neck pain intensity, the current study reported similar findings. In a large UK NHS based study, Dziedzic and colleagues\textsuperscript{138} reported decreases in pain intensity of between 1.2 and 1.8 NRS points in their three treatment arms. Similarly, Chiu and co-workers\textsuperscript{139} reported a decrease of 1.4 points in their exercise intervention group. Other studies have employed 100mm visual analogue scales (VAS) to assess pain outcome. Assuming a 10mm change approximately corresponds to a one point NRS change, Bronfort et al\textsuperscript{135} reported similar mean reduction (20-27mm) as found in the IBMT group.

Interestingly, Ylinen and colleagues\textsuperscript{101} reported larger decreases in their strength training group, similar to the one employed in the current study, with a 40mm decrease observed in mean pain intensity. Similarly, Hakkinen and co-workers\textsuperscript{159} employed the same intervention and found comparable reductions in pain (37mm). Two explanations exist for the disparity in findings between these studies and the current investigation. Firstly, NRS and VAS findings may not be comparable, with a one point change not equating to a 10mm reduction in pain intensity as postulated. Indeed Grotle and colleagues\textsuperscript{160} suggested that differences in responsiveness to change exist between the VAS and NRS in patients with LBP. Secondly, differences in trial methodology may account for the contrasting findings. Both Ylinen\textsuperscript{101} and Hakkinen\textsuperscript{159} recruited participants from occupational health departments, rather than hospital physiotherapy.
departments, as in the current study. This is likely to have resulted in the recruitment of a cohort with significantly different demographic characteristics. For example, whilst all participants in the aforementioned studies were office workers, only 56% of the current population were working, with only 46% of the sample working full time. This is may have resulted in significant differences in socioeconomic characteristics of the sample, which have previously been shown to be related to treatment outcome\textsuperscript{52,53}.

Moreover, the studies of Ylinen\textsuperscript{101} and Häkkinen\textsuperscript{159} recruited exclusively female participants, aged between 25 and 53. The current study placed no upper age limit on recruitment, which means that the current study is more likely to be representative of the population as a whole. Furthermore, as acknowledged by Ylinen and colleagues\textsuperscript{101}, physiological differences exist between male and female muscle morphology and force generation, which may affect the manner in which men and women respond to training regimes. Moreover, physiological aging processes are known to be responsible for a progressive deterioration in muscle strength and endurance\textsuperscript{161}. As the current cohort included more elderly participants it is likely that they exhibited greater losses in muscle strength than in the previous studies. It is therefore possible that any greater improvements observed by Ylinen\textsuperscript{101} and Hakkinen\textsuperscript{159} are attributable to greater selectivity in participant recruitment.
11.6 Summary of changes in neck pain intensity

Interactive Behavioural Modification Therapy resulted in superior pain outcomes than PNEP alone. This may be attributable to greater reductions in pain intensity, or a greater number of patients making a MCIC in disability. It is feasible that this difference is accounted for by a sub-group of patients who obtain more benefit from IBMT. Alternatively, superior exercise compliance may have underpinned the superior results observed in the IBMT group. However, some caution should be exercised when interpreting these results, due to the high proportion of missing data in the analyses. Further research is warranted, both to replicate the findings of this thesis and to further investigate whether the superior findings in the IBMT group were underpinned by a sub-group of patients who benefit more from this treatment.
11.7 Changes in cognitive factors

This study hypothesised that IBMT would result in greater changes in cognitive factors than PNEP and that changes in catastrophizing and self-efficacy beliefs would be particularly related to reductions in pain and disability. However, no significant differences were observed in the changes in catastrophizing and functional self-efficacy beliefs between the two groups, with both groups reporting small increases in functional-self-efficacy beliefs and larger decreases in catastrophizing and pain vigilance and awareness. In contrast, significant differences were observed with regards to changes in pain-related fear, with the IBMT group reporting significantly larger reductions. As discussed previously (p228), it is possible that the superior pain and disability outcomes observed with IBMT were at least partly underpinned by changes in pain-related fear.

Moreover, the non-significant differences in reductions in catastrophizing and improvements in self-efficacy do not imply that purported relationship between these cognitive factors and levels of pain and disability is invalid. Conversely, reductions in catastrophizing may indeed have partially underpinned improvements in pain and disability, however, both interventions appear to have been equally efficacious in modifying this variable. It is noteworthy that, although PNEP did not expressly aim to extensively address cognitive factors, participants were given a verbal explanation for their symptoms and were reassured that there was no serious cause for their pain. Moreover, participants were also given all of the written information covering the topics discussed in the IBMT groups. It is therefore plausible that for many patients oral and written
re-assurance may have been adequate to address their concerns and thus reduce catastrophizing.

Alternatively, reductions in catastrophizing may have been underpinned by different mechanisms in the two groups. Whereas IBMT aimed to reduce catastrophizing by challenging participants’ beliefs that pain was a sign of harm, PNEP may have reduced catastrophizing by alternative methods. The strengthening component of PNEP involved high intensity loading of the neck and upper limbs. Exposing patients to such high intensity activity may have increased patients’ confidence in using their neck and changed the perception that pain is a sign of impending harm. In turn, this may have led them to re-engage in functional activities. Alternatively, the PNEP intervention may have increased neck strength and flexibility, resulting in an increased capacity to perform physical activities, which, over time may have resulted in a reduction in catastrophizing.

In support of this notion, a previous study examined the meditational effects of catastrophizing on reductions in disability in patients who had taken part in a RCT of three different treatments for CLBP\textsuperscript{162}. Participants received either graded physical activity, treatment based around cognitive behavioural principles or a combination of the two. All three groups demonstrated decreases in levels of disability and there were no significant differences between the groups. Interestingly, all groups exhibited decreases in catastrophizing, which were found to mediate reductions in disability in all of the treatment groups. Moreover, the graded activity intervention was specifically
designed to exclude CBT-based treatments and therefore did not explicitly aim
to modify catastrophizing. This would suggest that the changes observed in
catastrophizing were caused either directly from the physical effects of exercise,
or from the behavioural changes that exercise brought about. It is plausible that
similar mechanisms underpinned the reductions in catastrophizing observed in
the current study.

An alternate reason for the non-significant differences in change in some of the
cognitive measures may be that not all participants in the current study
exhibited high levels of catastrophizing or low self-efficacy beliefs. Further
exploratory analysis (data not shown) revealed that many participants did not
display high baseline catastrophizing or low self-efficacy scores. From a
theoretical standpoint, as IBMT aims to enhance treatment outcome by
modifying cognitive factors, it is unlikely to offer benefits beyond conventional
physiotherapy treatments in patients who do not present with these risk factors.
As discussed previously (p228-230) it would appear that there is a sub-group of
patients with CNP with cognitive risk factors who do not respond well to
conventional physiotherapy interventions\textsuperscript{52,53}. It is plausible that IBMT may be
more effective than conventional physiotherapy interventions in modifying
cognitive factors in this particular group of patients. However, the effects of any
additional benefits incurred may not have been apparent when results from
other patients, who benefited equally from IBMT or PNEP, were also
considered. Consequently, no additional treatment effect was observed when
only group level findings were considered. On the basis of this, the effects of
IBMT in modifying cognitive factors may be enhanced by specifically selecting
patients who are most likely to benefit from this type of intervention. However, further research is required to investigate this hypothesis in detail.

It should also be noted that, in study one, reduced self-efficacy beliefs displayed the strongest relationship with levels of pain and disability. However, in study three both groups reported relatively small increases in self-efficacy beliefs (PNEP 1.0, IBMT 3.2). This is likely due to the fact that the populations in studies one and three differed significantly with regards to their baseline functional self-efficacy beliefs. In study one, participants reported a mean functional self-efficacy score of 48.1, whereas in study three participants reported a much higher mean score (63.2). This suggests that participants in study three were already moderately to highly confident in performing functional activities, leaving little scope for further improvement in self-efficacy beliefs. This point is further re-enforced by anecdotal reports from the treating clinicians and treatment fidelity assessments that some of the participants in the IBMT group struggled to identify functional goals to work towards. One of the key components of IBMT is the augmentation of self-efficacy beliefs through functional goal setting. Participants who are already confident in their ability to complete functional tasks are therefore less likely to benefit from this approach, which in all probability accounts for the lack of significantly larger increases in self-efficacy in the IBMT group.

In support of this concept, a previous study exploring the efficacy of IBMT techniques in patients with CLBP reported significantly lower baseline levels of self-efficacy, more in keeping with those reported in study one of this thesis.59
Moreover, much larger increases in self-efficacy were observed following IBMT treatment in the previous study, suggesting that the high baseline self-efficacy scores observed in the current study may account for the relatively minor magnitude of the improvements observed. It is therefore possible that greater increases in self-efficacy beliefs would have been observed in a cohort of patients with lower baseline self-efficacy beliefs, although it is unclear whether the magnitude of change would differ significantly between IBMT and PNEP. Furthermore, it is unclear why participants in study three reported higher levels of self-efficacy compared to those in study one, given that no such disparity was observed in the other cognitive measures. However, an interesting area for future study would be to compare the efficacy of PNEP and IBMT in a cohort of patients selected specifically as they displayed low functional self-efficacy beliefs.

In summary, IBMT resulted in significantly larger decreases in pain-related fear, whilst both treatments brought about reductions in catastrophizing and pain vigilance and awareness and small improvements in functional self-efficacy beliefs. This was likely due to high baseline levels of self-efficacy beliefs amongst the current population. Greater changes in the cognitive factors may be observed in more highly selected populations and future research is warranted to further explore this.
11.8 Healthcare utilisation

Rates of further primary care, secondary care and independent sector healthcare utilisation were low in both groups at six month follow up, with no significant between group differences. Indeed only five of the patients providing data sought further help from their GP and no patients were referred on for secondary care intervention. Only five participants received additional physiotherapy, three of whom received one additional session as per the trial protocol and two of whom who paid for private treatment, undergoing four and twelve treatments respectively. Finally, only two of the patients underwent alternative healthcare interventions (one acupuncture treatment, one treatment not stated).

This finding suggests that both PNEP and IBMT interventions were by and large successful in encouraging self-management of neck pain in the six months following treatment. However, it is notable that only 33 participants provided data for healthcare utilisation. It was not possible to carry data forward in this analysis, therefore it is feasible that healthcare utilisation was higher amongst those participants who did not provide follow up data. Given that the return rate of follow up questionnaires was significantly lower amongst patients receiving PNEP, it is feasible that significant differences may have existed between the groups. Nevertheless, these findings suggest that, even though not all patients experienced clinically significant reductions in pain and disability, the majority were sufficiently re-assured about their condition that they did not feel the need to seek further healthcare input.
Similar findings have been reported in a previous study which explored physiotherapy interventions for patients with neck pain\textsuperscript{138}. In this study, the lowest rates of future healthcare utilisation were observed in an exercise and advice only group, as compared to the same intervention combined with either manual therapy or pulsed short wave diathermy. In the exercise and advice group, rates of GP consultation were comparable to those observed in the current study. Moreover, rates of consultation with other healthcare providers were lower in both groups of the current study than reported by Dziedzic and colleagues. It is plausible that this may be due to differences in the populations examined. The socio-demographic characteristics of many of the participants in the current study have been associated with lower rates of healthcare consultation\textsuperscript{168}, which may account for the low rates of secondary care referral. Alternatively, it is plausible that healthcare consultation was higher amongst those participants who did not provide follow up data, meaning that a referral rates to secondary care were actually higher than suggested by the current findings.

The current findings have important cost implications for the NHS, as patients with chronic pain conditions are frequently referred for expensive investigations and secondary care appointments, which account for significant levels of healthcare expenditure\textsuperscript{7}. Consequently, treatments such as those examined in this study, which result in low levels of further healthcare intervention may result in significant cost savings. However, it should be noted that the current study did not include a full cost-effectiveness analysis or a GP care only control
group. Consequently, strong conclusions can not be drawn about the cost effectiveness of the interventions and further studies are required to fully explore their cost-effectiveness. Moreover, such studies should include a usual GP care only comparison group to enable assessment of the additional costs and benefits incurred by adding either form of physiotherapy to “usual” care.
11.9 Patient perceptions

Patient satisfaction was significantly higher in the IBMT treatment group. Moreover, a greater proportion of participants receiving IBMT reported that their symptoms were improved compared to the PNEP group. These findings are unsurprising, given the superior clinical outcomes observed with IBMT. Moreover, these findings are in line with previous work calculating MCIC in patients with CNP\textsuperscript{148,153}. In these studies MCIC was calculated based on patient perceptions of treatment efficacy. It is therefore consistent with previous work that patient perceived outcomes were similar to the analysis of MCIC in the current study.

It is also possible that patient satisfaction was higher in the IBMT group as participants randomised to this group received longer weekly treatment sessions. It is possible that the extra time spent receiving treatment resulted in greater treatment satisfaction, rather than the specific content of the programme. That said, it should be noted that IBMT was delivered in small groups. Consequently, although the overall time patients were in the physiotherapy department was greater, not all of this time was spent in one-to-one treatment with the therapist. It is therefore unclear whether the greater treatment time significantly influenced patient satisfaction. An interesting area for future research would be to compare the efficacy of IBMT to exercise alone, whilst controlling for the effects of treatment duration.
It should also be noted that, as with the between-group and MCIC analyses, the superior outcomes in the IBMT group could be underpinned, at least in part, by the high proportion of missing data. In the participant perceived improvement and participant satisfaction analyses those patients who did not provide data were classified as not improved and not satisfied with treatment. As a greater proportion of participants did not provide follow up data in the PNEP group, this may have led to the superior outcomes in the IBMT group. As with the other analyses, future studies are required to confirm the findings of the current thesis.
11.10 Limitations

Of the 665 patients who were invited to participate in the trial, only 107 (16%) agreed to take part, of which only 57 (9%) were suitable for inclusion. This figure is lower than several previous NHS-based physiotherapy trials recruiting patients with CNP, which have reported recruitment rates between 28-48%\textsuperscript{128,138,149}, however it is similar to a large scale NHS RCT of patients with LBP\textsuperscript{150} which recruited 11% of patients invited to participate. It is possible that low recruitment meant that participants in the trial differed from those who declined to participate. However, the participants in the current study appear to be broadly similar those reported in other large UK based CNP trials and therefore it would appear that the current sample did not differ significantly from other UK NHS based populations. The results of this trial are therefore likely to generalise to patients treated in routine NHS practice.

There are several reasons why the current study may have recruited a lower proportion of patients than previous trials. Firstly, it should be noted that within the physiotherapy departments participating in the current study, only 60% of patients who are referred for physiotherapy and invited to contact the department for an appointment do so. As all patients referred with CNP were invited to participate in the trial, it is likely that 40% of these patients would not routinely attend for physiotherapy regardless as to whether they were invited to participate in the trial or not. Therefore, it is likely that the proportion of patients who actually attended physiotherapy and who agreed to participate in the trial was in the region of 27%. This figure is more in line with the trials discussed
previously and therefore differences in methods of recruitment may go some way to explaining the apparently low recruitment rate in the current trial.

Alternately, as the trial was exploring changes in several cognitive factors, as well as pain and disability, the pre-treatment questionnaire was quite large, which may have discouraged patients from completing it and taking part in the trial. In support of this notion, a previous trial exploring response rates with different lengths of questionnaire reported that longer questionnaires were associated with lower response rates than shorter ones\textsuperscript{163}. Moreover, a study exploring the influence of the stated length of a questionnaire reported that participation rate decreased when the stated length of the questionnaire was longer\textsuperscript{164}. Together, these studies appear to suggest that larger questionnaires may indeed discourage some patients from participating in studies.

A further possible explanation for the low recruitment rates in the current study may be that the patient information leaflet clearly explained that one of the interventions was a group based treatment. It is possible that some patients did not want to be treated in a group environment. Some support is leant to this hypothesis by the fact that, amongst participants in the current trial, 59.5% expressed a preference for PNEP, compared to only 10.5% expressing a preference for IBMT. There are several potential reasons which may explain patient preference for one to one treatment. Patients may have felt that one-to-one treatment will be more tailored to their individual needs, they may have been uncomfortable in a group environment or felt that group based treatment may lack the flexibility to allow appointments at a convenient time. Some
credibility can be given to this final suggestion, as the one patient who withdrew from the IMBT group did so as they could not attend the group due to work commitments, whilst a further two participants randomised to IBMT were treated individually (according to IBMT principles) as they could not attend the group due to work commitments. However, as patients were free to decline to participate without stating why, these suggestions remain speculative.

A further limitation of the trial was the low return rate of the follow up questionnaires. Of the 57 participants who participated in the trial, only 37 (65%) provided follow up data. This is lower than previous NHS based trials of patients with CNP, which have reported follow up rates of between 82 and 93\%\textsuperscript{128,138,149}. In a similar fashion to the low initial recruitment rate, the low follow-up questionnaire return rate may be accounted for by the fact that the questionnaire was assessing numerous outcomes. This may have discouraged many people from providing follow up data. Several participants could not be contacted to remind them to return the questionnaire as they could not be reached on the telephone numbers they provided. It is also possible that some participants had changed address and therefore did not receive the follow up questionnaire. However, it is unlikely that this accounted for all of the participants who did not provide follow up data.

It is noteworthy that participants providing follow up data were significantly older than non-responders. Interestingly, Sluijs and colleagues\textsuperscript{155} demonstrated that compliance with physiotherapy exercise programmes was better amongst older participants. They suggested that younger patients’ were less compliant due to
greater pressures on their time, for example caring for young children or full
time work. It is possible that similar mechanisms underpin the superior
questionnaire return rates amongst older participants, in that they may have had
fewer time pressures and therefore were more willing to complete and return
the questionnaire.

It is notable that the distribution of non-responders was not equal throughout the
groups. Significantly fewer participants randomised to PNEP provided follow up
data, which suggests that the treatment received impacted on likelihood of
returning the questionnaire. It is plausible that improvements in participants’
condition did not meet their expectations, leading to dissatisfaction with
treatment. In turn, this may have discouraged participants from returning the
questionnaire. Therefore, it is feasible that participants did not provide follow up
data due to a lack of improvement in symptoms. In the primary analyses it was
assumed that this was the case and last known data were carried forward.
Moreover, the results were not substantially altered when the sensitivity
analyses were carried out. Nevertheless, the relatively low proportion of
participants providing follow up data limits the strength of the conclusions that
can be drawn from study three of this thesis.

A further consideration is that the literature searches for studies one, two and
three were performed using only the Medline database. Although Medline is
considered to be the largest medical database, referencing approximately 5400
journals\textsuperscript{170}, it is feasible that some articles were published in journals which are
not listed in Medline, meaning that they were inadvertently excluded from the
search. However, in an effort to minimise the chance of excluding articles, a manual search of all references lists of the articles obtained was undertaken. No further articles were identified in the manual search, suggesting that all relevant articles were identified in the initial literature search. Nevertheless, future searches should also be performed on alternative databases, such as Psychinfo, or Cinahl to insure that no relevant articles are excluded from the literature search.

Finally, the current study did not include a no-treatment or GP care comparison group. The primary aim of this study was to compare whether physiotherapy treatment could be enhanced by the addition of IBMT principles to an exercise-based programme, rather than comparing physiotherapy to other treatment strategies. Consequently, a no-treatment comparison group was not included in the present study. Nonetheless, it is possible that improvements observed in both treatment groups were due to spontaneous improvements due to the passage of time. However, given the chronicity of the sample (mean pain duration = 4.4 years) the author of this thesis feels that it is unlikely that all participants spontaneously recovered over the six month follow up period. Nevertheless, given the recurrent and episodic nature of neck pain, the possibility that many participants were referred for physiotherapy because they were experiencing a transient flare up of pain can not be excluded. Future studies should aim to address this by comparing the efficacy of IBMT treatment to GP only care.
11.11 Study three summary

Adding IBMT to PNEP did not result in significant between-group differences in levels of disability. However, that IBMT did not prove to be conclusively superior to PNEP does not mean that cognitive factors were not important determinants of adjustment in patients with CNP. In contrast, participants in both groups reported reductions in many of the cognitive factors. Moreover, it should be noted that key components of the PNEP regime were giving an explanation for ongoing pain, reassuring patients that pain did not have a serious cause and encouraging return to functional activities. It is feasible that for many patients an intervention consisting of advice, reassurance and exercise is sufficient to modify cognitive factors and improve clinical outcomes.

Contrastingly, it should be noted that IBMT did result in significantly greater reductions in mean pain intensity and pain-related fear. Moreover, a significantly greater proportion of participants made clinically meaningful reductions in pain and disability when treated with IBMT. Finally, participants perceived greater benefit and were more satisfied with treatment when treated with IBMT. However, only 65% of participants provided follow up data, resulting in a large proportion of data being carried forward in the final analyses. This limits the strength of the conclusions that can be drawn from study three, given that no significant differences were observed in the primary analysis.
11.12 Study three clinical implications

Both treatments employed in study three resulted in reductions in pain and disability, providing further evidence for the efficacy of exercise based treatments. Moreover, providing an explanation for ongoing pain, re-assuring patients that pain was unlikely to be caused by a serious problem and encouraging participation in usual activity were key components of both treatments. On this basis, physiotherapists should consider offering a programme of progressive cervical stretching and strengthening exercises when treating patients with CNP. Such exercise programmes should be supplemented by re-assurance and advice to remain active, as outlined previously.

Whilst study three did not provide conclusive evidence to suggest that adding IBMT to PNEP substantively improves outcome, superior outcomes were observed for some outcomes (see section 11.11). Given that patients were more likely to make clinically meaningful improvements in disability and pain when treated with IBMT, offering IBMT may be warranted. However, definite recommendations to include this treatment can not be made and further research is warranted to further explore this relationship.
Chapter 12: Thesis summary

12.1 General summary of studies one, two and three

Cognitive factors were significantly related to levels of adjustment in patients with CNP. The relationship between cognitive factors and levels of disability and depression remained significant regardless of whether neck pain was idiopathic in nature or resulted from CWAD. However, cognitive factors were related to levels of pain intensity to a lesser extent in those participants with CWAD, as compared to those with idiopathic CNP. Greater levels of catastrophizing and reduced functional self-efficacy beliefs were particularly strongly related to levels of adjustment in the cross-sectional analyses.

In study three, no significant differences were observed in reductions in disability when interactive behavioural modification therapy was added to a progressive neck exercise programme. However, greater reductions in pain intensity and pain-related fear were observed. Moreover, IBMT resulted in a significantly greater proportion of participants making minimal clinically important changes in pain and disability. Participants in the IBMT group were also more satisfied with treatment and perceived greater improvement following physiotherapy than those receiving PNEP. Future healthcare consultations were low in both groups, with no significant differences emerging between the groups.
Unfortunately, only 65% of participants provided follow up data, meaning that a large proportion of data were carried forward. This limits the strength of the conclusions that can be drawn from study three. Nevertheless, interesting associations were observed that warrant further research.
12.2 Thesis Conclusion

Cognitive factors appear to be significantly associated with levels of disability and depression in patients with chronic neck pain, regardless of the mechanism of onset. In contrast, cognitive factors appear to more strongly related to levels of pain intensity in patients with idiopathic CNP than those with CWAD.

However, specifically targeting these cognitive factors did not result in the hypothesised greater reductions in levels of disability in the primary analysis. Nevertheless, this does not mean that cognitive factors are unrelated to levels of pain and disability. On the contrary, changes in the cognitive factors were observed in both treatment groups in study three and it is feasible that treatment consisting of exercise and re-assurance may be sufficient to modify cognitive factors adequately in many patients.

In contrast to the primary analysis in study three, a greater proportion of participants made clinically meaningful improvements in pain and disability when cognitive factors were specifically targeted. It is feasible that a sub-group of patients may exist who obtained more benefit from IBMT treatment. However, this suggestion remains speculative and future studies are required to further examine this hypothesis.

In summary, it would appear that cognitive factors are significantly associated with levels of adjustment. However, this thesis was not able to conclusively demonstrate that specifically targeting these factors significantly improves
outcome of physiotherapy treatment. In contrast, some superior treatment outcomes were observed, which may justify the inclusion of IBMT treatment, particularly in instances where therapists identify that cognitive factors are significant barriers to recovery. Nevertheless, based on the current findings, it can not be concluded that IBMT treatment is warranted for all patients with CNP.
12.3 Thesis clinical implications

- When treating patients with chronic neck pain, physiotherapists should assess levels of pain-related fear, catastrophizing and functional self-efficacy beliefs.

- Physiotherapists should consider offering a programme consisting of reassurance, a detailed explanation for ongoing pain and a structured stretching and strengthening programme.

- Offering treatment specifically designed to modify cognitive factors may result in a greater proportion of patients making clinically important reductions in pain and disability. On this basis, physiotherapists should consider offering such treatments, particularly in instances where cognitive factors are identified as significant barriers to recovery.
12.4 Future directions

Study three of this thesis explored the efficacy of two different physiotherapy interventions. Whilst both of the interventions resulted in improvements in levels of pain and disability, study three did not include a comparison group who did not receive physiotherapy treatment. Moreover, no previous studies have compared the efficacy of physiotherapy to other healthcare strategies in the UK NHS. Future studies are required to assess whether evidence-based physiotherapy interventions, such as those considered in study three, are more effective than other types of treatment, for example General Practitioner management.

In order to fully assess the efficacy of physiotherapy management of CNP, it will be necessary to perform a large, multi-centre randomised controlled trial, comparing clearly defined physiotherapy interventions to usual General Practitioner care. Moreover, the trial should be accompanied by a full economic analysis to delineate whether the additional costs associated with physiotherapy treatment are warranted in terms of improved quality of life and reductions in other healthcare expenditure, for example medication use and secondary care referrals.

Furthermore, study three of this thesis hypothesised that the superior outcomes observed for some measures in the IBMT group may be explained by the existence of sub-groups of patients with high or low cognitive risk factors. Interestingly, a recent study explored treatment outcomes in patients with CLBP
who were treated in primary care. In this study, participants in one arm of the trial were referred to physiotherapy as deemed appropriate by the assessing primary care clinician, where they then received standard physiotherapy care. In the other arm, participants were stratified to three different physiotherapy interventions, based on scores on a brief questionnaire assessing common epidemiological and cognitive risk factors. Participants with low risk factors were managed with a brief, one-off educational session and encouraged to regularly participate in exercise. Participants in the medium risk group were stratified to usual physiotherapy and those in the high risk were treated with cognitively-informed physiotherapy. The trial reported that clinical and economic outcomes were significantly improved when this method of stratification was employed\textsuperscript{169}.

In light of the above study, it is possible that similar associations may be true in patients with CNP, i.e. clinical outcomes can be improved by stratifying care based on cognitive risk factors. Consequently, future randomised controlled trials should consider employing similar stratified methodology. This will enable the trial to assess not only the additional benefit of adding physiotherapy to General Practitioner care, but also whether patients respond differently to treatment interventions based on their cognitive risk factors.

Finally, further studies are required to further explore the precise relationship between cognitive factors and reductions in pain and disability. For example, study one of this trial suggested that greater levels of catastrophizing and reduced self-efficacy beliefs were the strongest determinants of disability,
whereas in study three, the only significantly larger change observed in the
cognitive measures in the IBMT group was in levels of pain-related fear. Future
randomised trials should perform secondary meditational analyses to determine
whether changes in cognitive factors do indeed underpin reductions in pain and
disability.

Moreover, studies should delineate whether this relationship differs depending
on the type of treatment offered. For example, changes in cognitive factors may
have been important determinants of changes in pain and disability in study
three, but it may have been that PNEP alone was equally as effective in
modifying these factors. Understanding the nature of this relationship will aid
the refinement of future treatments for CNP.
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