The role of patient held beliefs about injury and recovery in the development of late whiplash syndrome following an acute whiplash injury

by

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Declaration of the inclusion of published work

The systematic literature review contained in Chapter 1 of this thesis has been published:
Esther Williamson, Mark Williams, Simon Gates, Sarah E Lamb (2008) A systematic literature review of psychological factors and the development of late whiplash syndrome. Pain 135(1-2): 20-30

A small amount of information reported in Chapter 5 pertaining to the physiotherapy treatments that participants received as part of the Managing Injuries of the Neck Trial has been previously published in:
Esther Williamson, Mark Williams, Zara Hansen, Stephen Joseph and Sarah E. Lamb et al. (2009) Development and delivery of a physiotherapy intervention for the early management of whiplash injuries: The Managing Injuries of Neck Trial (MINT) Intervention. Physiotherapy 95(1):15-23

Abstract

This thesis has investigated the role of patient held beliefs about injury and recovery in the development of late whiplash syndrome (LWS) following an acute whiplash injury.
Beliefs about injury and recovery have the potential to influence outcome. These beliefs are potentially modifiable through physiotherapy management and gaining greater understanding into how they influence outcome can potentially improve physiotherapy management of acute whiplash injuries.

Mixed methods were used to investigate the role of these beliefs in the development of LWS. Following a systematic literature review, a prospective cohort study was carried out to identify risk factors for LWS as well as Neck Disability Index Scores and participant perceived improvement at follow up. This was complemented by a qualitative study designed to gain greater insight into the patient's experience of recovering from a whiplash injury. Patients' expectations of outcome were found to influence the development of LWS, in particular, their expectations of time to recovery. Patients' expectations of treatment benefit were found to influence outcome to a lesser degree. The patients' belief about their ability to cope with their neck problem (self-efficacy) was shown to influence outcome in the short term but not long term follow up. The use of passive coping strategies may moderate the influence of these types of beliefs. The qualitative study highlighted the importance of realistic expectations, the value of reassurance from health professionals and how the patient's understanding of pain are important in identifying potential barriers to recovery.

This thesis has also presented detailed information about the clinical presentation of individuals who have sustained a whiplash injury and explored patterns of recovery amongst individuals. This will help clinicians to understand the nature of whiplash injuries and how they impact on patients which has the potential to improve patient management.

Abbreviations

FABQ - Fear Avoidance Beliefs Questionnaire

CBA - Cognitive Behavioural Approach

CNS - Central Nervous System

CSOQ - Cervical Spine Outcomes Questionnaire

CSQ - Coping Strategies Questionnaire

ED- Emergency Departments

GHQ - General Health Questionnaire

IES - Impact of Events Scale

IPA - Interpretative Phenomenological Analysis

LBP – Low back pain

LWS – Late whiplash syndrome

MDCWP - Manchester Definition of Chronic Widespread Pain

MINT - Managing Injuries of the Neck Trial

MSPSS - Multidimensional Scale of Perceived Social Support

NDI - Neck Disability Index

NHS – National Health Service

PCS - Pain Catastrophising Scale

PTSD - Post Traumatic Stress Disorder

SF-12 - Short Form Health Survey

ROM - Range of Movement

WAD – Whiplash Associated Disorders

Introduction

This thesis investigated individuals who had experienced an acute whiplash injury. The introduction will provide an overview of whiplash injuries. It will also provide an overview of the rationale for choosing to investigate patient held beliefs about injury and recovery in a whiplash population.

i. Whiplash injuries

A whiplash injury is an acceleration-deceleration injury to the neck which is most commonly sustained during a road traffic accident (1). Whiplash injuries are a common problem and it is estimated that 250,000 whiplash injuries occur each year in United Kingdom (UK) (2). They also occur commonly in other countries with varying incidence (Table 1).

Table 1 Estimated incidence of whiplash injuries in other countries

Country	**Rate**
Australia	106-380 per 100,000 (3, 4)
USA	266-387 per 100,000 (5)
Canada	70 per 100,000 (1)
Netherlands	188 to 325 per 100,000 (6).

Whiplash associated disorders (WAD) describe the signs and symptoms experienced following a whiplash injury and are often graded in research and clinical practice using the WAD classification system developed by the Quebec Task Force (Table 2)(1). The types of symptoms reported following a whiplash injury include not only neck pain but shoulder, arm, thoracic and lumbar pain (7p102). Individuals can report headaches, dizziness and balance problems, sensory and motor disturbances and concentration problems (7p102).

Table 2 Whiplash Associated Disorders (1)

WAD Grade	Definition
0	No neck complaints or signs
I	Complaint of pain, stiffness or tenderness, but no physical signs.
II	Complaint of pain, stiffness or tenderness, and musculo-skeletal signs (decreased range of motion, point tenderness etc).
III	Complaint of pain, stiffness or tenderness and neurological signs (decreased or absent deep tendon reflexes, weakness and sensory deficits). Could also have musculo-skeletal signs.
IV	Fracture or dislocation

Many people recover fully from a whiplash injury but a proportion do not and the reasons for this are not fully understood. The term “late whiplash syndrome” (LWS) is used frequently in the literature (8-10) and describes ongoing problems following a whiplash injury. LWS is defined as the presence of pain, restriction of motion or other symptoms, six months or more after a whiplash injury, sufficient to hinder return to normal activities such as driving, usual occupation and leisure (11). LWS is reported in between 16% (12) and 71% (13) of individuals experiencing a whiplash injury depending on the outcome measure used. LWS represents a significant public health problem (2). Estimated costs to the UK economy were £2.5 billion per annum in 1990 (14) rising to £3.1 billion per annum in 2002 (2). Costs arise from National Health Service (NHS) treatment costs, social security payments, lost productivity due to work absence and damage to property (2).

Health care utilisation immediately following a whiplash injury in the UK is not well documented but individuals will often present at an Emergency Department (ED) initially after a whiplash injury (15, 16). Typical ED management of a whiplash injury consists of advice to use analgesics and basic neck exercises (15). Some departments also use soft collars with instructions that they should be removed regularly to perform neck exercises (15). Patients with more severe symptoms may be referred for treatment such as physiotherapy (15). Physiotherapy is a common treatment for WAD (1). The types of treatment delivered by physiotherapists include joint manipulation and mobilisation, soft tissue mobilisations, exercises, education and advice, Transcutaneous Nerve Stimulation and multimodal packages (i.e. a combination of treatments such as manual therapy, exercises and advice) (17). However, the efficacy of these common treatments has been shown to be less than ideal and there is a lack of good quality research to guide treatment choices (18).

ii. The setting for this thesis

In response to a need to improve the evidence base pertaining to whiplash injuries the National Institute of Health Research commissioned a randomised controlled trial to investigate the clinical and cost-effectiveness of ED advice and subsequent physiotherapy treatment for individuals following an acute whiplash injury. This trial was called the Managing Injuries of the Neck Trial (MINT) (HTA number 02/35/02). It is within the context of MINT that this thesis has been conducted.

I began working on MINT as a Research Physiotherapist in January 2005 and was presented with the opportunity to study for my PhD alongside the main trial. This provided me with the chance to attempt to answer one of many questions that warrant further investigation such as trying to understand the role of patient held beliefs about injury and recovery in the development of LWS.

As a research physiotherapist I worked as part of the MINT team who developed the trial interventions, trained research staff to carry out research clinics, trained clinicians to deliver the trial treatments, monitored the delivery of trial interventions, carried out participant follow up phone calls, assisted with data entry and contributed to publications pertaining to the trial. In addition, I conducted research clinics to assess, consent and randomise participants to take part in Step Two of MINT. I also carried out a qualitative study to provide feedback on the trial treatments alongside the qualitative study for this thesis.

As well as my responsibilities as a research physiotherapist, I also carried out my own research for this thesis. I have independently developed my own research questions, designed the studies to investigate these questions and carried out the necessary analyses.

iii. Rationale for choosing to investigate patient held beliefs

There are many factors that might contribute to the development of LWS. Previous reviews have concluded that collision characteristics are not involved (19). The role of age and gender are unclear (19, 20). It has been reported in several literature reviews that high initial pain intensity is related to poor outcome in whiplash patients (19-21). However, it is well known that pain is multi-factorial and that many other factors have the potential to influence outcome. Psychological variables are implicated in the development of long-term disability in low back pain (LBP)(22) and similar mechanisms may act in LWS.

There were many different psychological factors that warranted investigation. However, from a physiotherapist’s point of view the area of patient held beliefs about injury and recovery and their impact on outcome is of interest. It may be possible to influence these beliefs through physiotherapy treatment and, therefore, improve clinical outcomes. Examples of patient held beliefs that may be addressed through physiotherapy treatment include: fear-avoidance beliefs, expectations about recovery, expectations about treatment, beliefs about ability to cope with their condition and the beliefs about the meaning of pain. The role of patient held beliefs in the ongoing process of chronic pain is well documented. Much less is known about the role of beliefs in the acute situation although they are thought to have a very powerful influence on recovery (23p318).

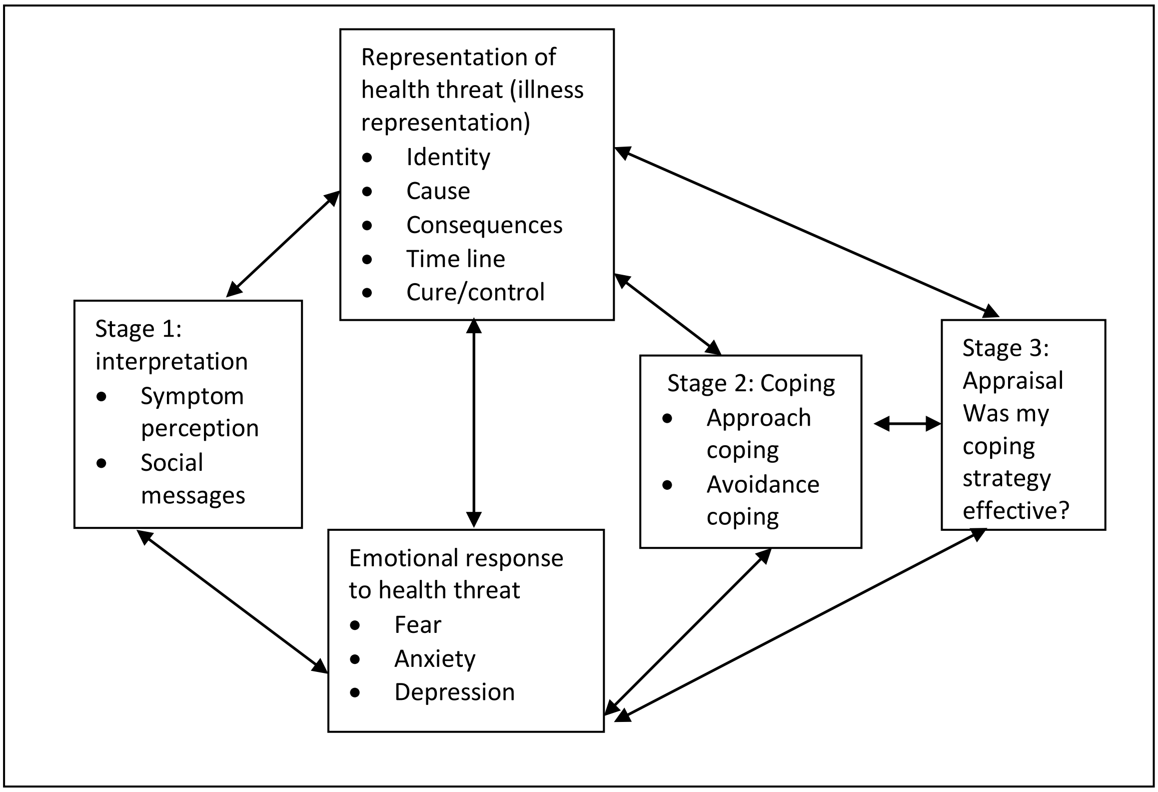
According to the New Oxford Dictionary (24p158) a belief can be defined as:
“something one accepts as true or real; a firmly held opinion or conviction”
A patient will develop beliefs as a result of their experiences over a lifetime and exposure to events, people and situations (25). When considering the role that beliefs may play in the recovery from injury, beliefs may be both helpful and unhelpful. It makes sense that unhelpful beliefs that may hinder recovery need to be addressed (23p321, 26).

In order to explore this concept further it was useful to look beyond the physiotherapy literature to other areas. One model found within the psychological literature that suggests how beliefs have the potential to influence outcome is Leventhal’s Self-regulation Model of Illness (27)(Figure 1). One of the central aspects of this model is that the individual seeks to attach meaning to the symptoms they experience during illness and form an illness representation. The illness representation is based on different types of illness beliefs which are the patient’s own implicit common sense beliefs about their illness. Illness beliefs help to provide a framework for coping with and understanding illness (28p38). The illness beliefs are influenced by internal factors such as the symptoms experienced as well as external factors such as the diagnosis given by the doctor or information from friends or family. Information from these different sources is interpreted and given meaning based on the person’s prior health and illness experiences to form beliefs (28p41, 29). The emotional reaction will also influence illness belief formation.

Leventhal’s model suggests that the resultant illness representation guides the choice of coping strategies used by the individual to deal with their illness. Further modification of the illness representation will occur following appraisal of the result of the coping strategies initiated (i.e. outcome). This model might be applied to patients following a whiplash injury and it provided a theoretic basis as to why beliefs may influence outcome in whiplash injuries.

I hypothesised that gaining insight into beliefs about injury and recovery would provide a greater understanding of the development of LWS. This involved not only identifying the beliefs that were predictive of LWS but also seeking to understand their importance in the context of other known risk factors (such as initial pain intensity), how they interacted with other risk factors and how beliefs were formed.

Figure 1 Leventhal's self-regulatory model of illness behaviour (as published in Ogden (28p41)



iv. Aim

This thesis aimed to investigate the role of patient held beliefs about injury and recovery in the development of late whiplash syndrome following an acute whiplash injury.

Specifically this thesis has:

1. Carried out a systematic literature review to identify the role of psychological factors in the development of LWS.
2. Reported a prospective cohort study to identify factors predictive of LWS, Neck Disability Index scores and participant perceived improvement at follow up including patient held beliefs.
3. Carried out exploratory analysis to see if the belief factors found to be predictive of LWS were moderated by other belief factors.
4. Carried out exploratory analysis to see if the belief factors found to be predictive of LWS were moderated by the treatments delivered as part of MINT.
5. Explored beliefs held by patients regarding their injury, recovery and the treatments received by carrying out a qualitative study.

v. What is the unique contribution of this thesis to the management of whiplash injuries?

This thesis has presented detailed information about the clinical presentation of individuals who have sustained a whiplash injury and explored patterns of recovery amongst individuals. This will help clinicians to understand the nature of whiplash injuries and how they impact on patients which has the potential to improve patient management.

There is an emerging body of literature regarding prognostic factors in whiplash but the area of patient held beliefs has been paid little attention. The identification of patient held beliefs that predict the development of LWS has important implications for patient management. Firstly, it may facilitate the identification of those at risk of developing LWS. Secondly, it could help to guide physiotherapy management by identifying factors that can potentially be modified to improve outcomes.

There is very little qualitative research in the area of whiplash injuries. This thesis sought to gain the participants' perspective of having a whiplash injury and to explore the issue of patient help beliefs within this perspective. By using mixed methods it has been possible to examine the findings of the cohort study in relation to individual participants' accounts and gain greater understanding of these findings. This is a novel approach that has not been seen in the published whiplash literature to date.

1.0 A systematic literature review of psychological factors and the development of late whiplash syndrome following an acute whiplash injury

1.1 Introduction

As a starting point to understanding the role of patient held beliefs in the development of LWS following an acute whiplash injury a systematic literature was carried out to discover what was already known. A systematic literature review was necessary as it allows a more objective appraisal of the evidence compared to a narrative review (30p3). Narrative reviews have been shown to be generally of poor quality and often an unreliable source of information (30p4). A systematic literature review ensures that a systematic approach is used and documented to minimise bias or misinterpretation (30p5).

This systematic literature review focused on psychological factors in general. A review by Scholten-Peeters et al (19) which included literature up to April 2002 reported on the limited research that was available regarding psychological factors. This review included psychological constructs such as acute psychological response to injury, previous psychological problems, stress unrelated to the injury, personality traits and cognitive function. This review did not include any studies that investigated patient held beliefs. The findings of this review were largely inconclusive but there was limited evidence that previous psychological problems and nervousness were predictive of poor outcome (19). Nervousness was measured using the nervousness scale of the Freiburg Personality Inventory, which is thought to reflect a tendency to report psychosomatic symptoms (57).

The literature had expanded with 13 articles reporting 11 cohorts being published since the review by Scholten-Peeters et al (19). The range of psychological factors under investigation had diversified including health related attitudes and behaviours, beliefs about pain, distress, depression, anxiety and ability to cope. In view of new developments in this area an updated review was necessary. This review aimed to provide a comprehensive and up to date review of psychological risk factors for LWS. Specifically it aimed to identify baseline psychological factors measured during the early phase of recovery (within 6 weeks) that were predictive of LWS.

1.2 Methods

1.2.1 Search strategy

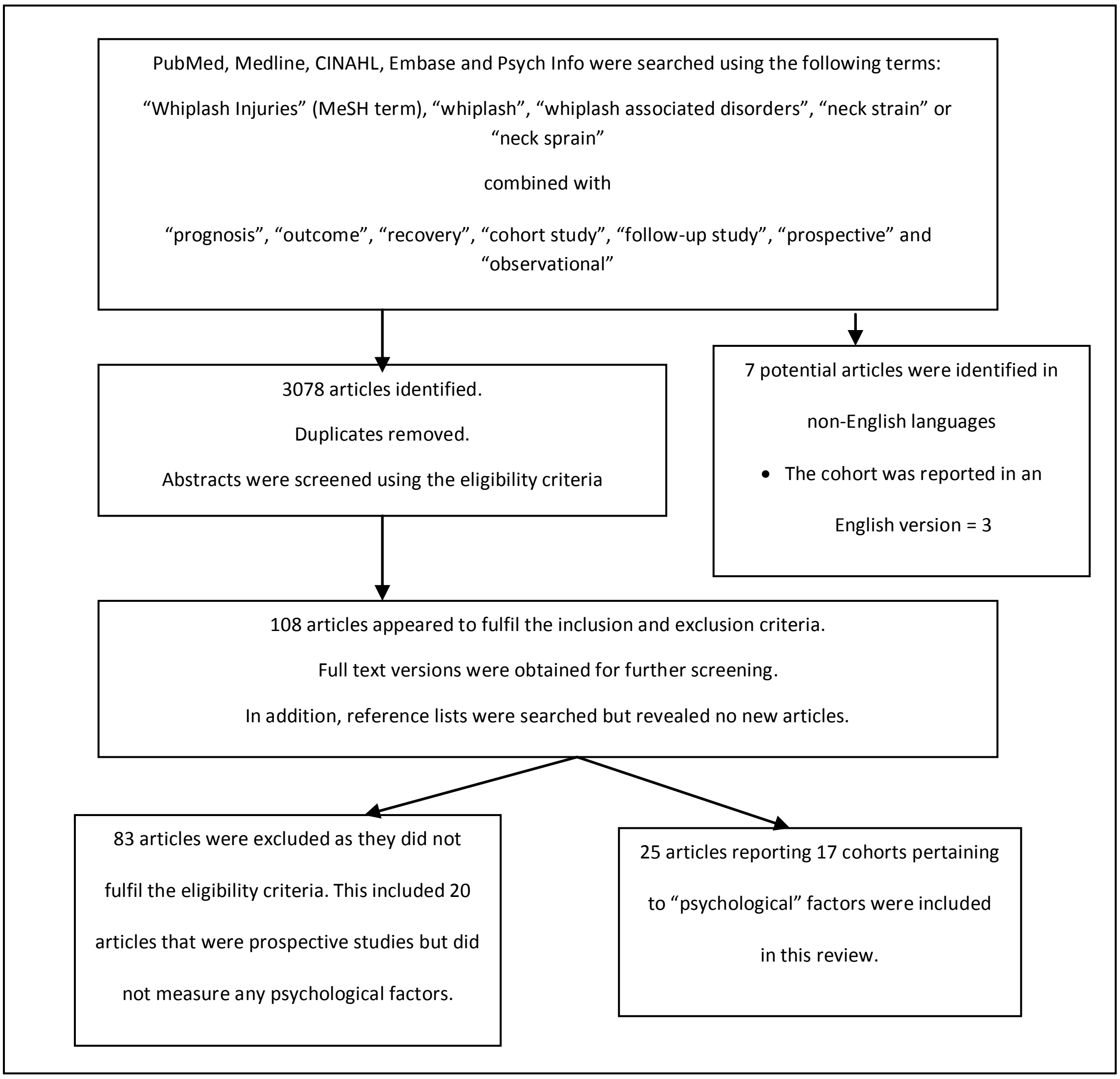
Searches were carried out using an electronic search strategy shown in Figure 2. Searches covered databases from their start to August 2006.

Articles were eligible for this review if they fulfilled the following criteria: prospective cohort or case-control studies investigating prognostic factors and the development of LWS; prognostic factors studied included a measurement of at least one psychological variable at baseline; cohort was assembled within 6 weeks of injury; 6 months minimum follow up; outcome measures used related to the clinical presentation of LWS (e.g. pain or disability due to neck problems 6 months post injury); English language. Studies were excluded if they were pertaining to neck pain other than that arising from a whiplash injury or if the outcome measure used did not relate to the development of LWS e.g. “time to claim closure”. Studies needed to be prospective in nature as this review was concerned with understanding the cause of LWS. To investigate causality possible risk factors needed to be measured before the outcome of interest (31). This will be discussed further in the Chapter 3.

A 6 week time limit was chosen to ensure that data were collected in the acute phase of the whiplash injury.

Factors were considered to be “psychological” if they were related to the mental or emotional state of a person (24). This included measures of constructs such as cognition, anxiety, depression, distress, beliefs and coping. This is a similar approach to that taken by Pincus et al (22) in their review of psychological prognostic factors for low back pain (LBP).

Figure 2 Search strategy



PubMed, Medline, CINAHL, Embase and Psych Info were searched using the following terms:

“Whiplash Injuries” (MeSH term), “whiplash”, “whiplash associated disorders”, “neck strain” or “neck sprain”

combined with

“prognosis”, “outcome”, “recovery”, “cohort study”, “follow-up study”, “prospective” and “observational”

3078 articles identified.

Duplicates removed.

Abstracts were screened using the eligibility criteria

7 potential articles were identified in non-English languages

- The cohort was reported in an English version = 3

108 articles appeared to fulfil the inclusion and exclusion criteria.

Full text versions were obtained for further screening.

In addition, reference lists were searched but revealed no new articles.

83 articles were excluded as they did not fulfil the eligibility criteria. This included 20 articles that were prospective studies but did not measure any psychological factors.

25 articles reporting 17 cohorts pertaining to “psychological” factors were included in this review.

1.2.2 Data extraction and quality assessment

Data extraction and quality assessments were carried out by four reviewers. Each article was assessed and had data extracted by two reviewers independently to reduce bias and as recommended by Egger et al (30p27). Four articles were assessed and data extraction carried by all 4 reviewers to establish consistency in the procedure. Data extraction was carried out using a standardised data extraction form and included the study characteristics (e.g. population, sample size, length of follow up), outcome measures and prognostic factors studied and results of the studies. Following independent data extraction the completed forms were compared and any discrepancies were resolved by discussion between the two reviewers in the first instance. If any discrepancies were unresolved then a third reviewer was consulted. Similarly, the quality assessment of the 25 eligible articles was also carried out by 2 reviewers who assessed the studies independently using a quality assessment tool based on recommendations by Altman (32) and Egger et al (30)(Table 3 (p31)).

The quality assessment was divided into 3 sections: patient sampling, measurements used and analysis. In the analysis section points were awarded if multivariable analysis was used as this is necessary in observational studies to attempt to reduce bias. Many factors could be controlled for but 4 factors were specified as being essential based on existing evidence. These were initial pain severity, age, gender and history of previous neck pain. Initial pain intensity is consistently reported as a strong predictive factor (19, 20). There is conflicting evidence regarding gender and age and their influence on recovery following a whiplash injury (19, 20). However, differences in pain perception are thought to exist between males and females (33) so could potentially influence recovery. Biomechanical changes associated with ageing may also affect capacity for recovery (34). A history of previous neck pain may also influence pain perception due to changes that occur in the nervous system in the presence of pain (35) resulting in greater pain intensity reported by this patient subgroup leading to poorer outcomes.

Any discrepancies in quality assessment were resolved by discussion and any remaining disagreements were referred to a third party (another reviewer) for adjudication. An overall quality score was then assigned to each article. Rather than using the total score as a cut off for deciding quality ratings, we used the scores of each section. Each section was of equal importance and this needed to be reflected in the quality rating. This was to prevent articles that scored very highly in one section but very poorly in others gaining a rating that may not reflect the overall methodological quality. Each article was graded as a high, adequate or low quality study according to the following definitions:

High quality = scored 75% or above for all 3 sections
Adequate quality = scored at least 50% for all 3 sections
Low quality = scored less than 50% for any one section

Table 3 Quality assessment tool

Section one: sampling of patients

1. Inclusion criteria are defined
2. Exclusion criteria are defined
3. Source population is defined
4. Adequate description of diagnostic criteria for classifying patients with a whiplash injury
5. Clinical and demographic characteristics are fully described
6. The sample is representative of the majority of patients with a whiplash injury
7. The sample is assembled at a common point in the course of their recovery (within a 2 week period)
8. The sample is complete (e.g. the majority of patients presenting with a whiplash injury were approached to take part)
9. Any treatment received is fully described (including no treatment)

Section two: measurements used

10. Outcome measures with established test-retest reliability in a pain population have been used
11. Those assessing outcome were blinded to baseline data
12. Prognostic factors were fully defined, including details of method of measurements
13. Measurements used for the prognostic factors are standardized or validated

Section three: analysis

14. Was the sample size adequate for the number of prognostic factors included in the analysis (minimum of 10 per factor)?
15. Loss to follow up is < 20%
16. Was multivariable analysis carried out?
17. Statistical adjustment for important prognostic factors including age, sex, previous neck pain and initial pain severity

Scoring: 2= criteria met; 1= criteria partially met; 0=criteria not met or unclear

1.2.3 Evidence synthesis

The results were tabulated to allow the comparison of results and to assess overall levels of evidence for each prognostic factor. Meta-analysis was not carried out. Meta-analysis is not advisable in cohort studies where there is a danger of producing precise but biased estimates of associations due to the variability in the prognostic factors and outcome measures used (36). A large number of psychological measures were used in the studies. Findings were grouped together into the psychological constructs represented by the different measures. This was done based on the description of the measure and the psychological construct that it aimed to measure. For example personality traits were measured using the Temperament and Character Inventory, Eysenck Personality Inventory-1, Frieburg Personality Inventory and the Millon Clinical Multiaxial Inventory. Some of the measures used measured multiple psychological constructs so could not easily be placed in one psychological construct. If these measures contained subscales measuring distinct psychogological factor then results were extracted for each subscale. This was not always possible depending on the data presented. For example, the Millon Behavioural Health Inventory was used by Kasch et al (37). This is described as providing information regarding a patient's style of relating to health professionals, problematic psychosocial attitudes and stressors, psychosomatic factors and indicators of a poor response to either illness or treatment interventions (38). Outcome measures used also varied greatly between studies.

The overall levels of evidence for each risk factor were defined as strong, moderate, limited and inconclusive according to the definitions below. These definitions do not reflect the strength of association found between the prognostic factor and the development of LWS but identified how often an association was observed based on a statistically significant association being reported. This is a similar approach used by other systematic reviews

(19). This approach could potentially be biased when the results from one cohort are published in more than one article but this was taken into consideration in the definitions below. It was important that all the articles pertaining to each cohort were included as different prognostic factors were sometimes investigated in different articles.

Strong evidence: Consistent findings in at least 2 high quality articles from different cohorts.
Moderate evidence: Consistent findings in at least 2 adequate quality articles from different cohorts.
Limited evidence: Findings in one adequate quality article or at least 2 low quality articles from different cohorts.
Inconclusive evidence: Inconsistent findings or insufficient research (e.g. evidence from one low quality cohort only).

1.3 Results

1.3.1 Study characteristics

This review included 25 articles reporting data from 17 cohorts. The studies included in the review are presented in Table 4 (p34). This summarises the prognostic factors investigated. The majority of studies recruited patients from Emergency Department settings (n= 11 cohorts, 12 articles). There was one cohort (7 articles) that recruited patients from a General Practice setting with two recruiting patients from both an Emergency Department and General Practice (3 articles). The remaining cohorts were based on subjects from orthopaedic departments (2 cohorts, 2 articles) and insurance company records (1 cohort, 1 article). All but two of the articles reviewed were prospective cohort studies with the remaining two being case control studies. Sample sizes ranged from 29 in a case control study (39) to 765 in a prospective cohort study (40). Cohorts were most commonly followed up for 1 year (7 cohorts) or 6 months (4 cohorts) with two cohorts providing up to 3 years follow up (41, 42). Loss to follow up ranged from 0% (43) to 53.9% (42). Mean loss to follow up was approximately 14% with 10 cohorts having less than 10% loss to follow up.

1.3.2 Methodological quality

58% of articles (14 out of 25) were rated as low overall quality and the remainder, as adequate overall quality. The majority of articles scored at least an adequate quality rating for patient sampling (>50% for this section). The biggest shortcoming in patient sampling was that articles failed to report whether treatment was provided and if so, what this was during the course of the follow up (17 out of 25 articles). Approximately a third of articles received low quality scores for measurements used (<50% for this section) with the most problematic area being a lack of blinding of outcome assessors to the patient's baseline data in 20 of the articles. 14 articles also failed to use outcome measures with established test-retest reliability. Articles received the lowest scores in the analysis section with only 5 articles being rated as high quality for their analysis (score >75% in this section). 16 articles had insufficient sample size, 11 articles did not carry out any multivariable analysis and 15 articles did not adjust for any of the specified factors of age, gender, neck pain intensity and previous neck pain. The quality scores are available in Table 5 (p37).

Table 4 Included studies grouped in cohorts

Cohort number	Author	Type of study	Population studied	Number of subjects*	Length of follow up	Psychological factors studied	Other prognostic factors studied
1	Nederhand et al (44)	Prospective Cohort	Emergency Department	82/90	6 months	Fear avoidance (TSK), catastrophising (PCL-E)	Gender, age, collision direction, functional status, EMG, disability (NDI), pain intensity (VAS)
2	Olsson et al (45)	Prospective Cohort	Emergency Department	123/130	1 year	Psychological response to pain (MPI)	Pain intensity, age, sex, condition severity (WAD Grade)
3	Kyhlback et al (46)	Prospective Cohort	Orthopaedic Department	83/98	1 year	Self-efficacy (SES)	Disability (PDI), pain intensity (VAS), age, WAD grade, gender
4	Hendriks et al (47)	Prospective Cohort	General Practice and Emergency Department	119/125	1 year	Psychological distress (SCL-90)	Age, gender, education, marital status, crash related factors, pre-existing health factors, pain medication, neck range of movement (ROM), neck pain intensity, number of complaints, ability to perform ADL, radicular complaints, work activities, absent from work, diagnostic imaging, use of collar
5	Pettersson et al (48)	Case Control	Orthopaedic Department	39/40	2 years	Personality traits (TCI)	Age
6	Soderlund et al (49)	Prospective Cohort	Emergency Department	53/59	6 months	Coping (CSQ), Self-efficacy (SES)	Disability (PDI)
7	Miettinen et al (42)	Prospective Cohort	Insurance company records	144/312	3 years	Psychological distress (GHQ-12), Depression (BDI)	Symptoms, Disability (NDI), Ability to work, previous symptoms, crash characteristics
8	Sterling et al (50) Sterling et al (41)	Prospective Cohort	Emergency Department, General Practice, advertisement	76/80 65/80	6 months 2-3 years	Post traumatic stress (IES), Psychological distress (GHQ-28), Fear avoidance (TSK)	Neck ROM, proprioception, EMG, pressure pain thresholds, thermal pain thresholds, brachial plexus provocation test, sympathetic function, disability (NDI), pain Intensity (VAS), compensation
9	Borchgrevink (51)	Prospective cohort	Emergency Department	88/99	6 months	Personality traits (MCMI-1)	
10	Gargan et al (43)	Prospective cohort	Emergency Department	50/50	2 years	Psychological distress (GHQ-12)	Neck ROM, symptom severity
11	Mayou and Bryant (52)	Prospective cohort	Emergency Department	57/63	1 year	Depression (BDI), anxiety (SAS), personality traits (EPI), previous psychological problems	Gender, age, initial physical symptoms, driver/passenger status, compensation

12	Mayou and Bryant (53)	Prospective cohort	Emergency Department	187/278	1 year	Previous psychological problems, perceived threat, blame and anger	Gender, compensation
13	Radanov et al (54) Radanov et al (55) Radanov et al (56) Radanov et al (57) Radanov et al (58) Di Stefano and Radanov (59) Radanov et al (60)	Prospective cohort Prospective cohort Prospective cohort Prospective cohort Prospective cohort Case control Prospective cohort	General Practice	78/92 98/113 117/137 117/137 117/137 42/42 117/137	6 months 1 year 6 months 6 months 1 year 2 years 2 years	Psychosocial stress not related to the injury, well being (WBS), personality traits (FPI), cognitive function (CFQ, DST, CBTT, NCT, PASAT, TMT, CVLT)	Gender, age, educational attainment, vocational related variables, crash related variables, initial pain intensity (VAS), initial subjective complaints, neurological examination , timing of onset of symptoms, neck ROM, radiological examination, history of pre-traumatic headache, previous head trauma, previous whiplash injury, type and frequency of pre-traumatic headache, sleep disturbance
14	Karlsborg et al (13) Smed (39)	Prospective cohort Prospective cohort	Emergency Department	34/39 29/29	7 months	Psychological distress (SCL-90), cognitive function (CFS, WCST), psychosocial stress unrelated to the accident	Gender, age, WAD Grade, number of symptoms at baseline, MRI results, motor provoked potentials
15	Kasch et al (61)	Prospective cohort	Emergency Department	132/141	1 year	Health related attitudes and behaviours (MBHI)	Gender, age, BMI, pain severity, neurological symptoms, number of symptoms, neck ROM, work load (cervical muscles), speed difference between vehicles, compensation
16	Kivioja et al (62)	Prospective cohort	Emergency Department	91/96	1 year	Coping (CSQ)	Initial pain severity, previous neck and shoulder pain, age, sex
17	Atherton et al (40)	Prospective cohort	Emergency Department	480/765	1 year	Psychosocial work factors (WS), psychological distress (GHQ-12), somatisation (MSPQ)	General health, number of GP visits in previous 12 months, previous neck pain, present of widespread chronic pain, collision factors, initial injury severity (VAS), initial disability (NDI), number of symptoms, WAD grade, age, gender

* Number at final follow up/number recruited

TSK =Tampa Scale of Kinesiophobia
NDI = Neck Disability Index
MPI = West Haven-Yale Multidimensional Pain Inventory
SES = Self-efficacy Scale
CSQ = Coping Strategies Questionnaire
CBTT = Corsi Block Tapping Test
WBS = Well Being Scale
GHQ-12 or 28 = General Health Questionnaire-12 or 28
IES = Impact of Events Scale
EMG = Electomyography
EPI = Eysenck Personality Inventory

PCL-E = Pain Cognition List - Experimental
VAS = Visual Analogue S
PDI = Pain Disability Index
SCL-90 = Symptoms Checklist-90
PASAT = Paced Auditory Serial Addition Task
CFQ = Cognitive Failures Questionnaire
TMT = Trail Making Test
BDI = Beck Depression Inventory
MCMI-1 = Millon Clinical Multiaxial Inventory
SAS = Spielberger Anxiety State
FPI – Frieburg Personality Inventory

WS = Karasek's demand-support-control model of workplace strain – 8 items
NCT = Number Connection Test
TCI = Temperament and Character Inventory
DST = Digital Span Test
Californian Verbal Learning Test
CFS = Cognitive Function Scanner
WCST = Winconsin Card Sorting Test
MBHI = Millon Behavioural Health Inventory
MSPQ = Modified Somatic Perceptions Questionnaire
CVLT = Californian Verbal Learning Test

Table 5 Quality scores

Cohort no.	Article	Section 1	1	2	3	4	5	6	7	8	9	%	Section 2	10	11	12	13	%	Section 3	14	15	16	17	%	**Quality rating**
1	Nederhand et al (44)		2	2	2	2	1	0	2	0	0	61		2	?	2	2	75		2	2	0	0	50	**Adequate**
2	Olsson et al (45)		2	2	2	2	2	1	1	2	2	89		1	?	2	2	63		2	2	2	0	75	**Adequate**
3	Kyhlback et al (46)		2	2	1	2	1	0	1	0	0	50		2	2	1	2	88		2	2	2	0	75	**Adequate**
4	Hendriks et al (47)		2	2	1	2	2	0	2	0	2	72		2	2	1	1	75		0	2	2	0	50	**Adequate**
5	Pettersson et al (48)		2	2	2	2	2	0	2	2	0	78		1	2	2	1	75.0		?	2	0	0	25	**Low**
6	Soderlund et al (49)		2	2	2	2	2	1	0	0	2	72		2	?	2	2	75.0		?	2	0	0	25	**Low**
7	Miettinen et al (42)		1	1	2	2	1	0	?	0	0	39		0	2	2	1	63		?	0	2	0	25	**Low**
8	Sterling et al (50)		2	2	2	2	2	1	?	?	2	72		2	?	2	2	75		0	2	2	1	63	**Adequate**
	Sterling et al (41)		2	2	2	2	2	1	?	?	0	61		2	?	2	2	75		0	2	2	1	63	**Adequate**
9	Borchgrevink (51)		2	2	2	1	1	1	2	0	0	61		0	0	2	2	50		2	2	0	0	50	**Adequate**
10	Gargan et al (43)		2	0	1	0	1	1	2	2	1	56		0	2	1	1	50		0	2	0	0	25	**Low**
11	Mayou and Bryant (52)		1	0	2	1	1	1	0	2	1	50		1	?	1	1	38		2	2	0	1	63	**Low**
12	Mayou and Bryant (53)		1	1	1	1	1	1	?	2	0	44		1	?	1	1	38		2	0	2	1	63	**Low**
13	Radanov et al (54)		1	1	1	2	1	1	2	0	0	50		0	?	2	1	38		0	2	2	1	63	**low**
	Radanov et al (55)		2	2	1	2	2	1	2	0	0	67		0	0	2	2	50		0	2	0	1	38	**Low**
	Radanov et al (56)		2	1	1	2	2	1	2	0	0	61		2	0	2	2	75		0	2	2	?	50	**Adequate**
	Radanov et al (57)		2	1	1	2	1	?	2	0	0	50		0	0	2	2	50		0	2	0	0	25	**Low**
	Radanov et al (58)		2	2	1	2	2	1	2	0	0	67		0	0	2	1	38		0	2	2	?	50	**Low**
	Di Stefano and Radanov (59)		2	2	1	2	2	0	2	0	0	61		0	0	2	2	50		0	2	0	0	25	**Low**
	Radanov et al (60)		2	2	1	2	2	1	2	0	0	67		0	0	2	1	38		0	2	0	0	25	**Low**
14	Karlsborg et al (13)		2	2	2	2	2	0	2	0	1	72		0	?	1	1	25		0	2	2	1	62	**Low**
	Smed (39)		2	2	2	2	2	0	2	0	0	67		0	?	2	0	25		0	?	0	0	0	**Low**
15	Kasch et al (61)		2	2	2	2	1	0	1	2	2	78		1	0	2	1	50		2	2	2	1	88	**Adequate**
16	Kivioja et al (62)		2	2	2	2	2	1	2	1	0	78		0	0	2	2	50		2	2	2	2	100	**Adequate**
17	Atherton et al (40)		2	2	2	2	1	1	2	2	0	78		0	0	2	2	50		2	0	2	2	75	**Adequate**

2= criteria met, 1= criteria partially met, 0=criteria not met or unclear (?)

1.3.3 Findings

The results were separated into two categories based on the type of outcome measure used; those based on symptom report (e.g. presence of pain, pain intensity and number of symptoms) and those based on disability (e.g. Neck Disability Index). This delineation was made as it has been shown that pain ratings and disability do not always correlate (63), hence factors associated with pain or other reported symptoms may not be the same as those associated with disability. The statistically significant results have been summarised in Table 6 (p40) and Table 7 (p45). Results for factors that were not statistically significant are not reported in these tables. Borchgrevink et al (51) and Pettersson et al (48) had no significant findings and were excluded from these tables.

Twenty-two different psychological factors were investigated and the summary of results for each factor is included in Table 8 (p48). The majority of findings were inconclusive. No psychological factors were identified for which there was strong evidence to support a positive or negative association with the development of LWS. Limited evidence was found to support an association with the development of LWS for lower levels of self-efficacy (46, 49). Self-efficacy is a concept developed by Bandura (64). It was defined by the authors of these studies as a personal belief of how successfully one can cope with difficult situations (65). Soderlund et al (49) and Kyhlback et al (46) used the Self-efficacy Scale (66) which looks specifically at a patient’s confidence to perform activities of daily life despite pain. Limited evidence was also found to support an association between higher levels of post-traumatic stress and LWS (41, 50). Post-traumatic stress refers to psychological distress directly related to a traumatic event (i.e. the whiplash injury in this instance) (67, 68) rather than general psychological distress which was also included in the review.

No association was seen between general psychological distress and the development of LWS based on the findings of 6 cohorts (moderate evidence). General psychological distress is a term used to encompass distress, anxiety, depressive symptoms and depressive mood (22, 69, 70). The measures used screen for the presence of these types of symptoms but do not provide a definitive diagnosis. Some studies used specific measures of depression or anxiety and these were reported separately. No association was also reported between personality traits and the development of LWS based on the findings of 6 cohorts (moderate evidence).

No association was found between well being, social support, life control, psychosocial work factors or health related attitudes and behaviours based on the results of one cohort each (limited evidence). Findings regarding the following constructs were considered inconclusive: psychosocial stress not associated with the accident, previous psychological problems, blame and anger about the accident, perceived threat at the time of the accident, cognitive function, anxiety, depression, somatisation (psychological symptoms manifest themselves as physical symptoms (71)) , irritability, familiarity with whiplash symptoms, fear avoidance beliefs (avoidance of activity due to a fear of causing pain or re-injury (72)), catastrophising (an exaggerated negative response to pain (73, 74)) and coping strategies.

Table 6 Results based on symptomatic report

Cohort number	Study	Outcome measurement used	Time of follow up	Factors associated with poor outcome - univariate results	Test used	Factors associated with poor outcome - multivariable results	Final model included:
2	Olsson et al (45)	Symptomatic versus asymptomatic. Symptomatic = report of residual pain related to the accident.	1 Year		Cluster analysis followed by regression	Higher scores on the level of percieved interference scale of the MPI (b = -2.451 exp (b) = 0.086.	Age, Sex, WAD grade and MPI variables.
3	Kyhlback et al (46)	Pain intensity (VAS)	1 Year		General Linear Model	Male gender (ß=0.43 p<0.01). Lower self-efficacy scores (ß=-0.32 p<0.01) Higher WAD grade (ß=-0.23 p<0.05)	
6	Soderlund et al (49)	Symptomatic versus asymptomatic. Symptomatic = self reported pain > 1/2 standard deviation below the group mean VAS score (=0.97).	6 months	Higher initial scores on the catrastrophising subscale (t=2.17, p<0.05) Lower initial scores on the contol over pain subscale (t=3.03, p<0.05) of the Coping Strategy Questionnaire. Lower initial self-efficacy score (t=2.09, p<0.05). Higher initial disability scores (t=3.06, p<0.05). Asymptomatic patients also exhibited more active coping strategies than those who were symptomatic (Wilk's lambda = 0.85, p<0.05).	Independent sample t test.		
10	Gargan et al (43)	Recovered versus non-recovered. Recovered = symptoms classified as intrusive or disabling.	2 years	Reduced cervical ROM at 3/12 post injury is associated with non recovery (OR = 13.29 (CI 2.36-85.83). Abnormal GHQ score at 3/12 post injury is associated with non recovery (OR = 7.27 (CI 1.01-64.58).	Student t tests X^2 test with Yates's correlation		
11	Mayou and Bryant (52)	Recovered versus non-recovered. Non-recovered = presence of Physical symptoms.	1 year		Logistic regression	A report of neck pain at the time (p<0.01). Women passengers were at greater risk of non-recovery than a driver of either sex (p<0.01)	Age, gender, driver-passenger status, neuroticism, previous psychological problems, memories of the accident, mood score and neck symptoms immediately following the accident.

12	Mayou and Bryant (53)	Recovered versus non-recovered. Non- recovered = report of moderate or severe pain.	1 year		Logistic regression	Unadjusted results: Not feeling to blame for the accident (rate ratio = 3.7) or if the patient's initial emotional response to the accident was anger (rate ratio = 2.14). Adjusted results: patients claiming compensation at 3/12 post injury (rate ratio = 4.81) or had high anger cognition at 3/12 post injury (rate ratio = 2.68).	Unclear	
13	Radanov et al (54)	Recovered versus non-recovered. Non-recovered = presence of symptoms	6 months		Stepwise regression	High initial neck pain intensity (p=0.0019), older age (p=0.0036), injury related subjective cognitive impairment on Cognitive Function Questionnaire (p=0.0009).	Age, injury mechanism, lifetime history of psychological or behavioural problems, psychosocial stress (current and lifetime), personality dimensions, Well being, cognitive function, initial neck pain intensity, initial headache intensity, neurotic symptoms in childhood.	
13	Radanov et al (55)	Recovered versus non-recovered. Non-recovered = presence of symptoms	1 year	Higher levels of baseline neck pain intensity ($p<0.01$, U=937.5) Higher levels of baseline headache intensity ($p<0.06$, U=807.5). Restricted neck ROM at baseline (p=0.007, X^2=7.05). Earlier report of neck pain post injury: Mean time = 7.0 hours +/-15.1(SD) in non-recovered versus (Mean time=11.0 hours +/-16.9 (SD) in recovered (p=0.038).	Mann Whitney U test X^2 test			
13	Radanov et al (56)	Presence of headache versus no headache.	6 months		X^2 test, Multivariable analysis.	A history of pre-traumatic headache ($p<0.001$)	Presence of neck pain at 6/12 and neck pain intensity at 6/12. Age, gender, mechanism of injury, timing of initial symptoms, personality traits.	
13	Radanov et al (57)	Non-recovered versus recovered. Non-recovered = presence of symptoms	6 months	Older age ($p<0.05$). Higher baseline scores on the Cognitive Failures Test (indicating cognitive impairment) ($p<0.05$)	Mann Whitley U test			

13	Radanov et al (58)	Non-recovered versus recovered. Non-recovered = presence of symptoms.	6 months		Stepwise regression	Initial neck pain intensity (t=4.595, p<0.001), sleep disturbances (t=4.381, p<0.0001), age (t=4.222, p =0.0001), previous history of head trauma (t=3.287, p=0.0014), forgetfulness (t=3.129, p=0.00023), history of pre-traumatic headache (t=3.037, p=0.0003), symptoms of radicular irritation (t=2.422, p=0.0172), score on neuroticism scale on Freiburg personality inventory (t=-2.334, p =0.0215), complained of poor concentration at baseline (t=-2.568, p=0.00117).	The following factors were entered into the initial model but the final model is not reported: Age, gender, injury mechanism, a history or head injury or whiplash, the type and frequency of pre-traumatic headaches and all findings from the baseline assessment (neck pain, headache, fatigue, shoulder pain, anxiety, sleep disturbances, back pain, sensitivity to noise, poor concentration, blurred vision, irritability, sensitivity to light, dizziness, forgetfulness, difficulty swallowing).
			1 year		Stepwise regression	Age (t=3.824, p=0.0002, previous history of head trauma (t=3.333, p=0.0012), sleep disturbances (t=3.097, p=0.0025), intensity of initial neck pain (t=3.068, p=0.0028), pre-traumatic headache (t=2.951,p=0.0039), score on nervousness scale of Freiburg personality inventory (t=2.277, p=0.0249) and score on neuroticism scale on Freiburg personality inventory (t=-3.249, p=0.0016).	As above.

	Radanov et al (60)	Non-recovered versus recovered. Non-recovered = presence of symptoms	2 years	Older age (p<0.03) Head rotated or inclined (p<0.008) History or pre-traumatic headache(migraine) (p<0.0001). Initial neck pain intensity (p<0.008) Initial headache intensity (p<0.004) Anxiety p<0.023) Sleep disturbance (p<0.0001) Blurred vision (p<0.008) Forgetfulness (p<0.006) Symptoms of radicular deficit (p<0.043) Symptoms of cranial nerve or brainstem disturbance (p=0.004) Multiple symptom score (p<0.026) Radiological findings - sign of degeneration (osteoarthrosis) (p<0.017) Score on wellbeing scale (p<0.033) Cognitive variables: number connection test (p<0.0001), Trail making part A (p<0.026), Trail making part B (p<0.012), PASAT (p<0.023)	X^2 test. Mann-Whitney U test.		
13	Di Stefano and Radanov (59)	Non-recovered versus recovered. Non-recovered = presence of symptoms	2 years	Higher baseline neck pain intensity (U= 93.0 p=0.001) and headache intensity (U= 126.0, p=0.01). Worse scores on the Number Connection Test at baseline than asymptomatic subjects (p=0.003).	Mann Whitney U test, Wilcoxon signed ranks test with Bonferroni correction		
14	Karlsborg et al (13)	Number of symptoms.	7 months		Logistic regression	The presence of stress unrelated to the whiplash injury (p=0.0078)	unadjusted
14	Smed (39)	Number of symptoms.	7 months	The report of stress at 1/12 post injury (p=0.024). The presence of stressful life events during the early recovery phase (P=0.0037)	Mann Whitney test Wilcoxon-Pratt one sample rank test.		

16	Kivioja et al (62)	Recovered versus non-recovered. Recovered = no neck pain now.	1 year	Significantly more females (22/49) reported neck pain at follow up than males (9/42) (p,0.05). Lower initial pain intensity was associated with recovery (P<0.05).	Mann-Whitney U test, X^2 test, Logistic regression	Report of neck pain or shoulder pain in 4/52 prior to RTA (Exp (B) = 4.5 CI (1.1-8.76), p=0.035)	Gender, age, neck and shoulder pain before accident, initial pain intensity, catastrophising.
17	Atherton et al (40)	Report of persistent neck pain. Defined as neck pain at all follow up time points (1, 3 and 12 months post injury).	1 year		Multiple logistic regression	Factors associated with persistent neck pain: Pre-collision widespread body pain (one month) OR 1.9 (CI 1.1 to 3.2), Vehicle other than a car OR 1.8 (CI 1.04-3.2), Number of other symptoms reported = 6-10 OR 2.0 (1.2-3.3), initial NDI ≥ 22 OR 1.9 (1.2-2.9).	Gender, age, GHQ, presence of widespread body pain, vehicle type, initial NDI, number of symptoms.

Table 7 Results based on Disability or Functional Outcome Measures

Cohort number	Study	Outcome measurement used	Time of follow up	Factors associated with poor outcome - univariate results	Test used	Factors associated with poor outcome - multivariable results	Final model included:
1	Nederhand et al (44)	Recovered versus non-recovered based on Neck Disability Index. Scores >15 = non-recovered.	6 months	Non-recovered had higher mean BMI (p=0.015), higher initial neck pain intensity (p=0.000), higher TSK scores (p=0.000), higher scores on catastrophising subscale of PCL-E (p= 0.000), lower isometric muscle activity (p=0.004) and higher initial NDI (p=0.000). Initial NDI>15 is predictive of poor outcome with 54.3% probability. If this is combined with an initial TSK score >40 this increased to 83.3% probability.	Mann-Whitney U, Student t-test, chi-square test. ROC curves.		
3	Kyhlback et al (46)	Pain Disability Index	1 Year	Initial high pain intensity (r= 0.38, P<0.01) Low ratings of self-efficacy (r= -0.48, p<0.001).	General Linear Model	Patients with initial high self-efficacy had lower disability at follow-up (β= -0.56, P<0.001)	Age, Sex, WAD Grade, WAD grade/sex.
4	Hendriks et al (47)	Functionally recovered versus non-recovered. Functionally recovered = VAS <30mm for neck pain OR VAS >78mm for activities AND no pain medication use during follow-up.	1 Year		Multiple logistic regression	Female gender (OR 4.596 [1.507-14.015]), low level of education (OR 3.511 [1.054-11.696]), high initial neck pain intensity (OR 1.020 [1.002-1.038]), higher levels of somatisation (OR 1.110 [1.030-1.195]). Less initial work limitation reduced the risk of poor outcome (OR 0.986 [0.975-0.998]).	Seen by PT or GP.
7	Miettinen et al (42)	Change in health status due to whiplash injury. Self report. Subjects rated the effect of whiplash injury on their health as no change, slightly worse or significantly worse. Slightly worse or significantly worse = a change in health status.	3 years		Binomal linear regression (logistic regression)	NDI score (>20) (p<0.05, OR 11.2).	Age, gender, marital status, condition of health before the accident, symptoms after the accident, scores on Beck's depression inventory, General Health Questionnaire, Neck Disability Index, Work Ability Index.

8	Sterling et al (50)	Neck Disability Index	6 months		Multiple logistic regression	Factors predicting mod/severe disability (NDI>30) High Initial NDI (B=0.06, p= 0.028, OR=1.06 CI 1.007-1.12) Older age (B=0.13, p=0.01, OR=1.13 CI 1.03-1.23) Reduced cold pain threshold (B=0.26, p=0.01, OR=1.29 CI 1.05-1.58) High Impact of Events Scale scores (stress reaction) (B=0.11, p=0.005, OR 1.11 CI 1.03-1.2). Was able to correctly classify 86.7% of patients as to whether they had severe/moderate symptoms or not using these variables. Factors predictive of mild disability (NDI score 10-18): Initial NDI score (OR 1.15 [1.03-1.28]), GHQ-28 total (OR 1.15 [1.04-1.28]) and Cervical Extension ROM (OR 1.1 [1.03-1.25]).	Age, gender, initial NDI score, physical measures of motor function, physical measures of sensory function, sympathetic nervous system function, GHQ-28, TSK, Impact of events scale.
8	Sterling et al (41)	Neck Disability Index	2-3 years		Multiple logistic regression	Factors predicting NDI Score: Initial NDI (p=0.001) Age (p=0.008) Cold pain thresholds (p=0.026) Impact of Events Scale scores (p=0.018) Factors predicting moderate/severe disability (NDI>30): High initial NDI OR= 1.05 (CI 1-0-1.1) Older age OR=1.1 (CI 1.0-1.13) Reduced cold pain threshold OR=1.1 (1.0-1.13). High Impact of Events Scale Score OR=1.03 (CI 1.03-1.20)	Left cervical rotation, sympathetic nervous system function, compensation status, initial NDI, age, cold pain thresholds, Impact of Events Scale.
11	Mayou and Bryant (52)	Poor social outcome. A global social outcome was determined by an interviewer to estimate changes to work, leisure and other social changes attributable to the injury. Poor social outcome not clearly defined.	1 year		Logistic regression	Patients with a history of previous psychological problems were 5 times more likely to have a poor social outcome (p<0.05)	Age, gender, driver-passenger status, neuroticism, previous psychological problems, memories of the accident, mood score and neck symptoms immediately following the accident.

15	Kasch et al (61)	Disability. Patients completed a 6 point scale to rate work capacity and handicap. Patients were considered handicapped (or non-recovered) if they selected items 3, 4, 5 or 6.	1 year		Cox regression analysis	Reduced total cervical ROM in the first week is associated with increased disability (B=2.53 CI 1.26-5.11, p =0.01). ROM was considered to be decreased if it was 2 standard deviation below the total cervical ROM of the control group.	Cervical muscle workload, pain (VAS), number of symptoms, gender, speed differences >26km/hr, age>31, BMI>30, lawsuit during first month post injury.

Table 8 Overall strength of evidence for psychological prognostic factors in whiplash

Psychological factor	Articles supporting an association with late whiplash syndrome	Study Quality	Articles failing to show an association with the development of late whiplash syndrome	Study Quality	Overall level of evidence
Personality traits	Radanov et al (58) (S)	Low	Borchgrevink (51) (S)	Adequate	No association found based on moderate evidence.
			Radanov et al (54) (S)	Low	
			Radanov et al (55) (S)	Low	
			Radanov et al (56) (S)	Adequate	
			Radanov et al (57) (S)	Low	
			Radanov et al (60) (S)	Low	
			Pettersson et al (48) (D)	Low	
			Mayou and Bryant (52) (S)	Low	
General psychological distress	Sterling et al (50) (D)	Adequate	Hendriks et al (47) (D)	Adequate	No association found based on moderate evidence.
	Gargan et al (43) (S)	Low	Karlsborg et al (13) (S)	Low	
			Smed (39) (S)	Low	
			Miettinen et al (42)(D)	Low	
			Olsson et al (45) (S)	Adequate	
			Sterling et al (41) (D)	Adequate	
			Atherton et al (40) (S)	Adequate	
Self-efficacy	Kyhlback et al (46) (S & D)	Adequate			Limited evidence for an association with the development of LWS
	Soderlund et al (49) (S)	Low			
Post traumatic stress	Sterling et al (50) (D)	Adequate			Limited evidence for an association with the development of LWS.
	Sterling et al (41) (D)	Adequate			
Psychosocial work factors			Atherton et al (40) (S)	Adequate	No association found based on limited evidence
Wellbeing	Radanov et al (60) (S)	Low	Radanov et al (54) (S)	Low	No association found based on limited evidence.
			Radanov et al (55) (S)	Low	
			Radanov et al (56) (S)	Adequate	

			Radanov et al (57) (S)	Low	
			Di Stefano and Radanov (59) (S)	Low	
Life control			Olsson et al (45) (S)	Adequate	No association found based on limited evidence.
Social support			Olsson et al (45) (S)	Adequate	No association found based on limited evidence.
Health related attitudes and behaviours			Kasch et al (37) (D)	Adequate	No association found based on limited evidence.
Psychosocial stress not related to the injury	Karlsborg et al (13) (S)	Low	Radanov et al (54) (S)	Low	Inconclusive
	Smed (39) (S)	Low	Radanov et al (58) (S)	Low	
			Radanov et al (1995) (S)	Low	
Previous psychological problems	Mayou and Bryant (52) (S)	Low	Mayou and Bryant (53) (S)	Low	Inconclusive
			Radanov et al (54) (S)	Low	
Blame and anger	Mayou and Bryant (53) (S)	Low	Radanov et al (57) (S)	Low	Inconclusive
			Radanov et al (60) (S)	Low	
Perceived threat	Mayou and Bryant (2002) (S)	Low			Inconclusive
Cognitive function	Radanov et al (54) (S)	Low	Radanov et al (55) (S)	Low	Inconclusive
	Radanov et al (55) (S)	Low	Di Stefano and Radanov (59) (S)	Low	
	Radanov et al (56) (S)	Low			
	Radanov et al (57) (S)	Low			
	Di Stefano and Radanov (59) (S)	Low			
Anxiety	Radanov et al (1995) (S)	Low	Radanov et al (1994b) (S)	Low	Inconclusive
			Mayou and Bryant (52) (S)	Low	
Depression	Miettinen et al (42)(D)	Low	Mayou and Bryant (52) (S)	Low	Inconclusive
Irritability	Radanov et al (60) (S)	Low	Radanov et al (58) (S)	Low	Inconclusive
Familiarity with symptoms of whiplash			Radanov et al (60) (S)	Low	Inconclusive
Fear-avoidance	Nederhand et al (44)(D)	Adequate	Sterling et al (50) (D)	Adequate	Inconclusive
			Sterling et al (41) (D)	Adequate	

Catastrophising	Nederhand et al (44)(D)	Adequate	Kivioja et al (62) (S)	Adequate	Inconclusive
	Soderlund et al (49) (S)	Low			
Coping strategies	Soderlund et al (49) (S)	Low	Kivioja et al (62) (S)	Adequate	Inconclusive
Somatisation	Hendriks et al (47) (D)	Adequate	Atherton et al (40) (S)	Adequate	Inconclusive

(S) Outcome measure based on symptomatic report
(D) Outcome measure based on disability or function

1.4 Discussion

This review highlights the need for further research as most findings were inconclusive or based on limited evidence. Self-efficacy and post-traumatic stress maybe related to the development of LWS but these factors warrant further research. An association was seen between self-efficacy and both symptoms and disability. Post-traumatic stress was measured by the Impact of Events Scale (IES) (75). The IES measured the patient's distress reaction directly related to their whiplash injury but it is not a true diagnosis of Post traumatic Stress Disorder (PTSD) according to the criteria presented by the DSM-IV (67, 68). The association between post-traumatic stress and LWS was only investigated in relation to disability so the influence on symptoms remains unknown.

One surprising finding was that no significant association was reported between general psychological distress and LWS based on a moderate level of evidence. This is even though psychological distress is thought to be an important factor in the transition from an acute to chronic states in conditions such as LBP (22). Some initial analysis showed that distress influenced outcome following whiplash injury (40). However, when injury severity was controlled for this was no longer true. One cohort study did show an association between psychological distress and LWS at 6 months follow up but this effect was no longer evident at the long term follow up (41, 50). No association was reported using a variety of methods to measure psychological distress (Symptoms Check List-90, General Health Questionnaire 12 and 28 and Multidimensional Pain Inventory) and using both symptoms and disability as outcomes.

No significant association between personality traits and LWS was also reported based on a moderate level of evidence. This was consistent with findings in the neck and back pain literature with a review by Linton (69) concluding that there was no support for a “pain prone” personality.

A number of different factors were reported to have no significant association with LWS based on limited evidence. These included psychosocial work factors, wellbeing, life control and social support. These findings were based on the results of one cohort each and only used symptoms as an outcome. Further research is warranted to confirm these findings and to investigate their impact on disability.

Findings were inconclusive for a number of factors (fear avoidance, catastrophising and coping strategies) that are often highlighted in models of disability development (e.g. (76)). Each of these factors was investigated by two cohorts and the findings were conflicting. However, a common finding was that these factors were significantly associated with LWS in studies that carried out univariate analysis (44, 49) but not when multivariable analysis was carried out (50, 62). This suggests that when factors such as initial pain intensity are included in the analysis these factors are not predictive of outcome. Factors such as fear avoidance, catastrophising and coping strategies used maybe the mechanism through which pain intensity influences outcome. For example, if a patient reports high levels of pain then they are more likely to be fearful of movement (fear avoidant) and fail to return to their usual activities. This requires further confirmation.

Although, there were 22 different psychological factors identified in this review, it was also apparent that there were potentially other psychological factors that warranted investigation. Specifically, in regard to patient held beliefs which is the focus of this thesis, there were only a limited number of factors related to patient held beliefs. Factors related to patient held beliefs about injury and recovery included self-efficacy, fear avoidance, catastrophising and coping. There were other types of beliefs that could potentially influence outcome. For example, beliefs about prognosis (i.e. how long patients think they will take to recover) or beliefs about treatment (what a patient believes will help them to recover). The next step of this thesis was to identify other types of beliefs that warranted further research and this process is described in Chapter Three.

1.4.1 Limitations

It was inappropriate to carry out meta-analysis for this review due to the use of different outcome measures and prognostic factors. This meant the only quantitative analysis possible was a "vote counting" procedure where the number of studies with significant findings was compared to the number of studies with non-significant findings for each factor. This approach was also used by Scholten-Peeters et al (19) and is problematic because it does not consider strength of association. Also, studies that are underpowered may fail to reach statistical significance even when associations exist, so reliance on statistical significance may fail to find associations. If it had been appropriate to use meta-analysis this would have overcome this problem and allowed an estimate of the strength of association of each risk factor with LWS.

Publication bias is a problem for systematic reviews in general as studies with significant findings are more likely to be published. Particular to this review was the potential for bias due to the exclusion of non-English articles. However, of the 7 articles that were potentially eligible, 3 (77-79) were also reported in English. Of the other 4 articles 2 had no abstract available in English (80, 81). The two remaining articles (82, 83) were both prospective studies with 62 and 122 subjects respectively but it was unclear from the abstracts whether they included any psychological factors. Attempts were made to contact both authors but these were unsuccessful.

1.4.2 Methodological issues

The aim of this systematic literature review was to identify psychological risk factors for LWS. Unfortunately the outcome measures used were not necessarily consistent with the definition of LWS. For example, the presence of neck pain at follow up did not specify if symptoms were sufficient to interfere with return to normal activities as specified by the definition of LWS by Balla (11). Attempts were made to ensure that the studies included in this literature review reflected the concept of LWS as closely as possible by specifying that the outcomes used needed to measure symptoms or disability present greater than 6 months post injury.

A major shortcoming of the included studies was that they failed to use outcomes with established test-retest reliability in pain populations. If an outcome measure is not reliable then results based on it are questionable. Outcome measures used in the research presented were extremely variable and lacked consistency. For example, many studies used a dichotomous outcome where patients were categorised as recovered or non-recovered but these definitions varied. Mayou and Bryant (53) defined non-recovered as the report of moderate or severe pain while Radanov et al (55) defined it as the report of any symptoms.

The appropriateness of measures used for the prognostic factors for this patient group also needs to be considered. The inconclusive findings for some constructs may be due to the tools used. For example, use of the Beck Depression Index in pain populations has been criticised because the items relating to somatic symptoms may reflect physical symptoms experienced by patients rather than their mood (84).

The statistical analyses presented were problematic for many studies. Even when the investigator is primarily interested in one possible prognostic factor multivariable analysis is essential to control for bias (85p257). Due to the multi-factorial nature of pain and disability many constructs may influence outcome. Some studies failed to carry out multivariable analysis but carried out high numbers of univariate analysis. Radanov et al (60) carried out over 90 univariate analyses. Under such circumstances some associations will be found that are more than likely due to chance. Univariate analysis is an essential step to select factors to be included in the multivariable analysis but conclusions based solely on univariate analysis may be subject to bias and should be interpreted cautiously. Two articles did carry out multivariable analysis and controlled for all 4 pre-specified factors demonstrating that this is achievable. Inadequate sample sizes was a frequent problem and larger studies are needed if comprehensive models are to be tested when considering prognostic factors in the development of LWS.

1.4.3 Previous systematic reviews

This review identified 16 articles that were not included in the earlier review by Scholten-Peeters et al (19). In light of this, differences between the review by Scholten-Peeters et al (19) and this review would be expected. Associations between LWS and self-efficacy and post-traumatic distress were reported in new research. The two reviews were in agreement that general psychological distress was not associated with the development of LWS. However, the presence of previous psychological problems was found to be associated with poor outcome by Scholten-Peeters et al (19), but was inconclusive in this review. Research pertaining to personality traits was deemed inconclusive by Scholten-Peeters et al (19) but we found moderate evidence that no association existed. Differences in the methodology used may also have contributed to the different findings. In this review outcome measures were based on the definition of LWS, meaning that studies with less than 6 months follow up or those using outcomes such as time to claim closure were excluded. Different criteria were also used to classify the quality of research. Scholten-Peeters et al (19) classified articles scoring 50% or more on the quality scoring as high quality research. We used three ratings of high, adequate and low quality. Scholten-Peeters et al (19) used an overall score to determine quality levels where as this review considered the scores of each of the three sections of the quality assessment. This approach has made it more difficult for studies to achieve a high quality rating but it was felt that it reflected more accurately the quality of the research presented.

1.4.4 The importance of these findings

This systematic literature review has demonstrated there is a significant statistical association between low levels of self-efficacy and high levels of post traumatic stress reaction with LWS. However, is can be difficult to evaluate the importance of these findings due to how findings are reported. A variety of methods are used and it is difficult to compare them. For example, in regards to self-efficacy, Soderlund et al (49), univariate results found that those who were symptomatic at 6 months follow up had statistically significantly lower self-efficacy scores at baseline which was significant to a level of $p<0.05$.

The mean difference between the two groups was 14 points on the Self-Efficacy Scale. Although, this appears to be a large difference between the two groups, the analysis has failed to control for important factors such as pain intensity so this does not give any indication of the true importance of these findings. In contrast, Kyhlback et al (46) reported multivariable linear regression analysis producing a different type of statistical output. Here lower self-efficacy is associated with greater pain and disability expressed using a standardised regression co-efficient (β). β indicates the number of standard deviations the outcome will change in response to a one standard deviation change in the predictor variable (86p239). So in the case of disability, a 16 point reduction in the Self-Efficacy Scale resulted in a 15 point increase in Pain Disability Index scores. In the case of pain ratings, an 18.8 point reduction in the Self-Efficacy Scale resulted in a 6 point increase in pain ratings. It would appear that self-efficacy ratings had a substantial influence on disability and a smaller influence on pain ratings.

Sterling et al (50, 87) reported the effect of a high baseline post traumatic stress reaction on outcome following logistic regress analyses in terms of odds ratios (OR). The OR indicates the change in odds of an outcome occurring with each unit change in the predictor variable (86p271). For each point increase in the IES score (score out of 75) the odds of being moderately/severely disabled at 6 months increased by 11% (50). This appears to have a considerable impact on outcome. The effect was smaller at the 2-3 year follow up where there was a 3% increase in odds with each point increase in the IES score (41).

1.5 Summary of findings

This systematic literature review highlighted the large degree of uncertainty pertaining to psychological risk factors for LWS. When factors related to patient beliefs about injury and recovery were examined, only self-efficacy was reported to be associated with LWS and this was based on limited evidence. Other factors related to patient beliefs about injury and recovery that were investigated were fear avoidance, catastrophising and coping. Their relationship with LWS was deemed inconclusive due to conflicting evidence. More research into self-efficacy, fear avoidance, catastrophising and coping was warranted. It was also obvious that there were other types of beliefs that had not been investigated. Further consideration was needed to identify such beliefs and decide whether they warranted further investigation.

This review also highlighted the need to ensure that the appropriate multivariable analysis was carried out to reduce the risk of bias to findings. Factors that were not related to beliefs needed to be considered when designing the next step of this thesis. In particular, the inclusion of a measure of post-traumatic stress was warranted.

1.6 The next step - study design

On completion of the systematic literature review it was apparent where further research was warranted in the area of patient held beliefs. The next step was to decide on the appropriate research methods to investigate the role of patient held beliefs about pain and injury in the development of LWS and to identify the specific objectives needed to achieve the overall aim of the research.

Essentially, this research hoped to identify certain beliefs that resulted in LWS. Establishing causation is extremely difficult and should not be confused with correlation (96). Correlation establishes a relationship between two variables but more is needed to suggest a causal relationship (31,96,97p290-297,98). Many studies use correlation analysis to suggest causation when it is not possible to do so. The most appropriate study design to identify causality is the prospective cohort study. Prospective studies are essential to understanding causality as they ensure that the causal factor is measured before the outcome of interest. In a prospective cohort study a group of subjects with different characteristics measured at baseline (i.e. different beliefs about injury and recovery) are followed up to see whether an outcome of interest occurs (i.e. develops LWS) (32p266). Therefore, it was decided that a prospective cohort study would be carried out as part of this thesis. The development of the prospective cohort study is described in Chapter 4.

Qualitative research has an important role to play in understanding the patient's experience of illness or injury (287 -290). By interviewing participants about their experiences it was hoped that a greater understanding of how beliefs influence recovery would be achieved. It was also hoped that these interview would reveal aspects of patient beliefs that were important in the development of LWS that was not addressed by the prospective cohort study. Therefore, it was decided than a qualitative study would be carried out alongside the prospective cohort study. This is described in Chapter 7.

1.7 Research objectives

The specific objectives of this research were to:

1. Carry out a prospective cohort study to identify factors predictive of LWS, Neck Disability Index scores and participant perceived improvement at follow up including patient held beliefs.
2. Carry out exploratory analysis to see if the belief factors found to be predictive of LWS were moderated by other belief factors.
3. Carry out exploratory analysis to see if the belief factors found to be predictive of LWS were moderated by the treatments delivered as part of MINT.
4. Explore beliefs held by patients regarding their injury, recovery and the treatments received by carrying out a qualitative study.

2.0 Systematic literature review update

2.1 Introduction

The systematic literature review in the previous chapter represented the state of the evidence at the end of August 2006 when the prospective cohort study was developed. The literature review was updated (to March 2010) to allow comparison between the findings of the prospective cohort study carried out for this thesis and the current evidence base. The search strategy outlined in Figure 2 was re-run. This resulted in 378 possible articles. After examining the abstracts 36 articles were collected. Of these 8 articles pertaining to 5 cohorts were identified that were eligible for the systematic literature review (Table 9). These articles were quality assessed using the criteria developed for the original review. Unfortunately, it was not possible to have more than one reviewer for this update. Data was extracted from the articles using the same methods used for the original review.

2.2 Results

2.2.1 Characteristics of additional studies

The additional cohorts identified included 3 from insurance company records and 2 from emergency department populations (See Table 9). Generally studies were larger than those included in the original review ranging from 91(88) to 2850 (89). All the studies identified were prospective cohort studies. Follow up ranged from 6 months (90) to 2 years (89). A wide range of prognostic factors and outcomes were, once again, investigated. Psychological prognostic factors that had not been investigated previously were causal beliefs about whiplash, helplessness, locus of control beliefs and expectations of recovery.

2.2.2 Quality assessment of additional studies

Generally these studies received higher quality scores than those in the original review with only one study being rated as low quality (88). Five studies were rated as adequate quality (89-93). There were no high quality studies in the original review but two studies published since then were rated as high quality (94, 95). Improvements were mainly seen in the analysis section of the quality criteria as the majority of studies had sufficient sample size and multivariable analysis was carried out in all studies. Although, research quality had improved, there were still some methodological issues. For example some of the measures of outcome and prognostic factors lacked reliability and validity (e.g. Buitenhuis et al (93), Kivioja et al (88)). See Table 10 for quality assessment scores.

Table 9 Additional studies grouped in cohorts

Cohort number	Author	Type of study	Population studied	Number of subjects*	Length of follow up	Psychological factors studied	Other prognostic factors studied
1A	Buitenhuis et al (93)	Prospective cohort study	Insurance company records	663/879	12 months	Concentration problems (VAS)	Age, sex, employment, work education, neck pain intensity (VAS), neck stiffness (VAS), Neck restriction (VAS), radiating symptoms (VAS), Paresthesia (VAS) headache intensity (VAS), dizziness (VAS), use of medication
	Buitenhuis et al (92)	Prospective cohort study	Insurance company records	110/140	12 months	Causal beliefs (CBQW), Catastrophising (PCS)	Disability (NDI), sex, age, paresthesia (VAS), radiating symptoms (VAS)
	Buitenhuis et al (91)	Prospective cohort study	Insurance company records	190/240	12 months	Post traumatic stress (SRS-PTSD)	Age, sex, loss of consciousness, hospital visit, hospital admittance, back pain intensity (VAS), neck pain intensity (VAS), neck stiffness (VAS), Neck restriction (VAS), radiating symptoms (VAS), Paresthesia (VAS) headache intensity (VAS), dizziness (VAS), use of medication, sleep disturbance (Y/N), frequency of neck pain, onset of neck complaints
2A	Carstensen et al (94)	Prospective cohort study	Emergency Department	529 and 651/740	12 months	Pre-collision psychological distress (W-7, SCL)	Pre-collision health problems, age, sex, education, occupation, collision variables
	Kongsted et al (95)	Prospective cohort study	Emergency Department	668/737	12 months	Post traumatic stress (IES), concentration difficulties, memory difficulties	Quality of life (SF-36), neck pain and headache intensity (VAS), crash data, age, sex, prior neck pain
3A	Berglund et al (89)	Prospective cohort study	Insurance company records	1705/2280	24 months	Helplessness (RAI), locus of control beliefs (HLC)	Age, sex, crash related factors, neck pain intensity (VAS), headache (Y/N), participant rated severity of whiplash injury. Socioeconomic status, education
4A	Holm et al (90)	Prospective cohort study	Insurance company records	1032/1259	6 months	Expectations of recovery (VAS), memory loss, anxiety and depression (HADS), post traumatic stress(IES), passive coping strategies (PMI)	Age, sex, education, family status, number of pain areas, severity of pain symptoms (VAS), prior injuries, general health prior to injury including prior neck pain and headache
5A	Kivioja et al (88)	Prospective cohort study	Emergency Department	76/91	12 months	Anxiety and depression (HADS), emotional distress	Age, sex, education, prior neck pain, neck pain intensity (VAS), WAD grade, neck stiffness, nausea, low back pain.

* Number at final follow up/number recruited

NDI = Neck Disability Index
VAS = Visual Analogue Scale
SCL-90 = Symptoms Checklist-90
IES = Impact of Events Scale
PCS = Pain Catastrophising Scale

CBQW = Causal Beliefs Questionnaire Whiplash
W-7 = Whitney 7 illness-worrying scale
SRS-PTS= Self Rating Scale for Post Traumatic Stress Disorder
RAI = Rheumatology Attitude Index
HLC = Health Locus of Control

CES-D= Centre for Epidemiologic Studies Department Depression Scale
PMI = Pain Management Inventory
HADS = Hospital Anxiety and Depression Scale
SF-36= Short form 36 Health Survey

Table 10 Quality scores of additional studies

Cohort no.	Article	Section 1	1	2	3	4	5	6	7	8	9	%	Section 2	10	11	12	13	%	Section 3	14	15	16	17	%	**Quality rating**
1A	Buitenhuis et al (93)		2	2	2	2	2	0	0	0	0	55		0	2	2	2	75		2	0	2	1	62	**Adequate**
	Buitenhuis et al (92)		2	2	2	2	2	0	0	0	0	55		0	2	2	1	62		2	0	2	1	62	**Adequate**
	Buitenhuis et al (91)		2	2	2	2	2	0	0	0	0	55		0	2	2	1	62		2	0	2	1	62	**Adequate**
2A	Carstensen et al (94)		2	2	2	2	2	1	2	0	2	83		1	2	2	1	75		2	1	2	2	87	**High**
	Kongsted et al (95)		2	2	2	2	2	1	2	0	2	83		1	2	2	2	75		2	1	2	1	75	**High**
3A	Berglund et al (89)		2	2	2	2	2	1	?	0	0	61		2	2	2	2	100		2	0	2	1	62	**Adequate**
4A	Holm et al (90)		2	2	2	2	2	1	0	0	0	61		2	2	1	1	75		2	2	2	2	100	**Adequate**
5A	Kivioja et al (88)		2	2	2	2	2	1	2	2	2	94		2	0	0	0	25		0	2	2	2	75	**Low**

2= criteria met, 1= criteria partially met, 0=criteria not met,?=unclear

2.2.3 Findings of additional studies

As in the original review, the results were separated into those based on symptomatic report and those based on disability ratings (See Table 11 (p65) and Table 12 (p67)). The updated overall strength of evidence summary is presented in Table 13 (p69). Despite further research into some psychological factors, the strength of evidence remained unchanged for these factors. The association between cognitive function, catastrophising and previous psychological problems with LWS remained inconclusive.

There was additional support for an association between elevated post traumatic stress reactions and LWS. One high quality study supported this association (95) along with one adequate quality study that supported an association between the presence of hyperarousal symptoms of PTSD but not avoidant and instrusive symptoms with LWS (91). One adequate quality study did contradict these findings and failed to show an association between post traumatic stress and LWS (90). On the balance of evidence, it was felt it was likely a relationship between post traumatic stress and LWS does exist so the level of evidence remained unchanged (limited evidence supporting an association with LWS). Differences in findings between studies may be related to the different factors included in the final model as it is not clear which variables were included in final model reported by Holm et al (90).

One low quality study (88) reported an association between general psychological distress and LWS. Due to the poor quality of the additional research it was felt that there was still enough evidence to support a lack of association and for the strength of evidence to remain unchanged. Therefore, the association remains unchanged with no association between general psychological distress and LWS based on moderate evidence.

There was a change in the strength of evidence for one factor. Additional support was seen for a lack of association between coping strategies and LWS (90). Although previously reported as inconclusive, it was felt that there was now sufficient evidence to suggest a lack of association between coping strategies and LWS based on limited evidence.
There were several factors that were not investigated in the original review but for which limited evidence now exists. Firstly, there was limited evidence that higher levels of helplessness (89), lower recovery expectations (90) and causal beliefs about neck pain (92) are associated with LWS. Causal beliefs were measured using the Causal Beliefs Questionnaire for Whiplash where the individual rated how likely different factors (psychological, severe injury, vertebral, muscular, whiplash injury) were the cause of their neck pain. Higher scores indicating greater certainty about the cause of neck pain on 3 subscales (psychological, vertebral and whiplash) at 6 months and 2 subscales (psychological and whiplash) at 12 months was associated with LWS. The psychological subscale (4 questions) measures the belief that pain is of psychological origin e.g. "my complaints are caused by me being emotionally upset". The vertebral subscale (3 questions) measures beliefs that pain arises from vertebral structures e.g. "my complaints are caused by my vertebrae not lining up". The whiplash subscale contains one question "my complaints are caused by whiplash".

There was limited evidence for a lack of association between locus of control beliefs and LWS (89). Also, there was limited evidence for a lack of association between anxiety and depression measured by the HAD questionnaire with LWS (88, 90).

Table 11 Results based on symptomatic report

Cohort number	Study	Outcome measurement used	Time of follow up	Psychological factors associated with poor outcome - multivariable results	Final model included:
1A	Buitenhuis et al (92)	Presence of post whiplash syndrome. Post whiplash syndrome was not defined.	6 and 12 months	6 months: Higher scores on 3 subscales of the causal beliefs questionnaire whiplash was associated with presence of postwhiplash syndrome: Subscales – psychological (OR 4.335 95%CI 1.562-12.030), vertebral (OR 3.686 CI 95% 1.467-9.258), whiplash (OR 3.430 CI 95% 1.618-7.272). Higher levels of catastrophising reduced the chances of post whiplash syndrome (OR 0.885 CI 95% 0.814-0.962). 12 months: Higher scores on 2 subscales of causal beliefs questionnaire whiplash was associated with presence of postwhiplash syndrome: Subscales – psychological (OR 2.670 95%CI 1.091-6.534), whiplash (OR 2.657 CI 95% 1.329-5.3143).	6 and 12 months: Age, sex, NDI
	Buitenhuis et al (91)	Presence of post whiplash syndrome. Post whiplash syndrome was not defined.	6 and 12 months	6 months: Whole SRS-PTSD did not predict outcome but the hyperarousal subscale was predictive of outcome. Higher scores were associated with the presence of post whiplash syndrome (OR 1.985 CI 95% 1.127-3.497). 12 months: Whole SRS-PTSD did not predict outcome but the hyperarousal subscale was predictive of outcome. Higher scores were associated with the presence of post whiplash syndrome (OR 2.238 CI 95% 1.280-3.947).	6 and 12 months: Age, sex, neck pain intensity, SRS-PTSD re-experiencing symptoms subscale, SRS-PTSD avoidance symptoms
2A	Carstensen et al (94)	Considerable pain (VAS 4-10) versus minimal pain (VAS 0-3)	12 months	High levels of pre-collision distress was associated with considerable neck pain at follow up (OR 2.1 95%CI 1.1-4.2).	Age, sex, education, occupation. Pre-collision illness, pre-collision pain, pre-collision neck pain, severe collision.
	Kongsted et al (95)	Considerable pain (VAS 4-10) versus minimal pain (VAS 0-3)		High level of post traumatic stress was associated with considerable neck pain at follow up (OR 2.1 95%CI 1.1-4.1).	Sex, neck pain intensity
3A	Berglund et al (89)	Neck pain intensity categorised as mild (0-30 on VAS), moderate (31-54) and severe (55-100)	2 years	Moderate levels of helplessness were associated with greater neck pain at follow up (OR 1.6 CI 95% 1.3-2.1). High levels of helpless were associated with greater neck pain at follow up (OR 2.7 CI 95% 2.1-3.4).	Sex, neck pain intensity, initial headache present, severity of whiplash injury, education, time

5A	Kivioja et al (88)	The presence of neck pain at follow up (VAS >30) versus no neck pain (VAS <30)	12 months	Emotional distress at the time of the accident was associated with increased risk of neck pain at follow up (RR 11 CI 95% 2.1-57.2)	Sex, prior neck pain, initial neck pain intensity, low back pain

Table 12 Results based on Disability or Functional Outcome Measures

Cohort number	**Study**	**Outcome measurement used**	**Time of follow up**	**Psychological factors associated with poor outcome - multivariable results**	**Final model included:**
1A	Buitenhuis et al (93)	The presence of work disability. Work disabled was defined as working fewer hours because of reported complaints	6 and 12 months	6 months: Concentration complaints were associated with work disability (OR 1.251 95%CI 1.149-1.362) 12 months: Concentration complaints were associated with work disability (OR 1.242 95%CI 1.128-1.368).	6 months and 12 months Age, neck pain intensity, neck stiffness, severity of restricted movements, radiating symptoms, paresthesia, headache intensity, dizziness, medication use.
2A	Kongsted et al (95)	Affected work capacity versus unaffected work capacity. Affected work capacity defined as any sick leave or days with reduced working because of the accident in previous month.		High level of post traumatic stress was associated with affected work capacity at follow up (OR 1.81 95%CI 1.0-3.4)	Sex, baseline pain intensity.
		Disabled versus non disabled. Non disabled defined as 0-6 on the Copenhagen Neck Functional Disability Scale.		High level of post traumatic stress was associated with persistent disability at follow up (OR 2.1 95%CI 1.1-4.2)	Sex, baseline pain intensity.
3A	Berglund et al (89)	Disability Rating Index categorised as mild (0-6), moderate (7-22) and severe (22-100)	2 years	Moderate levels of helplessness were associated with the great disability at follow up (OR 1.5 CI 95% 1.2-1.9). High levels of helpless were associated with greater disability at follow up (OR 3.5 CI 95% 2.1-6.1).	Sex, neck pain intensity, initial headache present, severity of whiplash injury, education, time
4A	Holm et al (90)	Pain Disability Index which was categorised as no/mild disability 0-4), moderate disability (5-21) and high disability (≥22)	6 months	Expectations of recovery as categorical variables: Patients who rated themselves as least likely to make a full recovery were more likely to have moderate disability (OR 2.0 CI 95% 1.0-3.8) and high disability (OR4.2 CI 95% 2.1-8.5) at follow up compared to those who thought they were very likely to recover. Patients who rated themselves in the intermediate category (less likely to recover) were also more likely to have moderate disability (OR 1.5 CI 95% 1.0-2.3) and high disability (OR 2.0 CI 95% 1.2-3.2) at follow up compared to those who thought they were very likely to recover. Expectations of recovery as continuous variables: Patients who rated themselves as less likely to recover had higher levels of	Not clear. Says that each confounder variable was added to the crude model and if it changed the crude estimates by more than 10% it was included in the final model. Does not state what was included in the final model.

				disability at follow up (Moderate disability OR 1.1 CI 95% 1.0-1.2 and High disability OR 1.2 CI 95% 1.1-1.3).	

Table 13 Overall strength of evidence for psychological prognostic factors in whiplash including additional studies (in bold) updated March 2010

Psychological factor	**Articles supporting an association with late whiplash syndrome**	**Study Quality**	**Articles failing to show an association with the development of late whiplash syndrome**	**Study Quality**	**Overall level of evidence**
Personality traits	Radanov et al (58) (S)	Low	Borchgrevink (51) (S)	Adequate	No association found based on moderate evidence.
			Radanov et al (54) (S)	Low	
			Radanov et al (55) (S)	Low	
			Radanov et al (56) (S)	Adequate	
			Radanov et al (57) (S)	Low	
			Radanov et al (60) (S)	Low	
			Pettersson et al (48) (D)	Low	
			Mayou and Bryant (52) (S)	Low	
General psychological distress	Sterling et al (50) (D)	Adequate	Hendriks et al (47) (D)	Adequate	**No association found based on moderate evidence.**
	Gargan et al (43) (S)	Low	Karlsborg et al (13) (S)	Low	
	Kivioja et al (S) (88)	**Low**	Smed (39) (S)	Low	
			Miettinen et al (42)(D)	Low	
			Olsson et al (45) (S)	Adequate	
			Sterling et al (41) (D)	Adequate	
			Atherton et al (40) (S)	Adequate	
Post traumatic stress	Sterling et al (50) (D)	Adequate	**Holm et al (D) (90)**	**Adequate**	**Limited evidence for an association with the development of LWS**
	Sterling et al (41) (D)	Adequate			
	Buitenhuis et al (91) (S) (Hyperarousal symptoms only)	**Adequate**			
	Kongsted et al (95) (D)	**High**			
Self-efficacy	Kyhlback et al (46) (S & D)	Adequate			Limited evidence for an association with the development of LWS
	Soderlund et al (2000)(S)	Low			
Helplessness	**Berglund et al (D) (89)**	**Adequate**			**Limited evidence for an association with the development of LWS**

Expectations of recovery	**Holm et al (D) (90)**	**Adequate**			**Limited evidence for an association with the development of LWS**
Causal beliefs about whiplash	**Buitenhuis et al (S) (92)**	**Adequate**			**Limited evidence for an association with the development of LWS**
Psychosocial work factors			Atherton et al (40) (S)	Adequate	No association found based on limited evidence
Wellbeing	Radanov et al (60) (S)	Low	Radanov et al (54) (S)	Low	No association found based on limited evidence.
			Radanov et al (55) (S)	Low	
			Radanov et al (56) (S)	Adequate	
			Radanov et al (57) (S)	Low	
			Di Stefano and Radanov (59) (S)	Low	
Life control			Olsson et al (45) (S)	Adequate	No association found based on limited evidence.
Social support			Olsson et al (45) (S)	Adequate	No association found based on limited evidence.
Health related attitudes and behaviours			Kasch et al (37) (D)	Adequate	No association found based on limited evidence.
Locus of control beliefs			**Berglund et al (D) (89)**	**Adequate**	**No association found based on limited evidence.**
Anxiety and Depression			**Holm et al (D) (90)**	**Adequate**	**No association found based on limited evidence.**
			Kivioja et al (S) (88)	**Low**	
Coping strategies	Soderlund et al (49) (S)	Low	**Kivioja et al (62) (D)**	**Low**	**No association found based on limited evidence.**
			Holm et al (D) (90)	**Adequate**	
Previous psychological problems	Mayou and Bryant (52) (S)	Low	Mayou and Bryant (53) (S)	Low	**Inconclusive**
	Carstensen et al (94) (S)	**High**	Radanov et al (54) (S)	Low	
Psychosocial stress not related to the injury	Karlsborg et al (13) (S)	Low	Radanov et al (54) (S)	Low	Inconclusive
	Smed (39) (S)	Low	Radanov et al (58) (S)	Low	
			Radanov et al (1995) (S)	Low	

Blame and anger	Mayou and Bryant (53) (S)	Low	Radanov et al (57) (S)	Low	Inconclusive
			Radanov et al (1995) (S)	Low	
Perceived threat	Mayou and Bryant (2002) (S)	Low			Inconclusive
Cognitive function	Radanov et al (54) (S)	Low	Radanov et al (55) (S)	Low	**Inconclusive**
	Radanov et al (55) (S)	Low	Di Stefano and Radanov (59) (S)	Low	
	Radanov et al (56) (S)	Low	**Kongsted et al (95) (D)**	**High**	
	Radanov et al (57) (S)	Low	**Holm et al (D) (90)**	**Adequate**	
	Di Stefano and Radanov (59) (S)	Low			
	Buitenhuis et al (93)(D)	**Adequate**			
Anxiety	Radanov et al (1995) (S)	Low	Radanov et al (1994b) (S)	Low	Inconclusive
			Mayou and Bryant (52) (S)	Low	
Depression	Miettinen et al (42)(D)	Low	Mayou and Bryant (52) (S)	Low	Inconclusive
Irritability	Radanov et al (1995) (S)	Low	Radanov et al (58) (S)	Low	Inconclusive
Familiarity with symptoms of whiplash			Radanov et al (1995) (S)	Low	Inconclusive
Fear-avoidance	Nederhand et al (44)(D)	Adequate	Sterling et al (50) (D)	Adequate	Inconclusive
			Sterling et al (41) (D)	Adequate	
Catastrophising	Nederhand et al (44)(D)	Adequate	Kivioja et al (62) (D)	Adequate	**Inconclusive**
	Soderlund et al (49) (S)	Low	**Buitenhuis et al (S)(92)**	**Adequate**	
Somatisation	Hendriks et al (47) (D)	Adequate	Atherton et al (40) (S)	Adequate	Inconclusive

(S) Outcome measure based on symptomatic report

(D) Outcome measure based on disability or function

2.3 Summary

As some time had passed since the original review, the systematic literature was updated to establish the current evidence base regarding psychological risk factors for LWS. Several new belief factors were included in this update including expectations of outcome which was also included in the prospective cohort study carried out for this thesis. Despite almost 4 years between the two reviews there was little change to overall findings. The new findings included:

- Limited evidence of a lack of association between the following factors and LWS: coping strategies (previously inconclusive), locus of control beliefs and anxiety and depression (measured by the HAD).
- Limited evidence of an association between the following factors and LWS: higher levels of helplessness, lower recovery expectations and causal beliefs about neck pain.

These findings will be discussed further in relation to the results of the prospective cohort study carried out as part of this thesis.

3.0 The development of a prospective cohort study to investigate the role of patient held beliefs about injury recovery in the development of LWS

3.1 Introduction

The aim of this chapter is to outline the development of the prospective cohort study carried out as part of this thesis. This will include a description of how factors were identified, the theoretical underpinning of each factor and a brief overview of the evidence to support a potential role in LWS.

3.2 Timing of data collection

As data collection for this prospective cohort study was taking part alongside data collection for MINT the timing of data collection was pre-determined by the design of MINT. Baseline data for this prospective cohort study were primarily collected between approximately 3-6 weeks post whiplash injury. However, some data was also available from the participant’s initial ED visit and MINT baseline questionnaire. Follow up data were available at 4, 8 and 12 months post ED attendance. The procedures for data collection are described in Chapter 4.

3.3 Identification of factors to be tested

The next step in designing the prospective cohort study was to decide which factors needed to be included in the study. The systematic literature had already highlighted some factors that warranted further investigation regarding their ability to predict LWS. These were self-efficacy, catastrophising, fear-avoidance and coping. Hill (31) suggests that support for causality can be drawn from other conditions where similar mechanisms may be at play so the wider pain literature was examined. The literature was searched to identify factors (related to patient held beliefs) shown to be predictive of outcome in acute or sub-acute populations with neck or back pain. This review primarily focused on evidence from prospective cohort studies. This literature is extensive so other systematic literature reviews were consulted to assist this process (22, 69).

Models of disability were also consulted (76, 99-102). There are many models in existence and some are based on empirical evidence while others are based on hypothesis. Where empirical evidence is lacking these models are still important as they provided an explanation of why a relationship may exist and warranted further investigation (i.e. plausibility).

Although this was not a formal systematic literature review, a search strategy was developed to identify the pertinent literature. Searches were carried out using electronic databases including Pubmed, Medline, CINAHL, Embase and Psychinfo using the search terms in Figure 3. Reference lists of relevant articles were searched. Abstracts were examined and the full articles were obtained if they appeared relevant.

To assist with the interpretation of findings it was important to understand the theoretical basis of each construct that was selected for inclusion in the study. Literature that outlined the theoretic underpinning of each factor was also examined.

As discussed in the systematic literature, it was essential to carry out a multivariable analysis that considered the influence of other potential factors such as pain intensity or previous neck pain. Therefore, as part of developing the prospective cohort study, it was also necessary to identify factors not related to patient beliefs that could influence outcome. Primarily, systematic literature reviews of prognostic factors for whiplash outcomes were consulted.

Figure 3 Search strategy used

Initial searches involved the terms back pain (MeSH term) and neck pain (MeSH term) in combination with the following:
Beliefs
Expectations
Health, knowledge, attitudes, practice (MeSH term)
Recovery of function (MeSH term) AND Prognosis (MeSH term)
Recovery AND prognosis
Attitudes AND prognosis

Following the identification of potential factors to be included further searches were carried out. For example:
Catastrophising AND prognosis
Catastrophising AND recovery
Catatstrophising AND outcome

The remainder of this chapter will present the factors that were selected for inclusion in the prospective cohort study.

3.4 Factors related to patient beliefs to be investigated

3.4.1 Coping

Although coping is not a belief, it is an overarching concept that is relevant to the belief factors that follow and needed to be included in this prospective cohort study.

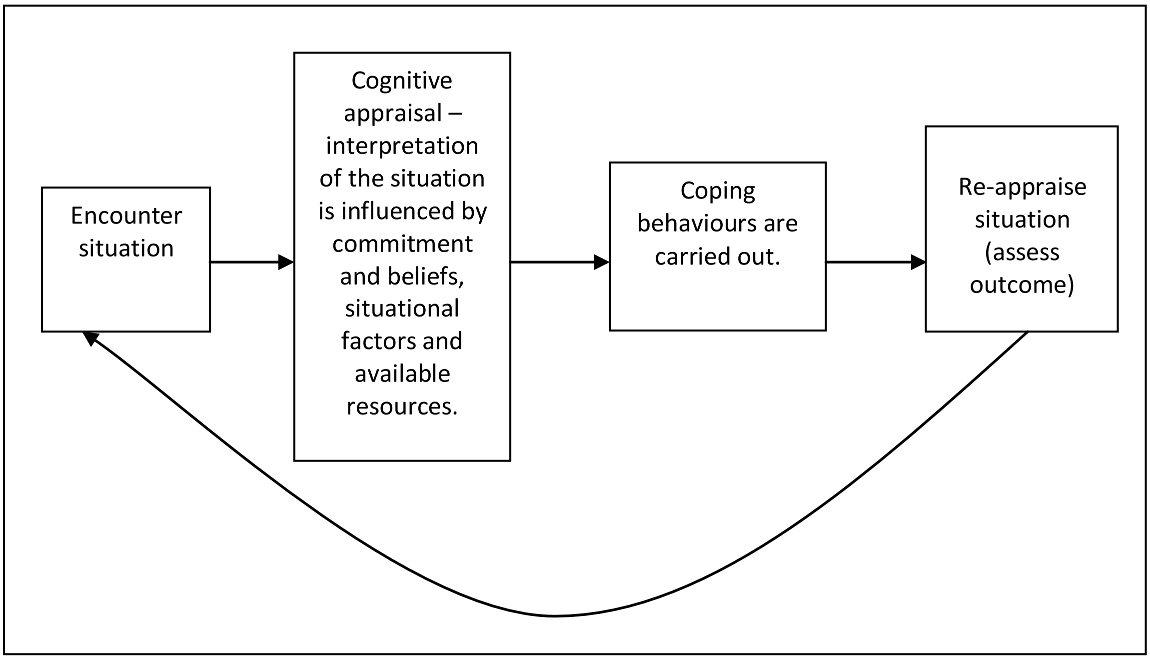
3.4.1.1 Overview

Coping is defined as:

"The thoughts and behaviours that people use to manage the internal and external demands of situations that are appraised as stressful."(103p31)

How an individual responds to a stressful situation differs greatly between individuals and dependent on the situation. Each individual will go through a process of cognitive appraisal where meaning is given to a situation (103p23). According to Lazarus and Folkman (103) the process of cognitive appraisal can be separated into primary appraisal (evaluating what is at stake) and secondary appraisal (deciding what can be done about it). Secondary appraisal is a complex evaluative process. The coping options and ability to carry them out are assessed and possible outcomes are considered (103p35). This is an ongoing process and as new information becomes available reappraisal will occur (103p38). See Figure 4.

Figure 4 The coping process



The appraisal process is influenced by many factors including the individual's beliefs (103p55). Lazarus and Folkman (103p63) define beliefs as:

"pre-existing notions about reality which serve as a perceptual lens. In appraisal, beliefs determine what is fact, that is "how things are" in the environment, and they shape the understanding of its meaning."

Lazarus and Folkman's model of coping suggests that an individual's beliefs about pain and recovery will determine their choice of coping behaviours and, subsequently, influence outcome. This provides an explanation of how beliefs about pain and recovery may influence outcome and is in line with the Leventhal's Self-regulation Model of Illness (27) discussed in the introduction. This places the beliefs about injury and recovery as part of the appraisal process of coping.

3.4.1.2 Classification of coping strategies

It is possible that the type of coping behaviour used is in itself a prognostic factor for recovery from injury. The suggestion that it is possible to identify ways of coping that are effective and ineffective has lead to a large amount of research in this area (104). Some feel that this is too simplified (104) and that coping strategies cannot be classified as "good" or "bad" as what may be helpful at one stage or situation may not be helpful at another (103p133-138, 104). Lazarus and Folkman (103) emphasise that coping is a process and not a stable trait or style. De Ridder (105) is in agreement that coping is a dynamic process that changes overtime in response to the demands of the situation. However, other authors suggest that it is possible to identify personality traits or coping styles that predict how an individual will respond to a stressful situation (106).

Different ways of classifying approaches to coping have been developed. Lazarus and Folkman (103) propose a framework of problem-focused coping and emotion-focused coping. Problem-focused coping involves addressing the problem causing distress by, for example, making a plan of action (104). Emotion-focused coping is aimed at ameliorating the negative emotions associated with a problem by, for example, seeking emotional support (104). People will tend to use both types of coping during a stressful situation and they may facilitate or impede each other (103p153).

Another classification used within the pain literature separates coping strategies into active (adaptive) and passive (maladaptive) coping strategies (107). This system was developed from observations that patients with chronic pain develop behavioural and cognitive coping strategies to help them to cope, tolerate and deal with their pain (108). It is proposed that the type of coping strategies used can potentially impact on severity of pain and function (108).

In relation to pain, coping is defined as:

" the purposeful cognitive or behavioural efforts to manage or minimise the negative impact of pain" (109)

Patients use active or adaptive coping strategies when attempting to control their pain or to function in spite of their pain (107). Active strategies involve an attempt by the patient to deal with the pain using their own resources (110). Active coping strategies include engaging in physical exercise or physical therapy, ignoring the pain, staying busy or active or clearing the mind of bothersome thoughts (107).

Patients use passive or maladaptive coping strategies when relinquishing control of their pain to others, or when allowing their lives to be adversely affected by pain (107). Passive strategies are characterised by helplessness and/or reliance on others (110). They include strategies such as wishing the doctor would prescribe better pain medication, thinking the pain is wearing one down, telling others how much the pain hurts and praying for relief (107).

It has been suggested that the active-passive conceptualisation of coping for pain populations is preferable to other approaches (110) as they are in line with current recommendations of pain management (111). It is also thought that the active – passive coping perspective demonstrates a predictive utility that other conceptualisations do not (110). However, this claim is based on cross-sectional analysis. One concern over this approach is the lack of consistency regarding the classification of active and passive strategies. For example, Snow-Turek et al (110) defined praying as a passive strategy but Blyth et al (112) defined it as an active strategy. Catastrophising is classified as a passive coping strategy by some authors (108, 110) but others consider that catastrophising is part of the appraisal process rather than a coping strategy (113). Catastrophising will be examined more closely in a separate section.

3.4.1.3 The use of active and passive coping strategies as a prognostic factor

The predictive ability of active and passive coping within acute and sub-acute spinal pain was examined further for evidence that this approach warranted further investigation. One study was identified that investigated active and passive coping in a sub-acute WAD population. This study was excluded from the systematic literature review as the outcome used was time to recovery which was not consistent with the definition of LWS (109). The use of passive coping strategies was related to longer recovery time (HRR=0.62, 95% CI 0.43-0.89) but use of active coping strategies did not influence outcome (109).

These findings were in agreement with the opinion that passive coping has greater potential to influence outcome than active coping (110, 111). The use of passive coping strategies has also been implicated in the development of neck and back pain. A prospective population based study found that individuals who reported using passive coping strategies when in pain were more likely to have developed disabling neck or back pain at 6 month follow up compared to individuals who did not use passive coping strategies (114). No association was seen with the use of active coping strategies (114)

The use of active and passive coping strategies has also been investigated in a small number of studies investigating acute/sub-acute LBP populations. A well conducted study by Jones et al (115) provided further evidence that high levels of passive coping strategies increased the risk of developing persistent and disabling LBP at 3 month follow up. However, 3 other studies found no relationship between coping strategies and outcome (116-118). Two of the studies were well conducted with multivariable models controlling for other important baseline factors (117, 118) but the third study had poor follow up (65%) so these results may not be a true indications of the role of coping in this cohort (116).

3.4.1.4 Summary

The concept of active and passive coping provided a framework to investigate coping and LWS further. From the systematic literature review, the association between the use of coping strategies and LWS was inconclusive. However, some evidence was found suggesting that the high use of passive coping strategies was predictive of time to recovery in WAD and the development of disabling LBP in the general population. Conflicting results were seen in studies that investigated the prognostic ability of passive coping strategy use in LBP. Due to the large degree of uncertainty that existed regarding the prognostic ability of use of coping of strategies in spinal pain including LWS it warranted further investigation and was included in the prospective cohort study.

3.4.2 Catastrophising

3.4.2.1 Overview

Catastrophising has been described as dwelling on the worst possible outcome in a situation where an unpleasant outcome is possible (119). Sullivan et al (74) broadly define catastrophising in relation to pain as:

"an exaggerated negative orientation toward noxious stimuli".

Sullivan et al (74) propose 3 components to catastrophising:

1. Rumination - increased attention to and generation of pain-related thoughts.
2. Magnification - exaggeration of the threat value of painful stimulus.
3. Helplessness - a tendency to adopt a helpless orientation to coping with painful situations.

Sullivan et al (73) outline 4 models that may explain the mechanism through which catastrophising influences pain and disability. Empirical evidence to support these models is generally lacking but they highlight the range of processes that are possible.

1. Schema-activation model:

A schema is a mental representation of a particular domain (in this case pain) and contains an individual's thoughts and beliefs associated with that domain (120). Schema help an individual to process and interpret information (120). The schema-activation model proposes that when an individual experiences pain they will lay down information representing the sensory and emotional aspects of the pain (73, 120). Incidents (such as a painful stimuli) will then automatically trigger the schema resulting in information being interpreted using the existing schema (25p11, 120). It is thought that individuals who tend to catastrophise possess a schema that contains excessively negative information about pain (73). Activation of such a schema will influence the emotional response to pain (such as distress and increased attention) leading to a heightened pain experience (73). Turk and Rudy (102) propose that this process of interpretation can potentially influence behaviour and lead to unhelpful behaviours such as avoidance in an attempt to manage the pain.

Sullivan et al (73) highlights a link between catastrophising and high levels of emotions such as distress as support for this model but this is based on experimental pain studies in normal subjects (74). Support for this model is mainly theoretical as it is recognised there are difficulties in actually determining if pain schema have been activated (73).

2. Appraisal model:

This model is based on the idea that catastrophising contributes to the appraisal process described previously by Lazarus and Folkman (73,103). It is suggested that the magnification and rumination components of catastrophising reflect the primary appraisal process that interprets the threat value of pain (73). The helplessness component is part of the secondary appraisal process that evaluates the potential effectiveness of coping strategies. Support for this model comes from studies demonstrating that catastrophising is related to other factors related to appraisal such as perceptions about ability to control pain (73). There is some evidence to support this. For example, Woby et al (121), demonstrated that patients with a tendency to catastrophise reported lower levels of control over their pain and less ability to decrease their pain. However, when exploring the relationships between these factors there was no attempt to control for other potential factors such as pain intensity so this needs further clarification.

3. Attentional model:

The third model is concerned with the role of attentional factors in the process of catastrophising (73). This model suggests that individuals who catastrophise have greater difficulty suppressing or controlling pain-related thoughts. This leads to a tendency to ruminate on their pain and the ability to perform cognitive tasks is affected by this pre-occupation (73, 122). It has been shown that patients with chronic pain exhibit a bias towards pain stimuli when processing information (122). It is thought that sensitivity to pain-related stimuli is a protective mechanism in the acute phase of injury recovery to prevent further injury and promote recovery (122). However, if there is continued sensitivity to pain cues in the chronic phase then it will prevent the return to normal function and becomes maladaptive (122).

4. Coping Model:

The final model is the communal coping model of pain (73). This model suggests that individuals who catastrophise communicate their pain to others through pain behaviours aimed at soliciting support and empathy to reduce their distress (123). Pain behaviours include facial expressions, vocalisations, protective and evasive movements (123). This type of behaviour may inadvertently become maladaptive (i.e. increased dependency on others) and contribute to ongoing pain and disability (73). This model suggests that pain behaviours are an effective way of communicating pain intensity and this has been demonstrated in experimental pain studies (123). Some support for this model has been demonstrated as punishing responses by others (e.g. your spouse gets annoyed when you are in pain) have been shown to partially mediate the relationship between catastrophising and function but not pain (124).

These four models present four possible mechanism by which catastrophising may influence outcome. However, Sullivan et al (73) suggests that these models do not exist in isolation and may explain different perspectives of catastrophising.

3.4.2.2 Catastrophising as a prognostic factor

The predictive ability of catastrophing within acute and sub-acute spinal pain was examined for evidence that further investigation was warranted. Conflicting findings emerged from a small number of prospective cohort studies that investigated catastrophising as a prognostic factor in acute/sub-acute neck and back pain. Three studies reported no significant association between baseline levels catastrophising and disability, pain, return to work or global perceived improvement at 6 and 12 months follow up (117, 118, 125). In contrast, two studies identified high levels of catastrophising as a risk factor for persistent symptoms at 3 and 6 months follow up (126, 127).

There was some evidence that catastrophising may have a role to play in the development of LBP. Participants in a population based survey who were asymptomatic at baseline but reported a tendency for catastrophic thinking when in pain were more likely to report LBP at 6 months follow up compared to those without this tendency (128).

3.4.2.3 Summary

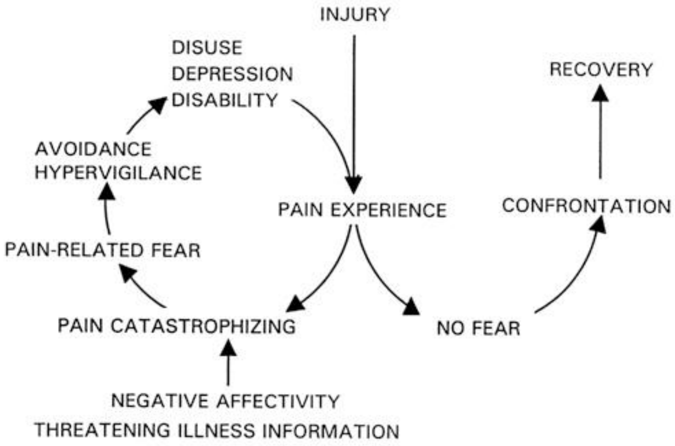
Theoretical models exist which suggest that catastrophising has the potential to influence outcome in painful conditions. However, the evidence from studies investigating LWS, neck pain and LBP is conflicting. Further investigation was warranted to understand the role of catastrophising in the development of LWS.

3.4.3 Fear Avoidance Beliefs

3.4.3.1 Overview

The fear-avoidance model as a way to explain ongoing pain was first suggested by Lethem et al (129). In the last 20 years there has been extensive research into this concept especially in LBP. Pincus et al (130) defines fear avoidance as a "fear of pain and movement". One of the central assumptions of this concept is that individuals will restrict their movements or activities because of a fear that they will cause pain or re-injury or might cause pain or re-injury (131, 132p211). This model proposes that if the avoidance of activity is sufficient and ongoing it will lead to disability. Vlaeyen et al (132p210) suggests that fear avoidance behaviour is a result of misinterpretation of the meaning of pain (catastrophisation). For example, pain is interpreted as being a sign of tissue damage even after the initial injury has healed. Misinterpretation of pain as threatening (catastrophic thinking) causes pain-related fear resulting in avoidance of movement and activity leading to disability (132p211, 133, 134p10)(See Figure 5). Misinterpretation may be fuelled by factors such as previous pain experiences (132p210). This becomes a vicious cycle maintained by the pain-related fear (133). When catastrophising does not occur there is no associated fear of pain or movement and an early resumption of normal activities will occur (133). It is also thought that the development of pain related fear results in hypervigilance and an excessive focus on pain related information (101).

Figure 5 The fear-avoidance model of chronic pain (101)



3.4.3.2 Fear avoidance beliefs as a prognostic factor

Fear avoidance beliefs are generally presented as a risk factor for disability although very little research exists in the area of WAD. There is a more extensive evidence base available when considering LBP. A systematic literature review was identified that investigated prognostic factors for recovery following acute LBP (130). This review concluded that there was little evidence to support the link between levels of fear avoidance early after the onset of LBP and prognosis. Pincus et al (130) state:

"In summary, the evidence from prospective cohort studies suggests that any causal link between fear avoidance and long-term measures of disadvantageous outcome is at best weak."

Instead, it was suggested that fear-avoidance may play a role in maintaining disability in the later stages of pain (130). Avoidance behaviour may be normal coping behaviour immediately after injury. Avoiding aggravating movements or activities and rest of the injured part is recommended in the management of acute soft-tissue injuries in the initial post injury phase (the first 72 hours) to reduce pain and facilitate tissue healing (135) . However, when avoidance behaviour continues beyond the initial post-injury phase it becomes problematic. Another possibility is that avoidance of activities is not only attributable to a fear or pain or re-injury but that other psychological factors contribute to avoidance behaviour.

The review by Pincus et al (130) review included 9 studies of which 7 included a measure of fear of pain. Fear of pain measures were either the Tampa Scale of Kinesiophobia (TSK) (72) or the Fear-avoidance Beliefs Questionnaire (FABQ) (136). Three studies (137-139) measured fear of pain within 3 weeks of injury and no relationship was seen between fear avoidance and outcome when it was measured early on. The remainder included participants with LBP of varying duration from 3 days up to 6 months. Three of these studies demonstrated no link between baseline fear of pain and outcome (140-142). Only one study found an association between fear of pain and outcome (128).

Eleven other studies were identified that were not included in the review by Pincus et al (130). Consistent findings were reported that work related fear avoidance beliefs (measured by the FABQ work subscale) were predictive of outcomes related to return to work (RTW) (125, 143-147). These findings contradict that of Pincus et al (130). One reason for this may be that the FABQ work subscale measures a very specific type of fear-avoidance beliefs and this appears to have a greater predictive value than a more general measure of fear-avoidance beliefs.

The findings in relation to disability and pain outcomes were not consistent. Some studies presented mixed findings depending on the outcome measure used and the timing of follow up. For example, Pool et al (118) reported that fear avoidance beliefs were predictive of disability at 12 week follow up but not at 1 year. George et al (148) found that fear avoidance beliefs predicted disability but not pain ratings. In total, seven studies reported findings that fear avoidance beliefs were predictive of outcome (118, 144, 145, 148-150) and 5 studies reported findings that they were not (118, 143, 148, 151, 152). All studies carried out multivariable analysis but differed in the factors included in the statistical models. For example, not all the models included a measure of emotional distress. Grotle et al (152) found that when distress was included in the model that fear avoidance was no longer predictive of outcome. This is in agreement with the review by Pincus et al (103) who concluded that distress/depression played an important role in the early stages of disability development.

3.4.3.3 Summary

Contradictory findings emerge regarding the role of fear avoidance as a risk factor for poor outcome in acute and sub-acute populations. The identified systematic literature review concluded that the link between fear avoidance beliefs and outcome was weak in LBP

(130). Subsequent research demonstrated consistent evidence that fear avoidance beliefs about work were predictive of RTW outcomes but the ability to predict pain and disability was much less clear. Research to date had focused heavily on LBP so further investigation into other conditions is warranted. Only two studies were identified in the systematic literature review (Chapter 1) that investigated fear avoidance in LWS and the findings were contradictory so further investigation was warranted.

3.4.4 Self-efficacy

3.4.4.1 Overview

The concept of self-efficacy comes from the work of Bandura (64). Soderlund and Lindberg (65) describe it as "a personal belief of how successfully one can cope with difficult situations". It is derived from social cognitive theory which presumes that personal characteristics will influence behaviour (153).

Self-efficacy incorporates two aspects (64):

1. efficacy expectancy – the conviction that one can successfully execute the behaviour required to produce an outcome
2. outcome expectancy – the person's estimate that the given behaviour will lead to certain outcomes.

Bandura (64) reports that given the appropriate skills and adequate incentives self-efficacy expectations are a major determinants of how an individual attempts to cope with a situation. These expectations determine (64):

1. What coping behaviour will be initiated

2. How much effort will be expended - the more confidence an individual has that they will succeed then the more effort will be used.
3. How long the coping behaviour will be sustained in the face of obstacles and aversive experiences – the more confidence an individual has that they will succeed the more likely they will be to persist even if it is difficult.

Coping behaviour will be determined by the patient’s belief in their ability to cope with the situation (76). This view firmly places self-efficacy beliefs as part of the appraisal process of coping as discussed earlier. Bandura (64) outlines four determinants of self-efficacy beliefs:

1. Performance accomplishments

According to Turk (76) this is the biggest influence. Turk (76p15) states:

“Mastery of experiences gained through performance accomplishments are hypothesised to have the greatest impact on establishing and strengthening self-efficacy expectancies because they provide the most information about actual capabilities.”

Successfully carrying out an activity will tend to increase self-efficacy while failure will tend lower self-efficacy.

2. Vicarious experiences

Observing others perform an activity without any adverse effects may also act to develop confidence that you would also be capable of performing the same activity. This is more likely if you see yourself as similar to the person performing the activity.

3. Verbal persuasion

Likely to be a weaker source of establishing self-efficacy but discouragement or encouragement from others may also influence perceptions about self-efficacy. The influence will depend on the perceived credibility of the persuaders.

4. Emotional arousal

Emotions such as anxiety or fear will also impact on an individual’s confidence in their ability to succeed at a task.

Self-efficacy beliefs will exist for any potential activity that an individual may take part in and will be situation specific (154).There has been interest in the role of self-efficacy in the management of painful conditions as it is potentially modifiable. Brister et al (155p116) describe self-efficacy in relation to chronic pain as:

“the individual’s beliefs that they can exercise control over their pain or related problems”.

A sense of personal efficacy is thought to enhance adaptation to pain (156). It is has been proposed that individuals with low self-efficacy may be reluctant to return to their usual activities due to fear of failure and uncertainty regarding their own abilities to do so (157). It is also suggested that patients who doubt their ability to control their symptoms will give up their efforts if they do not see results quickly (76). These hypotheses form the basis of many pain management approaches aimed at increasing patient’s ability to cope with their symptoms. Improving self-efficacy is also thought to facilitate maintenance of improvement following pain management treatment (158) and help to reduce pain related distress (76).

3.4.4.2 Self-efficacy as a prognostic factor

There is very little research on the influence of self-efficacy on recovery from acute or sub-acute spinal pain. In addition to the studies reported in Chapter 1, 2 other studies were identified that investigated self-efficacy and WAD. These studies were excluded from the systematic literature review because of the timing of data collection. Bunketorp et al (157) investigated self-efficacy as a prognostic factor in a sub-acute whiplash population (>6 weeks but <3months post injury). Self-efficacy (confidence to carry out activities despite pain) was predictive of outcome and explained 42% of the variance of disability at 3 month follow up (after controlling for gender, age, pain ratings and fear avoidance). These findings agree with those of Kyhlback et al (159) and Soderlund et al (160).

Soderlund and Lindberg (158) investigated a small group of chronic whiplash patients who were randomised to different physiotherapy approaches (usual physiotherapy versus additional CBT). No differences in outcome were seen between the two management approaches. However, self-efficacy (confidence to carry out activities despite pain) did influence levels of disability as patients with higher initial levels of self-efficacy tended to show lower levels of disability at 6 month follow up. Unfortunately this study only presented univariate results and did not control for other potential influences.

Self-efficacy has been investigated in LBP populations. Two studies that investigated self-efficacy and RTW provided some evidence that self-efficacy may be associated with more favourable outcomes in LBP. In the first study, higher levels of self-efficacy were associated with RTW when included in a multivariable analysis that contained other factors related to pain behaviour (147). This analysis did not control for factors such as pain intensity. In the second study, the association between self-efficacy and RTW status was investigated.

Higher self-efficacy reduced the risk of failing to RTW after making attempts to return to work. However, no association was seen with the other outcome categories of failing to return to work or partial success of returning to work. A third study also investigating LBP found that self-efficacy did not predict treatment response in participants taking part in an RCT (117).

3.4.4.3 Summary

The systematic literature review in Chapter 1 provided limited evidence that low self-efficacy was a risk factor for LWS. Two further studies investigating sub-acute and chronic WAD populations were in agreement with these findings. The evidence from other spinal conditions was lacking due to paucity of research although there was a suggestion that self-efficacy may influence RTW in participants with LBP. Theoretically, self-efficacy would appear be a concept that has the potential to influence the course of recovery and warrants further investigation in LWS to confirm previous findings.

3.4.5 Beliefs about outcome

3.4.5.1 Overview

Expectations of outcome have been demonstrated to have a powerful influence on behaviours and are thought to underlie placebo affects (161, 162). Cognitive factors such as the expectation of analgesia are associated with the activation of the pain relief pathways within the central nervous system (CNS) such as the endogenous opioid system and descending inhibitory pain pathways (161, 163, 164). Many studies have demonstrated that the circuits within the CNS known to be involved in the perception and intergration of the pain experience are susceptible to manipulation (161, 165) .These underlying mechanisms of expectancy are thought to play a central role in disability in patients with chronic pain (165) and their responses to different treatments (164). Importantly, it is thought that positive expectations are capable of inducing physiological changes within the CNS and have the potential to aid in an individual's recovery from "challenges to the organism" such as injury (161)

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Expectancies are shaped by a variety of factors including prior knowledge, direct personal experience, verbal information and observational learning (163, 166). Accordingly, health expectancies are formed through the cognitive processing of a range of factors with the individual taking into account their understanding of the causality of the situation, the expected duration or time frame of the situation, their ability to carry out the behaviour required for the desired outcome, the anticipated probability of a negative or positive outcome and the individual's goals (166). Expectations of outcome had not been considered in relation to WAD. However, when considering a chronic pain population a major influence on treatment expectancies will be the experience of multiple failed interventions leading to low expectations of treatment benefit (164). Janzen et al (166) define expectancies as "stored associations between behaviours and resulting consequences, which then guide subsequent behaviours" (p39) emphasizing once again the importance of previous experience. Boersma and Linton (150) suggest that negative expectations about recovery may partly be the product of pain related fear. They summise that if pain is interpreted as harmful then it is logical an individual would predict a poor outcome. There is some support for this theory as a relationship between expectations and fear avoidance has been demonstrated in cross-sectional analysis. It was shown that fear avoidance beliefs predict expectations of outcome in participants with LBP explaining 5% of the variance of expectation of outcome (150). However, pain frequency explained 32% of the variance of expectation of outcome suggesting that previous pain experiences was more closely related to expectations of outcome (150). Neither of these findings confirmed causality as it is not possible to do so using cross-sectional analysis.

Stewart-Williams (163) suggests that, although expectancies may have a direct influence on outcome through neurophysiological changes, their effects may also be mediated by other factors. The first is anxiety reduction, for example, an individual will feel less anxious if they are receiving a treatment they think will help. Another potential mediator of expectancies is related to schema theory (163). This theory suggests that once a schema is activated then individuals are more likely to notice any changes that are consistent with that schema. For example, if they are expecting relief from a treatment then they will notice small changes in their health they may not have normally noticed. Activation of the schema results in greater attention being paid to changes in symptoms resulting in a amplification of the effects of treatment (both positive or negative) (163). Finally, behavioural change may mediate the effects of expectancy (163). Janzen et al's (166)model of health expectancies argues that this resultant behaviour is the main way that expectations can potentially influence health outcomes. If outcome expectancy is positive then the individual will be more likely to engage in activities to obtain the desired outcome and results in greater compliance with treatment (166).

3.4.5.2 Expectations of recovery as a prognostic factor

Until recently there was very little research into expectations of recovery in the field of musculoskeletal pain conditions. A systematic review by Mondloch et al (167) found evidence that patients' recovery expectations predicted outcome in a variety of conditions including one study that investigated chronic LBP (168). Since this review by Mondloch et al (167) was published there has been greater interest investigating patient expectations as a prognostic factor for disability in a variety of pain conditions. A more recent review looked specifically at the ability of recovery expectations to predict outcome in non-chronic non-specific low back pain (NSLBP) (169). This review concluded that recovery expectations when measured within the first 3 weeks of NSLBP using a specific, time based measure can identify individuals at risk of poor outcome. There were a variety ways that expectations of recovery were measured (Table 14). Outcome measures were also variable. These included return to work status, days of sick leave, disability questionnaires such as the Oswestry Disability Index or presence of pain interfering with work or daily life. Regardless of the method of measuring expectations or outcome there were consistent findings that expectations were predictive of outcome (169). Predictive ability was strongest when measured early after onset of pain (169).

Table 14 Methods of measuring recovery expectations (169)

Methods of measuring recovering expectations	• Do you think you will be able to do your regular job without any restrictions 4 weeks from now (Yes/Not sure/Unlikely/Unable) • Do you think you will be back to your normal work within 3 months (Yes/Do not know/No) • Certainty you will be working in 6 months (0=not certain – 10=extremely certain) • Do you believe your back pain will disappear? (Yes/No) • Risk of developing chronic LBP (0=low risk – 10=high risk) • Perceived risk of not recovering (0=low risk – 10=high risk) • Expectation of recovery scale – 7 items related to workers own assessment and prediction regarding return to work, return to usual activities, progress of the injury and the expectations of those closest to them. • Expected duration of sick leave (1-10 days or >10 days)

A second recent review focused on the role of expectations in the prediction of return to work after injury (170). This review concluded there was some evidence to show that expectations did influence whether an individual was able to return to work. However, Fadyl and McPherson (170) felt that these conclusions should be drawn cautiously due to a lack of consistent definitions for RTW and valid measures of expectations. No other applicable studies were identified that were not already included in these reviews.

3.4.5.3 Expectations of treatment benefit as a prognostic factor

The discussion so far has focused on a range of expectations of recovery including how well an individual will recover, how quickly they will recover or how long they will be unable to work. Another type of expectation that warrants consideration is expectations of treatment benefit. When considering the findings of randomised controlled trials there has been interest in the influence of expectations on outcome. Four studies linked to RCTs were identified that investigated this question. No studies were identified that investigated acute spinal pain. Only one study investigated a sub-acute population (171). This study concluded that expectations of treatment benefit did not predict disability, pain or sick leave at 12 months follow up (171). The other three studies identified included a mix of both acute and chronic participants (172-174). One study reported there was no relationship between expectations of treatment benefit and outcome in patients undergoing treatment for LBP (172). The remaining two studies suggested that expectations of treatment benefit did influence outcome. However, in one study, the amount of variance of the outcome explained was small (174) and, in the other, the expected treatment benefit was only predictive in subgroups of patients but not all (173).

3.4.5.4 Summary

There is considerable support for the role of expectations of outcome as a prognostic factor in non-chronic LBP. However, no research was identified that investigated these factors in

WAD and further investigation was warranted to see if expectations of outcome also influenced outcome in WAD.

The role of expectations of treatment benefit is a potentially important concept when evaluating the effect of treatments in RCTs. It is difficult to draw firm conclusions of the role of expectations of treatment benefit in acute/sub-acute populations due to a lack of research in this area. Therefore, expectations of treatment benefit warranted further investigation as participants in this prospective cohort study were also taking part in an RCT.

3.4.6 Treatment preferences

3.4.6.1 Overview

It has been suggested that a patient's preference for treatment may influence the outcome of treatment (175) . The blinding of treatment allocation to the participant is not always possible in an RCT such as MINT where the treatment being given is obvious to participants. Hills and Kitchen (175) suggest that patients who are satisfied with their treatment are more likely to benefit from their health care, keep their appointments and comply with medical regimes. From this perspective you would expect that participants who receive their preferred treatment will be more likely to participate in and benefit from treatment. Alternatively, participants who do not receive their preferred treatment may be dissatisfied and less likely to adhere to treatment. Neurophysiological mechanisms may also be activated (a placebo-like effect) influencing outcomes (176). Similar mechanisms will be at play here that were discussed in relation to beliefs about outcome (Section 3.4.5) Individuals with strong treatment preferences may decline to take part in an RCT (176).

However, many will have an underlying preference for treatment but will still be willing to be randomised (177). This is potentially an important consideration when evaluating the effect of treatments in an RCT (177).

3.4.6.2 Treatment preferences as a prognostic factor

This is an area of recent interest to researchers. A systematic literature review by King et al (176) concluded that patient preference had little effect on outcome. The review included 2 studies that investigated treatment preference in chronic pain populations (178, 179) but provided no information about acute/sub-acute pain populations. A more recent review produced by the Preference Collaborative Review Group (180) examined the effect of treatment preference in RCTs that had collected data on patient preference at baseline. This review identified eight musculoskeletal trials upon which there were data available to carry out a meta-analysis (n=1383). The majority of studies investigated the management of neck and back pain which were primarily chronic populations or a mix of sub-acute and chronic patients. No studies included participants with acute or sub-acute spinal pain. The only study that focused on purely on a sub-acute population investigated participants with shoulder pain. After adjustment for baseline characteristics, trial and treatment allocation the review demonstrated that participants who received their treatment preference showed significantly greater benefit than those who were indifferent (mean effect size 0.162, 95% CI 0.011-0.0314, p=0.036). Surprisingly, there was no difference between those who received their preference and those that did not. Similarly, there was no significant different seen between those who did not receive their preferred treatment and those who were indifferent. However, this review provides evidence that patient preferences can influence outcome in musculoskeletal trials and this should be considered when designing randomised controlled trials.

The literature was also searched for other relevant studies that were not included in the review by the Preference Collaborative Review Group (180) . One study was identified that investigated whether treatment preference was a moderator of outcome in participants taking part in an RCT comparing treatments for chronic WAD (181). Stewart et al (181) presented a regression analysis that included baseline severity, treatment allocation, treatment preference and an interaction between the treatment allocation and treatment preference. Baseline severity and treatment allocation predicted the 6 week outcome. Treatment preference did not moderate outcome providing evidence that treatment preference did not influence short term response to treatment in chronic WAD (181). This study collected outcomes at 12 months but no further analysis was presented so the influence of treatment preference on longer term outcome is unknown.

3.4.6.3 Summary

The potential for treatment preference to influence outcome in musculoskeletal conditions has been demonstrated in a systematic literature review by the Preference Collaborative Review Group (180). However, very little is known about the influence of treatment preferences in acute/sub-acute cohorts due to a lack of research. No studies were identified that investigated treatment preference in acute/sub-acute WAD. Further investigation was warranted especially as this prospective cohort study was taking place in the context of an RCT and, therefore, treatment preferences were included in the factors investigated.

3.5 Other factors that may influence the development of LWS

To understand the true effect of patient beliefs on the development of LWS it was essential to include other potential confounding factors. The remainder of this chapter outlines other potential baseline variables that needed to be considered in the analysis.

There are many factors that may potentially influence recovery after injury. Pincus (182) recommends that psychological, social, demographic, work, and financial factors as well as information regarding clinical findings, ethnicity, lifestyle and the quality of medical care received should be included in baseline measurements of prospective studies investigating LBP. Many of these factors could also be important in understanding LWS. However, it was important to be selective when choosing factors so as to reduce the chance of problems associated with multiple testing due to type I errors. There was also little or no available evidence to suggest many of these factors influenced outcome in WAD. It was also important to consider the demands placed on participants as data was collected alongside data for the main trial.

Six systematic literature reviews were identified that investigated the prognosis of whiplash injuries to guide the choice of factors (19-21, 183-185). There was variability in the findings of the different systematic reviews due to the different methods used. For example, Walton et al (185) carried out meta-analysis but this limited the review to articles with enough data to carry out the meta-analysis. There were also differences in the criteria for selecting articles for example, Williams et al (21) included studies if the baseline data was collected within 6 weeks of injury but Walton et al (185) used a cut off of 3 weeks. Not all the reviews included all the factors of interest. For example, Kamper et al (184) included prognostic factors for which univariate analyses was reported in at least two cohorts so excluded factors only reported in one cohort. Also, the type of prognostic factors included was dependent on the studies available at the time of each review being carried out. Where the strength of evidence is deemed inconsistent the review reported studies with conflicting findings.

3.5.1 Initial injury severity

It is a sensible assumption that individuals with more severe injuries will be more likely to have a poor outcome. Measures of initial injury severity have been acknowledged as predictors of outcome in the literature (Table 15). These variables reflect the types of information that physiotherapists routinely assess in clinical practice so it was felt it was important that they be included. There is clear support for the measurement of initial pain intensity and initial neck pain related disability. The evidence for other factors was not as clear cut which suggested that further investigation was warranted.

Table 15 Injury severity factors included

Baseline injury severity factors to be included in this study	**Strength of evidence as presented in systematic literature reviews**
Baseline pain intensity	Strong evidence that high pain intensity is associated with poor outcome (19, 185) Consistent evidence (20, 183, 184) Moderate evidence (21)
Baseline neck related disability	Moderate evidence that a high level of disability is associated with poor outcome (21) Consistent evidence (183, 184)
WAD grade	Strong evidence that WAD grade II or III are associated with poor outcome compared to WAD I (185) Consistent evidence (183) Inconsistent evidence (19, 21, 184)
Cervical ROM	Limited evidence that restricted ROM is associated with poor outcome (19) Inconsistent (19, 21, 184)
High initial number of symptoms	Limited evidence that a higher number of symptoms is associated with poor outcome (19) Consistent evidence (111) Inconsistent evidence (21, 184)
Radicular symptoms	Consistent evidence that the presence of radicular symptoms is related to poor outcome (20) Inconsistent (19, 21, 184)

3.5.2 Psychological response to injury

The completed systematic review concluded an elevated level of post traumatic stress was predictive of LWS but that general psychological distress was not. It is common for individuals with chronic pain to experience negative psychological states such as anxiety, depression and anger (99). Psychological distress is thought to play a role in maladjustment to persistent pain (100). Several systematic literature reviews have consistently reported that distress (a term used to encompass psychological distress, anxiety, depressive symptoms and depressive mood) predicts poor outcome following an episode of LBP (22, 69, 70). The discussion on fear avoidance beliefs (see Section 3.4.3) also demonstrated that when a measure of distress was included in the analysis that fear avoidance failed to be predictive of outcome in acute LBP(152). This suggested that it was important to control for the affects of distress when analysing this prospective cohort study. Therefore, a measure of psychological distress was included as well as post traumatic stress reaction.

3.5.3 Pre-existing factors

It is thought that an individual’s previous experiences of pain will influence how they manage subsequent painful experiences (186). This may partly be due to learnt pain behaviours but also due to changes within the nervous system that may result in increased sensitivity to pain (Butler 2000). There was some evidence from the identified systematic literatures that a history of neck pain and the presence of pre-existing chronic widespread pain were potential risk factors for poor outcome in WAD (Table 16). For this reason both a history of previous neck pain and pre-existing chronic widespread pain were included for further investigation.

It is often taken for granted that older people will recover less well from injury but findings from five of the identified systematic review were conflicting (See Table 16). It remains unclear whether age is predictive of poor outcome in WAD but it warranted further investigation.

The final pre-existing factor to be included was social support. According to Ogden (28p212), social support refers to the: “perceived comfort, caring, esteem or help one individual receives from another” . The systematic literature in Chapter 1 concluded that there was limited evidence that social support was predictive of LWS. However, this was based on one study and requires further clarification as social support has been linked to health outcomes in a variety of conditions including heart disease (187), rheumatoid arthritis (188) and depression (189). Cobb (190) proposed that social support has a protective mechanism that can facilitate recovery from illness and compliance with treatment. Uchino (191) suggests two mechanisms by which social support may influence outcome. Firstly, social support may facilitate behaviours contributing to recovery and, secondly, it may have psychological influences such as reducing stress. There was evidence in two systematic literature reviews that social support is influential in determining outcome in musculoskeletal conditions. Steenstra et al (192) found that there was strong evidence that factors related to social support (social dysfunction and social isolation) prolongs duration of sick leave in individuals with acute LBP (overall pooled effect size 1.76 (1.01 to 3.06)). Mallen et al (193) reported low levels of social support as a generic risk factor for poor outcome in individuals with musculoskeletal pain who seek treatment in primary care. These reviews suggested that the role of social support in the development of LWS warranted further investigation.

Table 16 Pre-existing factors

Pre-existing factors to be included in this study	**Strength of evidence as presented in systematic literature reviews**
History of neck pain	Moderate evidence that a history of neck pain increases the risk of poor outcome (185) Inconsistent evidence (20, 21, 183, 184)
Chronic widespread pain	Limited evidence that pre-existing chronic widespread pain increases the risk of poor outcome (21)
Age	Consistent evidence that older age increases the risk of poor outcome (20) Almost significant (185) Inconsistent (183) Strong evidence against (19) Consistent evidence against (184)
Sex	Consistent evidence that being female is associated with poor outcome (20, 184, 185) Inconsistent evidence (183) Strong evidence against (19)
Social support	Not included in any of the identified systematic literature reviews.

3.5.4 Treatment factors

As this thesis is investigating outcome following physiotherapy treatment then the type of treatment must be included in the analysis to control for the effect of the treatment received. Another factor related to treatment is treatment attendance. This is one aspect of adherence (194). It has been hypothesized there is potentially a dose response between a treatment and the outcome. This suggests that if a patient completes their treatment as intended then a better outcome is achieved (195). Adherence has been shown to be related to outcomes in a number of conditions including anterior cruciate ligament reconstruction (196), low back pain (195, 197) and wrist fracture (198). The influence of treatment attendance on recovery in LWS is unknown but may potentially influence outcome so warranted further investigation.

3.6 Summary

This chapter has presented the development of the prospective cohort study that was carried out as part of this thesis. A summary of the baseline factors to be included in the prospective cohort study are listed in Table 17. The methods and results will be presented in the following chapters.

Table 17 Summary of baseline factors

Patient held beliefs about injury and recovery	Use of active or passive coping strategies Catastrophising Fear avoidance beliefs Self-efficacy Beliefs about outcome – expectations of outcome Beliefs about outcome – expectations of treatment benefit Treatment preferences
Injury severity factors	Pain intensity Neck pain related disability WAD grade Number of physical symptoms Cervical ROM
Psychological response factors	Post traumatic stress reaction Psychological distress
Pre-existing factors	Age Sex Pre-existing neck pain or chronic widespread pain Social support
Treatment factors	Treatment allocation Treatment attendance

4.0 Prospective cohort study: methods

4.1 Aims of the prospective cohort study

(1) To describe the clinical presentation and course of recovery of participants who have experienced an acute whiplash injury.

(2) To identify baseline factors predictive of recovery status (classified as having developed LWS or not) following an acute whiplash injury.

(3) To identify baseline factors predictive of Neck Disability Index scores at follow up in participants who experienced an acute whiplash injury.

(4) To identify baseline factors predictive of participant perceived improvement and compare these findings to those based on recovery status and NDI scores.

(5) To identify specific conditions under which the belief factors that were predictive of recovery status operate in relation to other baseline belief factors and treatment received as part of MINT (i.e. did other baseline beliefs or treatment moderate the effect of identified predictor variables?).

4.2 Patient Sample

4.2.1 Sample size

All participants taking part in this prospective cohort study were also taking part in Step 2 of MINT so the sample size was predetermined by MINT. The primary outcome for MINT was the Neck Disability Index. MINT aimed to detect a 3 point difference between the two groups being compared. It was determined that 211 per group were required, based on

90% power and 1% significance level. Allowing for a 30% loss to follow-up a total sample size of 300 per group was needed (600 in total).

When investigating a large number of variables there is a risk of type I errors (identifying an association when none exists) (269p87) if the sample size is not sufficiently large. However, it was thought that a sample size of 600 would be adequate for this prospective cohort study. Altman (32) provides a general rule of thumb that a minimum of 10 participants per variable included in a multivariable logistic regression analysis is needed. Pincus et al (22) suggests that at least 300 participants are needed for multivariable modelling. Based on these assumptions the sample size of 600 was adequate as the maximum number of baseline variables that could have potentially been included in the multivariable logistic regression analysis was 24. Another method of determining adequate sample size for studies using logistic regression analysis has been suggested. Peduzzi et al (312) recommend that a minimum of 10 participants classified as the outcome of interest (i.e. non-recovered or having developed LWS at follow up) are needed for each variable included in the logistic regression model. Based on this assumption the final logistic regression models at 4, 8 and 12 months were large enough to include 27, 20 and 18 variables respectively. The number of variables included in each of the final models was less than these values also indicating that the sample size was adequate for this study.

4.2.2 Brief overview of MINT

MINT tested a stepped care approach to the management of acute whiplash injuries. A stepped care approach matches the intervention to the needs of the patient, providing more intensive treatments to those with more severe clinical presentation (199). Step 1 investigated educational interventions in a National Health Service (NHS) Emergency Department (ED) setting (n=3533) (200) . Advice based on the Whiplash Book was compared to the usual ED advice. The WB is an educational booklet aimed at self-management and preventing chronic disability (201, 202). It provides extensive information about whiplash injuries and how to recover including exercises. Usual care advice leaflets were much briefer than the Whiplash Book and provide very limited information about injury management. See Appendix 1 for more information.

Participants in Step 1 were able to self-refer to Step 2 for further treatments if they were experiencing ongoing problems approximately 3 weeks post injury. Step 2 investigated the effectiveness of additional physiotherapy for those with ongoing symptoms three to six weeks after their injury (n=599). Patients were randomised to receive a package of physiotherapy or a control intervention (an advice session with a physiotherapist) (203). The physiotherapy package consisted of an assessment and up to 6 treatment sessions comprising of manual therapy, exercises, psychological strategies and self-management advice. The control intervention was a single advice session based on the advice given in the ED. This involved a brief assessment, revising the advice and exercises provided in the ED information (Whiplash Book or usual care leaflet) and answering questions. See Appendix 2 for further information.

4.2.3 Eligibility criteria

The eligibility criteria for the prospective cohort study were the same as Step 2 of MINT.

The inclusion criteria were as follows:

- Aged 18 years or over
- Able to give informed consent
- Less than six weeks post whiplash injury
- WAD grade I – III
- Neck symptoms reported in the 24 hours prior to assessment

The exclusion criteria were as follows:

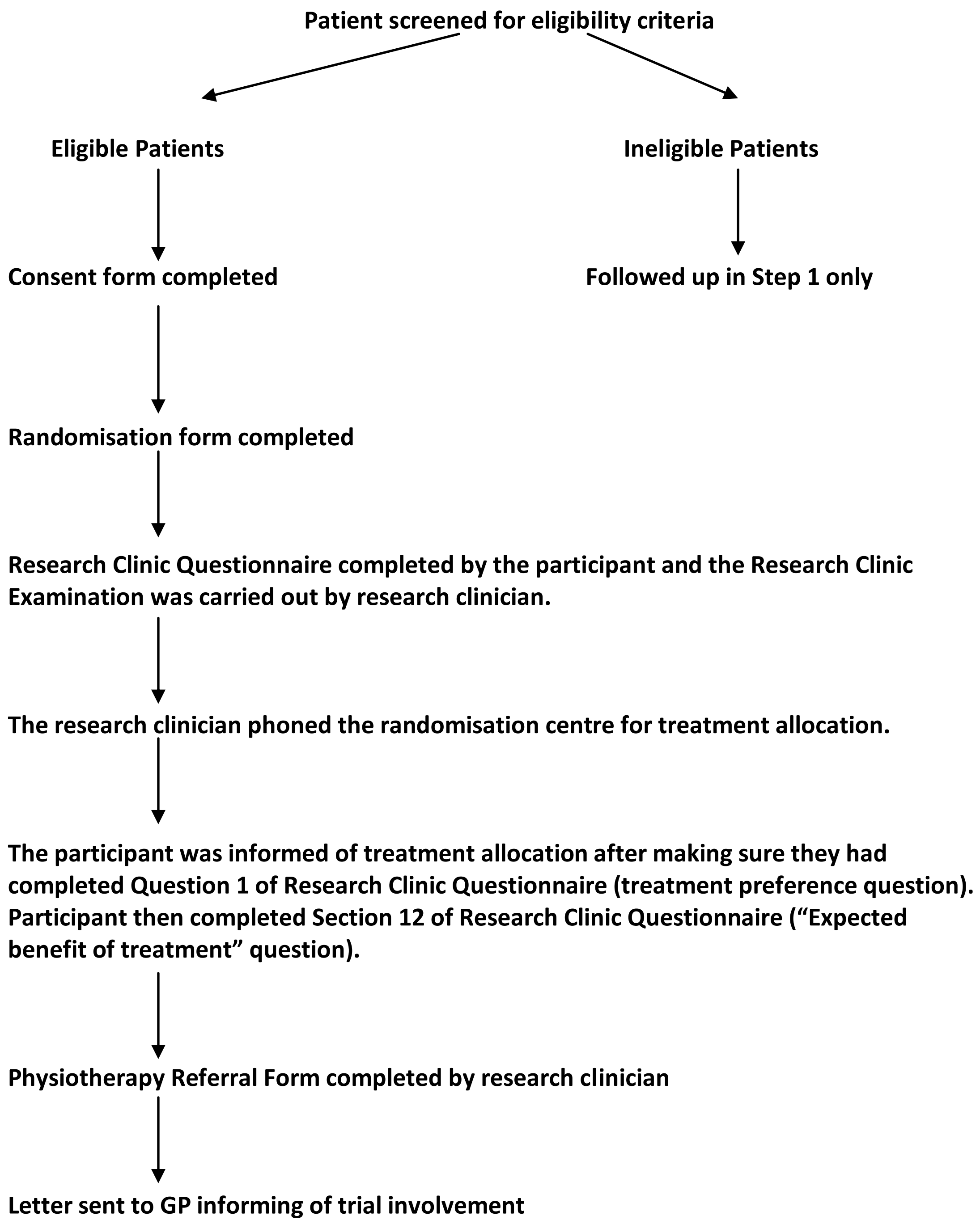
- Contraindications to Physiotherapy:
  - Central cord compression/upper motor neuron lesion
  - Complete nerve root compression/lower motor neuron lesion
  - Suspected vascular injury/haemorrhagic event
- Sustained a head injury with more than a transient loss of consciousness or with a Glasgow Coma Score of 12 or less at any stage of their assessment in hospital
- Sustained a fracture or was admitted to in-patient services
- Mental health disorders that would interfere with treatment

4.3 Data Collection

Baseline data was collected from January 2006 until November 2008. It was primarily collected when participants attended a research clinic to be assessed for eligibility for Step 2 of MINT. See Figure 6 for research clinic procedures. The majority of data came from the Research Clinic Questionnaire (See Appendix 3). A standardised examination (Research Clinic Assessment) was also completed by the research clinician (See Appendix

4). Data collection was carried out by the MINT research clinicians (physiotherapists and nurses). All research clinicians received training in data collection procedures. They were trained to ensure questionnaires were completed appropriately and in the use of the Cervical Range of Movement (CROM) device to measure neck ROM. Quality control visits were carried out to ensure that procedures were carried out correctly. Some data also came from the ED proforma (WAD grade in ED) and the main trial baseline questionnaire (history of previous neck pain). Follow up was carried out at 4, 8 and 12 months post ED attendance by postal questionnaire using the same questionnaires as Step 2 of MINT.

Figure 6 Research clinic procedures



Patient screened for eligibility criteria

Eligible Patients

Ineligible Patients

Consent form completed

Followed up in Step 1 only

Randomisation form completed

Research Clinic Questionnaire completed by the participant and the Research Clinic Examination was carried out by research clinician.

The research clinician phoned the randomisation centre for treatment allocation.

The participant was informed of treatment allocation after making sure they had completed Question 1 of Research Clinic Questionnaire (treatment preference question). Participant then completed Section 12 of Research Clinic Questionnaire ("Expected benefit of treatment" question).

Physiotherapy Referral Form completed by research clinician

Letter sent to GP informing of trial involvement

4.4 Selecting measurement tools

Following the identification of the factors to be included in the prospective cohort study, appropriate ways to measure each one needed to be identified. The literature was searched to identify the most commonly used methods of measurement for which there was evidence of reliability and validity. The following factors were taken into consideration:

1. The methods of measurement needed to be reliable. Reliability refers to the ability of an instrument to produce the same measurement when administered more than once and there is no evidence of change (204). Streiner and Norman (205) outline two main considerations when assessing reliability of a measure:

   Internal consistency: A measure of internal consistency is frequently reported as a measure of reliability (205). This involves testing for homogeneity amongst items that make up the questionnaire (204). Tests assess whether the responses to individual items are inter-correlated as well as showing correlation with the total score (204). Internal consistency is most commonly tested by calculating Cronbach's alpha which is a measure of the average correlation between items and the number of items in the questionnaire (204). One suggested minimal acceptable level for the Cronbach's alpha is 0.80 (205). A high Cronbach's alpha (such as 0.8) suggests that the responses to individual items are consistent and that all items in the questionnaire come from the same conceptual domain (i.e. the construct being measured such as disability). A high level of internal consistency in a measurement tool would appear desirable, however, in tools that measure more than one facet of health this may not be the case (206). Also, if there is high correlation between all the factors in a measurement tool then it may be that some items are redundant (206). A moderate level of internal consistency may be preferable so that each item adds new information to the measurement (206).

Stability: Stability refers to the reproducibility of a measure (205). Streiner and Norman (205) consider evidence of stability as more important than internal consistency when considering reliability. There are different types of stability to consider. Intra-tester reliability refers to the ability of an instrument to produce the same measurements when applied repeatedly by the same assessor on different occasions on the same subject (204, 205). Inter-tester reliability refers the ability of an instrument to produce the same measurements when applied by different assessors on a single occasion (204, 205). Another consideration is test-retest reliability which measures stability of a measure over time (204). An instrument is administered repeatedly over a period time on subjects where no change is expected to be seen in the domain being measured (204). A re-test interval of 2 to 14 days is generally used (205).

Different approaches may be used to assess reliability (205). The calculation of a reliability coefficient is frequently used and different methods are used depending on the type of data used (204, 205). Pearson's product-moment correlation is very commonly used (205). What is considered an acceptable level of correlation varies in the literature. It is suggested that a value <0.40 represents slight/poor agreement, 0.40-0.59 is fair/moderate agreement, 0.60-.074 is good agreement and 0.75 to 1.00 is excellent agreement (204). Streiner and Norman (205) recommend that a reliability coefficient of >0.50 is the minimum requirement but it will depend on a the test and the cost of misinterpretation. MacDowell (206) considers values >0.85 to be acceptable.

A second approach and often preferred method of calculating reliability is the use of an intra-class correlation co-efficient (ICC) (205,206). One reason for this is that measures such as Pearson's correlation coefficient do not take into consideration within subject or tester variance. For example, two sets of measurements may be highly correlated but actually show little agreement between the two sets of scores when the individual pairs of scores are examined (204, 205). The ICC takes this variability into consideration. It provides a measure of the similarity between the individual subjects actual scores rather than similarity in the relative standings of the overall scores (205,206). Measures such as Pearson's correlation coefficient tend to produce higher reliability measures than the ICC (205,206). An ICC >0.80 indicates an instrument is highly reliable (204).

Bland and Altman suggest another method to assess repeatability of a measure (207). This involves the construction of a Bland-Altman plot which plots the difference between the two sets of measurements against the mean of the two sets of measurements (207). This enables the calculation of the co-efficient of reliability which indicates the range of differences observed between the two sets of measurements (207). Whether this difference is clinically important will depend on the actual measure being investigated (207). This method provides important information on what may be considered an actual difference in scores (i.e. not one due to measurement error) when assessing clinical outcomes. This method was not used in any of the studies identified when examining the literature on measures for this study.

2. The methods of measurement needed to be valid. Validity is defined as:

   “the extent to which an instrument measures what is intended” (204p19).

   There are several types of validity but concurrent validity is most often reported when considering factors related to pain or disability and is commonly reported as evidence of validity (206). Concurrent validity evaluates how well one measure correlates with another measure of the same construct. This is usually done by calculation of correlation coefficients but should be interpreted cautiously as the same problems arise as described earlier that they quantify the association between two measures but not the agreement (206). Predictive validity may also be reported which compares the predictive value of one measure to another (204).

3. As data collection was taking place alongside the main trial data the burden placed on participants needed to be considered. It was hoped that the research clinic would take no longer than one hour. In this time the participant was provided with information about the trial, screened for eligibility, consented and randomised, completed a baseline questionnaire and had a physical assessment. It is estimated this process generally took between 45 minutes and one hour for each participant.

4.5 Baseline measurements – injury severity factors

4.5.1 Neck Disability Index (NDI)

The NDI is a measure of self-reported neck pain related disability (208). It consists of 10 questions that ask about pain intensity, personal care, lifting, reading, headache, concentration, work, driving, sleeping and recreation. Each question is rated on a 0-5 scale resulting in a total score out of 50. In this study the score was been converted to a percentage score (0-100) with a higher score indicating greater neck pain related disability.

The NDI is the most commonly used outcome measure for neck pain (209) and is considered to have adequate reliability in terms of test-retest and internal consistency (See Table 18 (p124)). A comprehensive systematic literature review reported test-retest reliability ranging from fair to excellent in 13 studies with 9 studies demonstrating excellent test-retest reliability (209). This questionnaire has been tested specifically in a WAD population and internal consistency was high in this population (210). A high level of internal consistency was confirmed by examining the responses of participants in this study (Cronbach's α=0.87).

Multiple comparisons have been made between the NDI and other measures. Overall, the content of the NDI has demonstrated validity as a measure of pain and disability in a range of neck conditions (209). Specific to a population with WAD, moderate correlations between NDI scores and pain intensity and pain interference with activity have been reported (210).

4.5.2 Modified Von-Korff Pain Scale

Von Korff et al (211) developed the Chronic Pain Grade Questionnaire as a simple method to grade the severity of chronic pain. It includes patient ratings of disability, pain intensity, days in pain and time since onset. This study used a modified version of the pain measure from the Chronic Pain Grade Questionnaire known as the Modified Von Korff (MVK) Pain Scale (212). The MVK Pain Scale assesses LBP over the last four weeks rather than 6 months as measured by the original questionnaire (212). This study used the MVK Pain Scale as described by Underwood et al (212) with some further modifications. Neck pain has been substituted for back pain. As participants in MINT had an acute injury which would potentially be improving over time a shorter time frame (one week) was used to capture pain intensity.

The MVK pain scale is the average of three scores: 1) pain right now, 2) the worst pain over the last week and 3) the average pain over the last week. Participants rated each one on a 0-10 scale. The average score is converted to a 0-100 score with a higher score indicating greater pain intensity.

Information regarding validity and reliability is limited (See Table 18). The Chronic Pain Grade Questionnaire has been shown to be reliable and valid in a population of chronic pain patients in the UK (213). Test-retest reliability of the MVK pain scale was examined in a community sample with stable LBP symptoms and was shown to have good repeatability (212). The MVK pain scale demonstrated moderate correlation with both the pain and physical function scales of the SF-36 (212). It is acknowledged that test-retest reliability and validity of the MVK pain scale have not been tested in a population with neck pain or over a one week time frame. However, a high level of internal consistency was confirmed by examining the responses of participants in this study (Cronbach's α=0.89).

4.5.3 Physical symptoms scale from the Cervical Spine Outcomes Questionnaire (CSOQ)

The CSOQ is an instrument for measuring complaints of the neck consisting of 6 subscales (214). The physical symptoms scale was used in this study to measure the number of symptoms experienced including radicular symptoms. Participants were given a list of 15 symptoms and asked to indicate if they were present or not. This included: 10 areas of pain and 5 other symptoms (difficulty swallowing, headaches, neurological symptoms in arms or legs, problems with hand and leg function). This resulted in a score out of 15 with a higher score indicating a greater number of physical symptoms.

Information regarding reliability and validity for the physical symptoms scale is limited (See Table 18). BenDebba et al (214) reported good test-retest reliability for the symptoms other than pain but did not report test-retest reliability on the number of pain symptoms. The report of the number of symptoms experienced has been used as a marker for injury severity before in studies investigating prognostic factors in WAD suggesting such a measure has validity in a WAD population (40, 47, 54). The recording of painful areas has also been used in the assessment of a variety of conditions and populations such as knee osteoarthritis (215), pain in nursing home residents (216), rheumatology patients and post-operative patients (217) and it has been shown to be reliable.

4.5.4 WAD grade

WAD grade was assessed using the system recommended by the Quebec task force and described in the Introduction (Table 2). WAD grade was assessed twice, firstly, when participants were assessed in the ED and, secondly, at the research clinic. Both were included in the analysis.

This system of WAD grading is used frequently in the whiplash literature and has been used as a baseline variable in other studies investigating prognosis in whiplash (159, 218-220). One criticism of the WAD system is its lack of ability to predict outcome (221). This may be because the WAD II classification includes a wide variety of symptoms and lacks the ability to discriminate between those with relatively mild symptoms and those with more severe ones (221). Despite its frequent use there is no information available on its reliability or validity. Acknowledging these shortcomings it remains in common use in the whiplash literature so it was included in this study.

4.5.5 Total active cervical range of movement (ROM)

Neck range of movement was measured using a Cervical Range of Movement (CROM) Device (Performance Attainment Associates, USA). The CROM device consists of a plastic frame worn like a pair of glasses. There are two gravity inclinometers and one compass goniometer mounted on the frame allowing the measurement of movement in three planes (Figure 7). The CROM device measures ROM in 2 degree increments.

All participants were positioned in a chair sitting with hips and knees at 90 degrees and their feet flat on the floor while hands rested on their lap. Standardised instructions were provided to ensure consistency in the measurements. For example, when measuring cervical extension the following instructions were given:

“I want you to look up at the ceiling as far as you feel possible, like this [demonstrate extension]. Make sure your mouth is closed. I want you to hold this position whilst I read the dial. Make sure you don’t let your head twist or drop or the side as you do this and keep sitting straight up. I will place my hand on your back to correct this if necessary.”

The movements were measured in a set order: flexion, extension, rotation to the right, rotation to the left, lateral flexion to the right and cervical lateral flexion to the left. To limit the number of factors in the analysis a total cervical ROM measurement was used by adding together the 6 measurements. This approach has been used previously and found to be predictive of disability one year after injury (37).

The CROM device was chosen to measure cervical ROM as it has been found to have “good” reliability and validity when used to measure active cervical ROM in both symptomatic and asymptomatic individuals (222) (See Table 18). In addition the CROM device was easily transportable, affordable and simple to use.

Figure 7 The CROM device (Performance Attainment Associates, USA)

Table 18 The validity and reliability of measures of injury severity

Questionnaire or method of measurement	**Validity**	**Reliability**
Neck Disability Index (208)	Correlates with pain intensity and pain interference in WAD population (r= 0.51 and 0.50 respectively) (210).	Test-retest reliability: r=0.48 – 0.99; ICC=0.50-0.98 (209, 223). Internal consistency: Cronbachs α = 0.70 to 0.96 (209, 223). Internal consistency in WAD population cronbach's α= 0.87 (210).
Modified Von-Korff Scale (212)	Correlates with pain and physical function scales of the SF-36 (r= -0.67 and -.64 respectively) (212)	Test-retest reliability: ICC=0.82 (212)
Physical symptoms scale of CSOQ (214)	No information available	Test-retest reliability for the non pain symptoms: ICC = 0.86 (214).
Cervical Range of Movement (CROM) device	Reported to have "good" validity". For example CROM device measurements correlates highly with X-ray measurements (r=0.98 for cervical extension) (222).	Reported to have "good" reliability. For example, intra-rater reliability measuring cervical extension ICC = 0.90-0.97 (222).

r=pearsons correlation coefficient, ICC = Intraclass correlation coefficient

4.6 Baseline measurements - patient beliefs

4.6.1 Fear Avoidance Beliefs Questionnaire physical activity subscale (FABQpa)

The FABQ was developed to assess patient beliefs with regard to the effect of physical activity and work on their LBP (136). As this study assessed patient beliefs about neck pain the words “back pain” were replaced with “neck pain” as has been done in other studies (224). The FABQ contains two subscales and this study used the physical activity subscale (FABQpa) which consists of 4 questions. Patients rate their agreement with each statement on a 7 point likert scale (0= completely disagree, 6=completely agree) resulting in a score out of 24. A higher score indicates more strongly held fear avoidance beliefs.

The FABQpa is a commonly used measure of fear avoidance beliefs but it had not been used in a whiplash population before. Another measure of fear avoidance (Tampa Scale of Kinesiophobia (TSK) (72) was used in the studies described in the systematic literature review (Chapter 1) and it was shown to be predictive of LWS in one study but not the other (44, 50). For this reason it was felt that an alternative measure should be tested. The FABQpa is also considerably shorter than the TSK which was an important consideration due to the time restraints of data collection. The FABQpa has been found to be a valid and reliable measure of fear avoidance (See Table 19 (p131)). Although the majority of work is in LBP, there is also evidence that it is a highly reliable measure in a neck pain population(225). A high level of internal consistency was confirmed by examining the responses of participants in this study (Cronbach’s α=0.80).

4.6.2 Pain Catastrophising Scale (PCS)

The PCS measures the frequency with which an individual expresses catastrophic thoughts when they are in pain (74). It contains 13 statements which the individual rates from 0 (not at all) to 4 (all the time) resulting in a score out of 52 with a higher score indicating a greater frequency of catastrophic thinking about pain. It is reported to have 3 subscales (magnification, rumination and helplessness) (74).

The reliability and validity of the PCS has been examined across a range of conditions demonstrating it was a robust measure of catastrophising (See Table 19). Importantly, there was evidence that it was a reliable and valid measure in a WAD population (226). A high level of internal consistency was confirmed by examining the responses of participants in this study (Cronbach's α=0.95).

4.6.3 Beliefs about doing neck exercises to help recovery after neck injury

This question was constructed for the purpose of this study to elicit beliefs about doing neck exercises after a neck injury. The aim of this question was to elicit beliefs specifically about exercising their neck as opposed to their beliefs about activity in general as is captured by the FABQpa. Participants were asked to rate their agreement with the statement "When you have injured your neck it is best to exercise your neck to help you recover" on a 7 point likert scale (0-6). The likert scale was anchored at each end by statements "completely disagree" and "completely agree" with the midpoint labelled "unsure". A higher score indicated greater agreement with the statement.

When the question was designed the published recommendations for the optimal number of response categories were considered. Preston and Colman (227) suggest that likert scales containing 7-10 response categories are the most reliable (correlation co-efficient ranging from 0.93-0.94) and are generally acceptable to research participants (227). A 7 point scale was chosen as this allowed the question to be formatted in the same way as the FABQpa to assist in the participants' ease of completion.

4.6.4 Self-efficacy - participant rated ability to cope with their neck problem

This question was also constructed for the purpose of this study to elicit patient beliefs about their ability to cope with their neck problem (self-efficacy). The patient rated their ability to cope with their neck problem by indicating their agreement with the statement "I feel I am able to cope with my neck problem even when it is painful" on a 7 point likert scale (0-6). The likert scale was anchored at each end by statements "completely disagree" and "completely agree" with the midpoint labelled "unsure". A higher score indicated greater agreement with the statement.

When designing the question, the same factors were considered as described above in Section 4.6.3. The decision to use a single question to measure self-efficacy was an attempt to limit the amount of information being collected at the research clinic. It was thought that the inclusion of another lengthy questionnaire (such as the pain self-efficacy questionnaire used by Soderlund et al (160)) was placing too much of a demand on participants.

4.6.5 Treatment preferences

To elicit participants' treatment preferences, the participants indicated their preferred treatment from the following options: one session of advice with a physiotherapist, I don't mind which treatment I receive or a course of physiotherapy. Participants completed the question prior to randomisation. This question has been used in other studies looking at treatment preferences in physiotherapy trials and as recommended by a recent systematic literature review (180, 228).

4.6.6 Participant rated expected benefit of treatment

Participants were asked to rate the expected benefit of the treatment they would receive as part of MINT. This question was taken from the credibility/expectancy questionnaire which is a series of questions derived by Devilly and Borkovec (229) and Borkovec and Nau (230) to assess treatment expectancy and credibility. Participants were asked "how confident are you that this treatment will be successful in reducing the symptoms due to your recent injury?" Responses were proved on an 11 point likert scale where 0 = "no confidence at all" and 10 = "complete confidence". Participants completed this question after randomisation, and when treatment allocation was known.

There was limited information available on the reliability of the credibility/expectancy questionnaire but the whole questionnaire has demonstrated a high level of test-retest reliability (229) (See Table 19). A single question was chosen rather than the whole questionnaire due to the time limitations of data collection.

4.6.7 Participant predicted time to recovery

This question was constructed for the purpose of this study to ascertain the participants' beliefs about the length of time it would take them to recover from their injury. The literature was searched to identify any established questionnaire that could be included, however, none were found. Participants were asked "How long do you think it will take you to recover from your neck injury"? Participants indicated one of six options: "In the next two weeks", "2-8 weeks", "2-6 months", "6-12 months", "More than a year" and "I am not sure I will recover". These boundaries were chosen as it was felt that they represented clear timeframes that participants would be able to distinguish from each other. It also provided a way to identify participants who felt their symptoms would persist beyond 6 months which is the time frame specified in the definition of LWS (11).

4.6.8 Coping Strategies Questionnaire (CSQ) – short version

The original CSQ assessed the frequency of use of different pain coping strategies (231). However, it contains 42 questions so Jensen et al (232) developed a short version of the CSQ to reduce the time needed for assessment. The original CSQ has 7 subscales (diverting attention, reinterpreting pain sensations, ignoring sensations, coping self statements and increased behavioural activities, catastrophising and hoping/praying) The short version of the CSQ takes one statement from each of the subscales and, therefore, consists of seven statements describing seven coping behaviours. Participants were asked to rate how often they engaged in the activity when they feel pain on a scale of 0 "never do" to 6 "always do that".

The original CSQ is a reliable and valid measure (231-233) (See Table 19). The short version of the CSQ was thought to be a suitable compromise. The single items chosen were those that showed the highest level of correlation with the subscale they belonged to (Jensen et al, 2003). Moderate to high correlations between the individual items and the original subscales were reported. This suggested that the single items were an adequate representation of the coping strategy measured by the original subscales.

The subscales of the CSQ have been categorised as active and passive coping strategies (110). For the purpose of this study the items were grouped based on the recommendations by Snow-Turek et al to produce two subscales. (110). The first representing the use of passive coping strategies and the second representing the use of active coping strategies. Two items were included the passive coping strategies score (catastrophising and praying/hoping items) which resulted in a score out of 12 with a higher score indicating great use of passive coping strategies. An acceptable level of internal consistency for the passive subscale was confirmed by examining the responses of participants in this study (Cronbach's α=0.73). Five items were included in the active coping strategies score (diverting attention, reinterpreting pain sensations, ignoring sensations, coping self statements and increased behavioural activities items) which resulted in a score out of 30 with a higher score indicating greater use of active coping strategies. An acceptable level of internal consistency for the active subscale was confirmed by examining the responses of participants in this study (Cronbach's α=0.63).

Table 19 The validity and reliability of measures of patient beliefs

Questionnaire or method of measurement	Validity	Reliability
Fear-avoidance beliefs questionnaire (physical activity scale) (136)	Correlates with another measure of fear-avoidance (72) in back pain populations (r=0.76) and neck pain populations (r= 0.44) (225, 234)	Test-retest reliability - ICC= 0.72 to 0.90 (235, 236) In patients with neck pain the FABQpa internal consistency - Cronbach's α=0.92 and retest reliability - r=0.85 (225).
Pain Catastrophising Scale (74)	Correlates with depression (r = 0.26 - 0.61) (74, 226, 237, 238), disability (r=0.57)(237), fear avoidance (r=0.51 (237) and pain ratings (r=0.26 to 0.57) (74, 226, 237-239)	Internal consistency - Cronbachs α =0.87- 0.95 (74, 226, 237-240). Test-retest reliability – ICCs= 0.80 to 0.96 and r=0.68-0.76 (74, 226, 237, 238).
Participant rated expectations of treatment benefit measured on an 11 point likert scale	No information available.	Test-retest reliability – r=0.83 for total questionnaire (229).
Coping Strategy Questionnaire- short version (232)	Individual items showed significant correlations with the relevant subscales from the original CSQ (r=0.58-0.85) (232)	No information available.

r=pearsons correlation coefficient, ICC = Intraclass correlation coefficient

4.7 Baseline measurements - psychological response factors

4.7.1 Impact of Events Scale (IES)

The IES (75) measures subjective distress related to a specific life event (242 p23). It can be used to assess psychological distress after any major life event (241). The IES consists of two subscales – intrusion and avoidance (241). The participant is asked to report the frequency of 15 symptoms in the past 7 days from a choice of “not at all”, “rarely”, “sometimes” or “often” which are assigned 0, 1, 3, or 5 points respectively. This results in a score out of 75 with a higher score indicating more severe psychological distress.

The IES was designed for use in a clinical setting as a measure of symptom severity or change in symptoms as treatment progresses and not as a diagnostic tool (242p23). The IES is not a suitable measure of Post Traumatic Stress Disorder (PTSD) and should not be used to diagnose PTSD (68, 242p23). PTSD is characterised by three groups of symptoms (intrusion, avoidance and hyperarousal) which must be present to make a diagnosis of PTSD (243). The IES does not assess hyperarousal symptoms and it is lacking in the range of intrusive and avoidant symptoms that it includes (68, 242p23). In addition, in PTSD these symptoms must be present for at least a month but the IES only measures symptoms over the last 7 days (68, 243). Acknowledging this limitation, it was felt that the IES was an appropriate measure of distress in WAD as there is evidence that it is predictive of future disability in this population (50). The internal consistency and test-retest reliability were both reported as satisfactory (68) (Table 20 (p134)). The IES also displayed concurrent validity as has been shown to correlate significantly with measures of PTSD and other measures of psychological distress (68). A high level of internal consistency was confirmed by examining the responses of participants in this study (Cronbach's α=0.91).

4.7.2 General Health Questionnare-12 (GHQ-12)

The GHQ-12 was developed by Goldberg and Williams (244). Sanchez-Lopez and Dresch (245) describe it as a measure of psychological well-being and as the most commonly used tool for screening for psychiatric disorders. The purpose of the GHQ-12 is not to provide a diagnosis but to identify individuals with psychiatric disorders (i.e. psychiatric cases) (204p85-86) . The GHQ mainly measures anxiety and depression although it contains questions that include somatic and functional status (204p27). The GHQ-12 consists of 12 items which assess the severity of different problems over the past few weeks. The respondent selects one of four options for each question, for example, better than usual, same as usual, less than usual or much less than usual. Several scoring systems have been described but the standard scoring system of 1,1,0,0 has been used in this study resulting in a score out of 12 (244, 246). A higher score indicates greater psychological distress or worse psychological well-being.

The reliability and validity of the GHQ-12 is well established and has been studied extensively in a variety of different conditions and populations (Table 20). It was found to have moderate to high internal consistency and satisfactory test-retest reliability. When considering the validity of the measure the GHQ-12 compares favourably with a diagnostic interview as a means of detecting psychiatric cases (primarily depression and anxiety but also dysthymia (chronic mood disorder), agoraphobia, panic disorder, somatisation disorder, chronic fatigue and hypochondriasis) (247). The GHQ-12 measures psychological state at the point of assessment compared to the “usual” state so it is not a measure of chronic psychological problems. This was important in the context of this study as the primary interest was participants’ psychological status compared to their usual state (i.e. before they sustained their whiplash injury) so made it a suitable choice for this study. A high level of internal consistency was confirmed by examining the responses of participants in this study (Cronbach’s α=0.89).

Table 20 The validity and reliability of the measures of psychological factors

Questionnaire used	Validity	Reliability
Impact of Events Scale (75)	Shows significant correlations with measures of PTSD and measures of psychological distress such as the Beck Depression Inventory (68).	Internal consistency - Cronbach’s α =0.73 to 0.86 (68). Test-retest – r=0.89 (intrusion subscale), r=0.79 (avoidance subscale) (75)
General Health Questionnaire-12 (244)	Able to detect the presence of a psychiatric cases with sensitivity of 76.3% and specificity of 83.4% when compared to diagnosis through interview (Composite International Diagnostic Interview) (247).	Internal consistency - cronbach’s α =0.76 to 0.9. (245, 248-253). Test-retest – ICC = 0.72-0.79 (248, 252, 254).

r=pearsons correlation coefficient, ICC = Intraclass correlation coefficient

4.8 Baseline measurements - treatment factors

The two variables related to treatment are not strictly baseline variables but needed to be included in the analysis as this prospective cohort study was being carried out in the context of an RCT where different treatments were being delivered. A description of the treatments delivered is included in Chapter 5.0.

4.8.1 Treatment allocation

Participants were randomly allocated to receive a single advice session with a physiotherapist or a package of physiotherapy treatment.

4.8.2 Treatment attendance

The physiotherapists who delivered the trial treatments completed a treatment log for each participant. From the treatment logs participants were classified into four categories of attendance: did not attend any sessions, attended assessment only, partial completion and completed treatment. In the physiotherapy arm participants were classified as partial completers if they attended for the assessment and at least one treatment session. Treatment was terminated when the participant failed to attend for subsequent treatment. Physiotherapy package participants were classified as having completed treatment if the treatment was completed as intended and discharge was by mutual agreement between the physiotherapist and patient. Those allocated to the advice session were deemed to have completed treatment if they attended for the advice session.

4.9 Baseline measurements - pre-existing factors

4.9.1 Demographics

The age and sex of participants was recorded.

4.9.2 History of previous neck pain

Participants were asked if they had experienced neck pain in the month prior to their whiplash injury on the baseline questionnaire for the main trial. Participants answered yes or no.

4.9.3 Manchester Definition of Chronic Widespread Pain (MDCWP)

Participants were classified as having chronic widespread pain if they fulfilled the Manchester Definition of Chronic Widespread Pain (MDCWP) (255). For participants to satisfy this definition they had to report pain in two sections of two contralateral limbs and in the axial skeleton which had been present for at least 3 months. This was assessed by the research clinician as part of the research clinic examination.

The MDCWP was developed to identify those individuals whose pain was truly widespread and is more stringent than other criteria (256). For example, the American College of Rheumatology criteria requires pain to be in the right and left side of the body rather than specifying two sections of two contralateral limbs (256). No formal studies reported on the validity or reliability of MDCWP. However, Hunt el al (256) report that individuals who fulfilled the MDCWP reported associated psychosocial features such as psychological distress, fatigue, low levels of self-care and non pain somatic symptoms suggesting that the MDCWP identifies individuals with well established chronic pain syndromes (256).

4.9.4 Multidimensional Scale of Perceived Social Support (MSPSS)

The MSPSS is a 12 item scale designed to measure the perceived adequacy of an individual's current levels of social support from family, friends and significant other (257). Individuals are asked to rate their level of agreement with twelve statements describing sources of social support on a 7 point likert scale anchored by "very strongly disagree" through to "very strongly agree". The MSPSS is scored by calculating the mean score of the individual item scores. This results in a score out of seven with a higher score indicating greater perceived social support.

The MSPSS is a reliable measure with high internal consistency and adequate rest-retest reliability (Table 21). Social support is thought to act as a buffer to the development of depression and the MSPSS has shown significant negative correlations with a range of depression measures (See Table 21). The validity of the MSPSS is further supported by evidence that it correlates with a measure of social support behaviours (258). A high level of internal consistency was confirmed by examining the responses of participants in this study (Cronbach's α=0.94).

Table 21 The validity and reliability of measures of pre-existing factors

Questionnaire	**Validity**	**Reliability**
Multidimensional Scale of Perceived Social Support (257)	Correlates with depression - r= -0.22 to -0.55 (257, 259, 260) and measures of social support behaviours (r=0.13-0.77) (258).	Internal consistency - cronbach's α = 0.77 to 0.94 (257, 260-263). Test-retest reliability – r= 0.73 to 0.85 (257, 262)

4.10 Summary of baseline data collection

A summary of baseline data collection is included in Figure 8.

Figure 8 Summary of baseline data collection

Belief factors:

- Fear avoidance beliefs questionnaire (4 items)
- Pain catastrophising questionnaire (13 items)
- Beliefs about doing neck exercises (1 item)
- Treatment preferences (1 item)
- Self-efficacy: ability to cope with neck problem (1 item)
- Expected benefit of treatment (1 item)
- Predicted time to recovery (1 item)
- Pain coping strategy questionnaire (7 items)

Injury severity factors:

- Neck disability index (10 items)
- Modified Von-Korff pain scale(3 items)
- WAD grade
- Physical symptoms scale from the cervical spine outcomes questionnaire (15 items)
- Total cervical range of movement

Psychological response factors:

- Impact of events scale (15 items)
- General health questionnaire-12 (12 items)

Pre-existing factors:

- Age
- Sex
- History of previous neck pain
- History of chronic widespread pain
- Multidimensional scale of perceived social support (12 items)

Treatment factors:

- Treatment allocation
- Treatment attendance

4.11 Additional participant data

The Short Form-12 Health Survey (SF-12) (acute version) scores for participants in this study were available from the main trial baseline questionnaire. The SF-12 is a generic measure of health related quality of life that is used extensively in medical research (264, 265). It contains two subscales: the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. Both subscales produce a score ranging from 0-100 with scores greater than 50 representing above average health status (265). Test-retest reliability has been demonstrated to be acceptable for the MCS (r=0.76) and good for the PCS (r=0.89)

(264). SF-12 scores were used to describe the clinical presentation of participants in this study.

4.12 Outcomes

4.12.1 Recovery status at 4, 8 and 12 month follow up

The NDI (described in section 4.5.1) was the primary outcome for MINT and has also been used in this study. The NDI was used to classify participants' recovery status (e.g. whether they have developed LWS or not).

This prospective cohort study aimed to identify factors predictive of LWS. Rather than selecting a total cut off score for the NDI, recovery status was classified using participants' responses to specific questions from the NDI. There were several considerations when deciding on this classification system. Firstly, the questions chosen needed to represent the domains found in the definition of LWS (11). Secondly, the response given to questions needed to indicate that the participant experienced a limitation of normal activity. Finally, the questions needed to assess activities that the majority of participants would take part in. For this reason the driving question was excluded as this question was not answered by participants who did not drive. Return to driving may also be affected by travel anxiety which is thought to occur in up to 20% of individuals involved in a road traffic accident (53). Based on these considerations the following pre-specified definitions were established prior to carrying out any analysis:

Recovery status was defined in the same way at each time point. However, at the 4 month follow up participants were classified as not recovered or recovered. Not recovered was defined as the presence of pain, restriction of motion or other symptoms sufficient to hinder return to normal activities such as driving, usual occupation and leisure at 4 month follow up. Participants were classified as “not-recovered” if they scored either ≥ 2 on Question 2 (personal care) OR Question 7 (work) OR Question 10 (recreation) of the 4 month NDI. A score of 2 or more indicated that the participant was unable to carry out this activity as normal. It should be noted that the term late whiplash syndrome could not be used at the 4 month follow up as symptoms must have been experienced for 6 months or more (11).

At 8 and 12 month follow up participants were classified as having developed LWS or not. LWS was defined as the presence of pain, restriction of motion or other symptoms sufficient to hinder return to normal activities such as driving, usual occupation and leisure 6 months of more following injury for the purpose of this study. Participants were classified as having LWS if they scored either ≥ 2 on Question 2 (personal care) OR Question 7 (work) OR Question 10 (recreation) of the 8 and 12 month NDI.

4.12.2 NDI score at 4, 8 and 12 months follow up

Another aim of the study was to identify factors that predicted NDI score at follow up. Therefore, the actual NDI scores at follow up were also used as an outcome.

4.12.3 Participant rated improvement at 4, 8 and 12 month follow up

On the 4 month follow up questionnaire participants were asked “Is your neck better, just the same or worse after the treatment you received 4 months ago?”

On the 8 and 12 month follow up questionnaire participants were asked “Is your neck better, just the same or worse since your last questionnaire 4 months ago?”

Participants rated themselves as “much better”, “better”, “same”, “worse” or “much worse”.

4.13 Ethical approval

Ethical approval for this research was given by the Trent Multi-centre Research and Ethics Committee (See Appendix 5).

4.14 Statistical analyses

SPSS 15.0 was used to carry out the statistical analyses in this thesis.

4.14.1 Descriptive statistics

Aim of analysis: To describe the clinical presentation and course of recovery of participants.

Descriptive statistics are presented for the all baseline data and outcomes at 4, 8 and 12 months follow up. Baseline differences between responders and non-responders at 4, 8 and 12 months follow up were compared using x^2 test, Mann-Whitney U test or Kruskall-Wallis test depending on the type of data involved. Baseline measures of Step 1 participants who were not randomised in Step 2 and those randomised to Step 2 are also presented. This was to allow a comparison between those who attended the ED following their injury and sought further treatment through Step 2 of MINT with those who did not.

4.14.2 Logistic regression analysis

Aim of analysis: To identify baseline factors predictive of recovery status at follow up.

The primary analysis was a logistic regression analysis. Logistic regression was chosen as the primary outcome (recovery status) was a binary variable (32). The aim of this analysis was to identify baseline factors predictive of recovery status at follow up. A logistic regression analysis was the appropriate analysis to fulfil this aim as this type of analysis allowed the identification of baseline factors that, when present, were associated with an increase in the odds of an individual being non-recovered or having LWS when compared to an individual who did not exhibit the baseline factor (32, 84). This information is expressed as an odds ratio which is defined as the ratio of the odds of an event occurring in one group compared to another (84). A logistic regression analysis also allowed multivariable analysis to be carried out so that the impact of baseline factors known to influence outcome could be adjusted for (32, 84). There were other ways to carry out regression analysis (Cox Regression, Poisson Regression or Negative Binomial Regression) but the distribution of the data was not appropriate for these approaches, for example, Cox Regression is used to compare survival data for two or more groups (32).

A forward stepwise method of logistic regression analysis was used. A forward stepwise method is recommended when the analysis is exploratory in nature as this analysis was (84, 319,320). When carrying out a forward stepwise method the initial model contains no variables (320). At each step, the variable that is most significantly associated with the outcome is then entered into the model (320). This is continued until none of the remaining variables are significant (320). It is thought to be preferable to a backward regression method where all variables are included in the initial model and at each step the variable that is the least significant is removed until no non-significant variables remain (320). The backward regression method may result in variables being retained in the model that are not necessary (320).

4.14.2.1 Coding of variables

Recovery status was coded as 1 = non-recovery/LWS and 0 = recovered. For this analysis the baseline factors and primary outcome were also dichotomised. Each factor was coded 0 or 1 with 1 indicating the presence of a potential risk factor and 0 indicating an absence of the potential risk factor. This was not the case where factors were categorical such as sex or treatment allocation. Several methods were used to dichotomise the data. Where available, published cut-offs were used to create the dichotomised variables. Where no published cut-offs existed tertile splits were used and the upper or lower third was selected as the risk factor depending on the measure. Tertile splits are standard epidemiological cut points used to identify those who exhibit a certain characteristic to a greater degree than others in a cohort. The upper third was used if a higher score was considered to be the possible risk factor (e.g. pain rating on the MVK pain scale). The lower third was used where a lower score was considered to be the possible risk factor (e.g. total cervical ROM). The remaining factors were dichotomised using a common sense approach where the category most likely to be the risk factor was allocated as such e.g. treatment attendance and treatment preference. It was felt that dichotomised variables provided the most easily interpreted and clinically meaningful way of handling the data (85p300-306). This method provided definite cut points to screen patients at risk of poor outcome in clinical practice. The cut-off points for each variable are listed in Table 22.

Table 22 Dichotomised version of baseline variables

Baseline measure	**Dichotomised version**	**Method (where applicable)**
Injury severity factors:		
NDI (0-100)	0= no/mild/moderate disability <50% 1= severe/complete disability ≥50%	Published categories (208)
MVK pain scale (0-100)	0 = low pain intensity ≤67 1= high pain intensity >67	Tertile split – upper 1/3 allocated as potential risk factor
Number of physical symptoms (0-15)	0 = low <6 1= high ≥6	Tertile split – upper 1/3 allocated as potential risk factor
WAD grade – in ED and at research clinic (1-3)	0= WAD Grade I 1= WAD Grade II or WAD Grade III	WAD II and III were grouped together due to the small numbers with WAD III.
Total cervical ROM	0= Better ROM 1= Restricted ROM	Tertile split – lower 1/3 allocated as potential risk factor
Patient held beliefs:		
FABQ (0-24)	0= Low level of fear avoidance ≤ 14 1= High level of fear avoidance >14	Published cut-off (266)
Beliefs about neck exercises following whiplash injury (0-6)	0 = Agree >4 1= Unsure/disagree ≤4	Tertile split – lower 1/3 allocated as potential risk factor
PCS (0-52)	0= low level of catastrophising <30 1= high level of catastrophising ≥30	Published cut-off (267)
Expectations of time to recovery	0= ≤ 6 months 1= > 6 months or unsure they will recover	Tertile split – upper 1/3 allocated as potential risk factor
Treatment preferences	0 = Got preferred treatment/had no preference 1= Did not get preferred treatment	"Did not get preferred treatment" was allocated as risk factor.
Expected benefit of treatment (0-10)	0= High expectations of treatment benefit >6 1= Low expectations of treatment benefit ≤6	Tertile split – lower 1/3 allocated as potential risk factor
Self-efficacy (0-6)	0 = Able to cope > 3 1= Unsure/unable to cope ≤3	Tertile split – lower 1/3 allocated as potential risk factor
CSQ Passing subscale (0-12)	Passive coping strategies 0= Low use <5 1= High use ≥5	Tertile split – upper 1/3 allocated as potential risk factor

Active subscale (0-30)	Active coping strategies 0= Low use <15 1= High use ≥15	
Psychological response factors:		
IES (0-75)	0= Mild/Moderate reaction ≤44 1= Severe reaction >44	Published cut-offs (75)
GHQ(0-12)	0 = Normal <4 1= Psychologically distressed ≥4	Published cut-offs (244)
Treatment factors:		
Treatment allocation	0= Advice 1= Physiotherapy	N/A
Treatment attendance	0= Attended 1 = Did not attend	“Did not attend any sessions” was allocated as the risk factor.
Pre-existing factors:		
Age	0 = <45 years old 1= ≥45 years old	Tertile split – upper 1/3 allocated as potential risk factor
Gender	0= Male 1= Female	N/A
History of previous neck pain	0=No 1=Yes	N/A
History of chronic widespread pain	0=No 1=Yes	N/A
Social support (0-7)	0= High social support ≥5.3 1= Low social support <5.3	Tertile split – lower 1/3 allocated as potential risk factor

4.14.2.2 Variable selection

The univariate relationship between each baseline variable and recovery status was examined to determine which factors would be included in the multivariable analysis. This was done using a x^2 test. A conservative level of significance was set at $p< 0.25$ to select factors (32p349, 268) and ensure that type II errors were avoided (an association is missed when one is present) (269p87). Factors with weak levels of univariate association may still be predictive of outcome in multivariable models due to complex interactions between factors (32p349, 269p87).

4.14.2.3 Logistic regression modelling to predict recovery status

Following the univariate analysis, a series of multivariable models were constructed to determine which factors were entered into the final multivariable model. Factors with a significant univariate relationship with the outcome were entered into a forward stepwise logistic regression model. Factors were entered in a single step. A separate model was constructed for each of the following baseline variables:

Injury severity factors
Pre-existing factors
Psychological response factors
Treatment factors

The final multivariable model was then constructed. A hierarchical approach was used for the final model. This approach involves entering variables into the model in blocks or steps (86). It is recommended that known predictors are entered into the model first (first step) (86). Potential new predictors are then entered in the second step (86). The factors that were predictive of outcome in the models above were entered into step one of the final model. As patient beliefs were the primary focus of this exploratory analysis all the belief factors with significant univariate relationships with the outcome were entered into the second step of the final model. Forward stepwise logistic regression was carried out.

Following the final logistic regression analysis the proportions of those classified as non-recovered or having developed LWS was presented for each identified risk factor. The number of risk factors present at baseline was also calculated for each participant and the descriptive data was presented. The relative risk of being classified as non-recovered/LWS was calculated according to the number of risk factors present. The risk ratio is the preferred method for presenting the association between risk factors and a condition (85p95, 270). The reference category was no risk factors.

4.14.2.4 Checking for multicollinearity and model fit

The final model for each logistic regression analysis was checked for multicollinearity (86p223). Multicollinearity occurs when two or more predictor variables are highly correlated (86p223) . This is problematic because if two predictors are closely related to each other then it is impossible to accurately estimate the unique contribution that each factor makes to the regression model (86p223). Collinearity statistics were calculated (See Figure 9 for an example of SPSS output of collinearity statistics). Firstly, variance inflation factor (VIF) was examined which assesses if two variables have a strong linear relationship (86p224). Values were examined to ensure they fell within the recommended limits: individual values <10 and average VIF<1 (86p224). Tolerance was also examined which is the reciprocal value of VIF and values should be greater than 0.1 (86p297). In the example given in Figure 9 both VIF and tolerance values are outside the recommended limits which is a clear indication that collinearity is a problem in this model.

Collinearity diagnostics were also calculated (See Figure 9). Eigenvalues indicate if the model is accurate and each value should be similar which demonstrates that the model would be unchanged by small changes in the measured variables(86p297). The condition index is another way of expressing the eigenvalues and is the square root of the ratio of the largest eigenvalue to the eigenvalue of interest (86p298). If one condition index is much larger than the others it indicates a problem with the data (as demonstrated in Figure 9) (86p298). Variance proportions were also examined. Variance proportions provide the proprortion of the variance of each predictor variable's coefficient variable that is attributed to each eigenvalue (86p298). Essentially, the data are examined for predictors that have high proportions of the variance on the same eigenvalue which indicates that the variances of their regression coffecients are dependent and is another indicator of collinearity (86p298). In the example given in Figure 9, State anxiety and Percentage of previous penalties scores both account for 99% of the variance of the regression coefficaint for the final eigenvalue which demonstrates further the collinearity present in the model between these two variables which is a source of bias in the model.

Figure 9 Example of SPSS output of collinearity statistics and diagnostics. Taken from Field (86p298)

Model		Collinearity Statistics	
		Tolerance	VIF
	Penn State Worry	.575	1.741
	Questionnaire State Anxiety	.014	71.764
	Percentage of previous penalties scored	.014	70.479

				Variance proportions			
Model	Dimension	Eigenvalue	Condition Index	(constant)	Penn state worry questionnaire	State anxiety	Percentages of previous penalties scored
1	1	3.434	1.000	.00	.01	.00	.00
	2	.492	2.641	.00	.04	.00	.00
	3	0.073	6.871	.00	.95	.01	.00
	4	0.001	81.303	1.00	.00	.99	.99

a. Dependent variable: result of penalty kick

Model fit was also examined following the recommendation of Field (86p293). Examining model fit is important as it determines whether the model produced fits the data well or was it influenced by a small number of cases (86p214). A well fitting model is more likely to generalisable to other samples (86p214). This involved examination of cook's distance, leverage, standardized residuals and DFBeta. Cook's distance indicates if any cases are having undue influence on the model and values should be <1 (86p293). Leverage also assesses the influence of individual cases on the model (86) p293. The expected leverage is calculated using the following formula: (k+1)/N where k is the number of predictors and N is the sample size. The data are examined for any values that are greater than 2-3 times this value (86p293) which would indicate these cases are having undue influence of the model. Standardized residuals were examined to identify any outliers (86p215). Outliers are cases that differ greatly from the main trend of the data and can result in bias in the model (86p215). Residuals should be normally distributed with 95% of scores falling between -1.96-+1.96 and 99% between -2.58- +2.58 (86p216). The data were examined for any residuals that fell outside these recommendations. The final measure that was examined is the DFBeta which is another method of identifying cases with a large influence on the parameters of the regression model (86p216). Values greater than 1 indicate a case may substantially influence the model (86p219).

4.14.3 Logistic regression analysis - predictors of participant perceived improvement

Aim of analysis: To identify baseline predictors of participant perceived improvement and compare these findings with those based on recovery status and NDI.

A second logistic regression analysis was conducted to identify risk factors for poor outcome using participant perceived improvement as the outcome variable. This variable was also dichotomised into two categories: 0=the participant rated themselves as better or much better; 1=the participant rated themselves as the same, worse or much worse. The logistic regression analysis was carried out as described in section 4.14.2.

4.14.4 Linear regression analysis

Aim of analysis: To identify baseline factors predictive of Neck Disability Index scores.

A second multivariable analysis was conducted using linear regression. The outcome was NDI score used as a continuous variable. A linear regression analysis was conducted to examine the effects of using continuous variables rather than dichotomised variables. It is acknowledged that dichotomising data can influence findings, for example, different cut points may result in different findings. Also, although splitting data often makes it more manageable, information is also lost and error may be introduced (85p302, 271). Statistical power is reduced (272) and there is a risk of residual confounding (85p328-329). Using continuous variable will allow the identification of more linear relationships between two variables which may not be obvious when dichotomised variables are used. Therefore, analysis using continuous variables may produce different findings (85p302-303).

4.14.4.1 Variable selection

The univariate relationship between each baseline variable and follow up NDI score was examined to determine which factors would be included in the multivariable analysis. A level of significance was set at p< 0.25 to select factors (32p349, 268).

4.14.4.2 Linear regression modelling

A similar approach was taken to the logistic regression analysis. Following the univariate analysis, a series of multivariable models were constructed to determine which factors were entered into the final multivariable model. Factors with a significant univariate relationship with the follow up NDI scores were entered into a linear regression model. Factors were entered in a single step. A separate model was constructed for each of the following baseline variables:

Injury severity factors
Pre-existing factors
Psychological response factors
Treatment factors

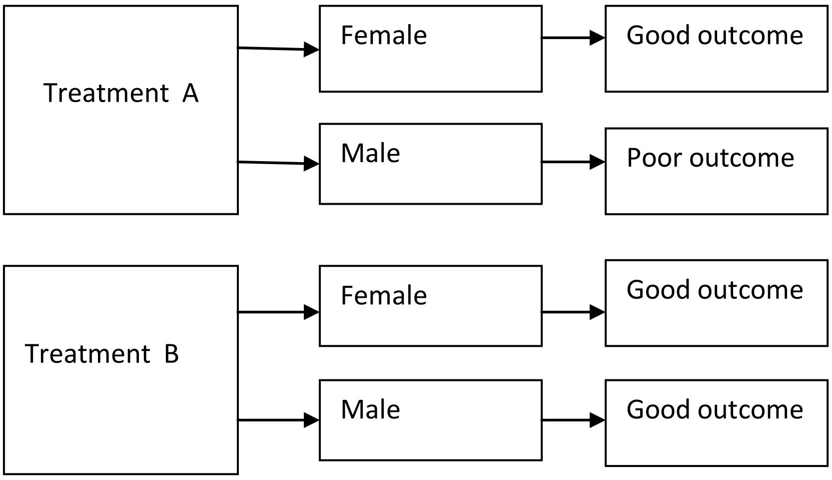
The final multivariable model was then constructed. The factors that were predictive of NDI score in the models above were entered into step one of the final model. As patient beliefs were the primary focus of this analysis all the belief factors with significant univariate relationships with follow up NDI scores were entered into the second step of the final model.

4.14.5 Moderator analyses

Aim of analysis: To identify specific conditions under which the belief factors that were predictive of recovery status operate in relation to other baseline belief factors (i.e. did other baseline beliefs moderate the effect of identified predictor variables?)

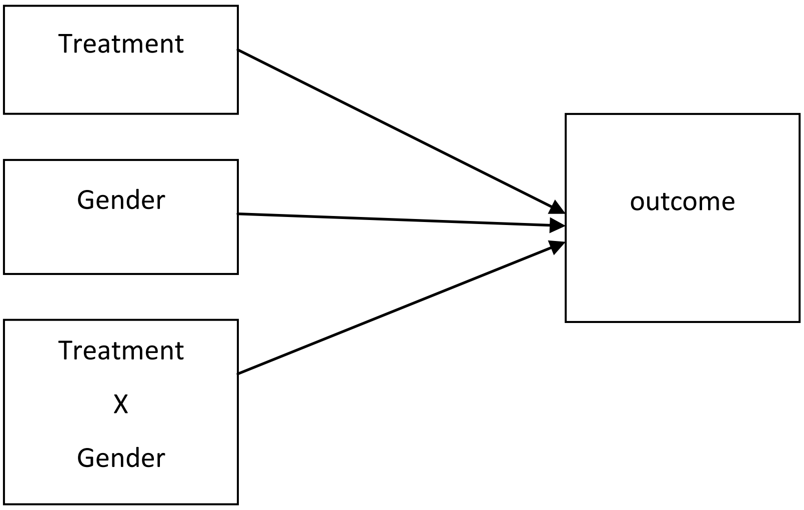
Moderators are variables that have the ability to modify the effect that a predictor variable has on the outcome variable (273, 274). Specifically, the moderator variable has the ability to affect the direction and/or strength of the relationship between an independent predictor variable and the outcome variable (274). It provides insight into the conditions under which a predictive factor may operate. For example, gender may moderate the effect of treatment on outcome (See Figure 10). In this example Treatment A is shown to be predictive of a good outcome in females but not in males whereas no difference was seen if patients who received Treatment B.

Figure 10 An example of a moderator variable



To test for a moderating effect between two variables an interaction between the two variables is included in the logistic regression analysis (Figure 11).

Figure 11 Factors entered into logistic regression analysis to test for moderation (adapted from Baron and Kenny (274)



An analysis was carried out to explore the interactions between the belief factors that were identified as prognostic factors and the other belief factors at baseline. This was carried out in two steps:

i. A forward step logistic regression analysis was carried out to identify if any of the baseline belief factors were predictive of the belief identified as a prognostic factor in the main analysis.

ii. The final step of the main analysis was then re-run to include an interaction between the identified prognostic factor from the main analysis with any factors found to be significant in step one.

Aim: To identify specific conditions under which the belief factors that were predictive of recovery status operate in relation to treatment received as part of MINT? (i.e. did treatment moderate the effect of identified predictor variables?)

Participants received either a package of physiotherapy or an advice session. It was possible that these treatments interacted with baseline variables and influenced outcome. To investigate this, a logistic regression analysis was run that included interaction variables between the trial treatments and some of the belief factors. The three belief factors that were identified in the main analysis and use of passive coping strategies (identified as important in the previous interaction analysis) were chosen to be included in the analysis. Therefore, the following interactions were included in the analysis at each time point:

Time to recovery*Treatment allocation
Ability to cope*Treatment allocation
Use of passive coping *Treatment allocation
Expectations of treatment* Treatment allocation

The interactions were included in step two of a forward stepwise logistic regression analysis. Step one included the non-belief factors found to be significant in the main analyses. The dependent variable was non-recovery/LWS.

4.14.6 Dealing with missing data

No guidance on dealing with missing data in the NDI was provided in the original paper outlining its development (208). More recently it has been suggested that missing data can be dealt with by converting the raw score (out of 50) to a percentage score (209). However, some authors consider the NDI score is not valid if two or more items are missing (275). The most common item to be missing is the driving item (question 7) as it is not applicable to people who do not drive. Therefore, in these cases, an NDI score was calculated by summing the 9 completed questions and then converted to a percentage score (out of 100). If other items were missing then a total NDI score was not calculated. However, for participants with missing items on the follow up NDI, recovery status was classified if the relevant sections were completed. These participants did not have a total NDI score.

The literature was searched for algorithms to deal with missing data in the other questionnaires used in the study. However, none were identified. Complex statistical methods do exist for the imputation of missing data but this was considered beyond the scope of this thesis. Therefore, if participants had missing data then they were excluded from any analysis that included the factors with missing data.

4.15 Summary

This chapter has outlined the methods of the prospective cohort study. The results are presented in the following chapter.

5.0 Prospective cohort study: results

5.1 Baseline measurements

Baseline data were collected from the 599 participants that were randomised into step 2 of MINT. Data was collected on average 32 days after injury (SD=10.9). There was no difference in the timing of data collection between those receiving the physiotherapy package and those receiving the advice session.

5.2 Description of study participants

5.2.1 Clinical presentation

5.2.1.1 Baseline symptoms

Neck symptoms were reported by the majority of participants at baseline but many participants also reported symptoms in other areas including the skull and shoulder where symptoms were reported by over half the cohort (See Figure 12). Headaches were also prevalent being reported by approximately 70% of the cohort (See Table 23). The most frequent neurological symptom to be reported was numbness, weakness and tingling in the arms and hands in approximately one third of the cohort (See Table 23). It should be noted that although neurological symptoms were fairly common, neurological signs were assessed to be present in only 12% of participants (those classified as having WAD III).

Figure 12 Distribution of symptoms experienced by participants (n=599) (n (%)) taken from physical symptoms scale from the Cervical Spine Outcome Questionnaire (CSOQ).

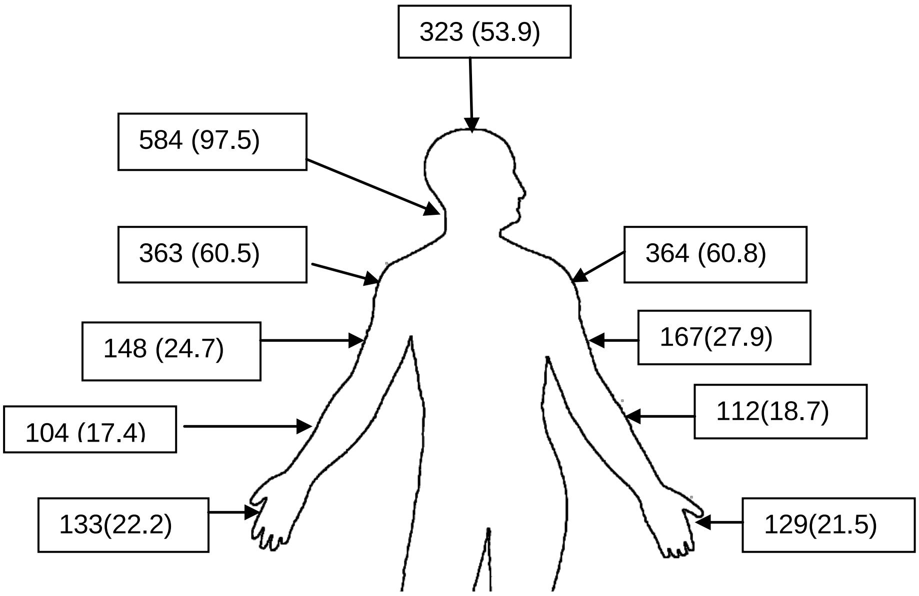


Table 23 Other symptoms reported by participants at baseline (n=599) taken from the physical symptoms scale of the CSOQ .

Type of symptom reported	N(%)
Difficulty swallowing	17 (2.8)[1]
Headaches related to neck condition	438(73.1)[2]
Numbness, weakness, tingling in arms or hands	218 (36.4)
Difficulty grasping, picking up holding things in hands	92 (15.4)[2]
Numbness, clumsiness, weakness in legs	40 (6.7)[2]

[1] missing data n= 2 [2] missing data n=1

5.2.1.2 *Combinations of symptoms at baseline*

The 15 items from the physical symptoms subscale of the CSOQ (reported above in Figure 12 and Table 23) were collapsed down into 5 main categories (Table 24) to allow collation of the different combinations of symptoms that were present at baseline (Table 25).

Table 24 Categories of symptoms present at baseline

Categories	**Definition**	**N(%)**
Proximal pain	Participants reported any of the following: neck pain, skull pain or shoulder pain.	599(100%)
Headaches (missing data =1)	Participants report headaches.	438 (73.1%)
Arm pain	Participants reported pain in either arm.	301 (50.3%)
Neurological symptoms (missing data = 2)	Participants reported at least one of the following: numbness, weakness, tingling in arms or hands or difficulty grasping, picking up holding things in hands or numbness, clumsiness, weakness in legs	249 (41.6%)
Swallowing problems (missing data=2)	Participants report swallowing difficulty.	17 (2.8%)

To help understand how the types of symptoms present at baseline impacted on the clinical presentation of participants the baseline NDI scores, number of symptoms and GHQ scores were stratified by type of symptom. All participants presented with proximal pain so those scores represent the mean of the cohort (n=599). Participants reporting other types of symptoms had higher NDI scores than the mean of the cohort. This indicated that participants reporting additional symptoms were more disabled at baseline. The difference ranged from an additional 7 percentage points if swallowing difficulty was reported to 3 percentage points for headaches and arm pain. Those reporting neurological symptoms tended to report the greatest total number of symptoms at baseline. Mean GHQ scores were not markedly different across the different types of symptoms.

Table 25 Baseline NDI, number of symptoms present and GHQ scores stratified by the type of symptoms reported at baseline.

Symptoms	Mean baseline NDI (SD)	Mean number of symptoms present at baseline (SD)	Mean GHQ (SD)
Swallowing problems (n=17)	49(15.7)	6(4)	6.35(3.87)
Neurological symptoms (n=249)	47(15.6)	8(3)	7.11(3.80)
Headaches (n=438)	45(16.0)	6(3)	7.74(3.88)
Arm pain (n=301)	45(15.9)	7(3)	6.95(3.80)
Proximal pain (n=599)	42(16.2)	5(3)	6.24(3.90)

Thirteen different symptom combinations were present amongst the cohort (Table 26). It was very common for participants to present with multiple types of symptoms as over 80% of the cohort had two types of symptoms or more. Only 16% of participants presented with proximal pain only localised to the head, neck and shoulder region.

Table 26 Symptoms combinations present at baseline (n=594)

Combinations of symptoms at baseline	Number of participants (%)
1. Proximal pain + arm pain + headaches + neurological symptoms	157(26.4)
2. Proximal pain + headaches	156(26.3)
3. Proximal pain only	99(16.7)
4. Proximal pain + arm pain + headaches	75(12.6)
5. Proximal pain + arm pain + neurological symptoms	38(6.4)
6. Proximal pain + headaches + neurological symptoms	32(5.3)
7. Proximal pain + arm pain	13(2.1)
Other combinations (combinations 8-13 combined)	24(4.0)
8. Proximal pain + arm pain + headaches + neurological symptoms + swallowing difficulty	10(1.7)
9. Proximal pain + neurological symptoms	7(1.2)
10. Proximal pain + headaches + swallowing difficulties	3(0.5)
11. Proximal pain + arm pain + neurological symptoms + swallowing difficulty	2(0.3)
12. Proximal pain + swallowing difficulties	1(0.2)
13. Proximal pain + arm pain + headaches + swallowing difficulty	1(0.2)

To help understand how the combinations of symptoms present at baseline impacted on the clinical presentation of participants the baseline NDI scores, number of symptoms and GHQ scores were stratified by the symptom combinations (Table 27). Symptom combinations 8-13 were collapsed into one category due to the small numbers seen in each category. The most noticeable observation was that participants with proximal pain only reported lower GHQ scores and lower NDI scores. This indicated that those with localised pain experienced less psychological distress and were also the least disabled. As expected, these participants also reported the least number of symptoms. The addition of symptoms resulted in greater disability and increased psychological distress compared to those with proximal pain only.

Table 27 Baseline NDI, number of symptoms present and GHQ scores stratified by symptoms combinations (n=594)

Combinations of symptoms at baseline	**Mean baseline NDI (SD)**	**Mean number of symptoms (SD)**	**Mean GHQ (SD)**
3.Proximal pain only	31(14.4)	2(1)	4.7(3.54)
5.Proximal pain + arm pain + neurological symptoms	35(10.8)	6(2)	5.8(3.8)
7.Proximal pain + arm pain	41(11.4)	5(2)	6.6(2.61)
2.Proximal pain + headaches	41(15.0)	4(1)	6.0(3.84)
4.Proximal pain + arm pain + headaches	42(17.1)	6(2)	6.5(4.04)
Other combinations (combinations 8-13)	44(16.5)	7(4)	6.4(3.89)
1. Proximal pain + limb pain + headaches + neurological symptoms	49(15.3)	9(2)	7.5(3.80)
6.Proximal pain + headaches + neurological symptoms	50(15.6)	5(1)	7.5(3.60)

5.2.2 Baseline characteristics

Table 28 and Table 29 contain the baseline characteristics of participants as well as the number and percentages of participants in each group for the dichotomised version of the variables. Table 30 contains information about treatment allocation and treatment attendance.

Table 28 Baseline characteristics - injury severity factors, psychological factors and pre-existing factors (n=599)

Pre-existing factors:	**Mean(SD) or n(%)**	**Dichotomised version n(%)**
Age	39.9(13.1)	<45 years old = 388 (64.8%) ≥45 years old = 211 (35.2%)
Sex	Female = 379 (63.3%) Male = 220 (36.7%)	Female = 379 (63.3%) Male = 220 (36.7%)
History of previous neck pain (in the month before injury)	Yes = 44(7.3%) No = 513(85.6%) Missing = 42(7.0%)	Yes = 44(7.3%) No = 513(85.6%) Missing = 42(7.0%)
Full fills the Manchester definition of chronic widespread pain	Yes = 15 (2.5%) No = 576(96.2%) Missing = 8(1.3%)	Yes = 15 (2.5%) No = 576(96.2%) Missing = 8(1.3%)
Multidimensional Scale of Perceived Social Support	5.58 (1.3)	High social support = 397 (66.3%) Low social support = 190 (31.7%) Missing = 12 (2%)
Injury severity factors		
Neck Disability Index	41.8(16.2)	No/mild/moderate disability= 408 (68.1%) Severe/complete disability= 181 (30.2%) Missing = 10 (1.7%)
Modified Von-Korff Pain Scale	57.31 (17.5)	Low pain intensity=425 (71%) High pain intensity= 168 (28%) Missing=6 (1%)
Physical symptoms scale from the Cervical Spine Outcomes Questionnaire	5.37 (2.9)	Low number symptoms=365 (60.9%) High number symptoms= 229 (38.2%) Missing = 5 (0.8%)
WAD grade in ED	WAD 1 = 265(44.2%) WAD 2 = 284(47.4%) WAD 3 = 25 (4.2%) Missing = 25 (4.2%)	WAD Grade 1= 265 (44.2%) WAD Grade 2/3= 309 (51.6%) Missing= 25 (4.2%)
WAD grade at research clinic	WAD 1 = 84 (14%) WAD 2 = 442 (73.8%) WAD 3 = 73 (12.2%)	WAD Grade 1 = 84 (14%) WAD Grade 2/3 = 515 (86%)
Total active cervical ROM	232.53 (67.1)	Better ROM= 389(64.9%) Restricted ROM= 206(34.4) Missing = 4(0.7%)
Psychological response factors		
Impact of Events Scale	28.4(18.5)	Mild/Moderate reaction = 439 (73.3%) Severe reaction = 133 (22.2%) Missing = 27 (4.5%)
General Health Questionnaire-12	6.3(3.9)	Normal = 176 (29.4%) Psychologically distressed = 417 (69.6%) Missing = 6 (1%)

Table 29 Baseline characteristics – patient held beliefs (n=599)

Belief factors	**Mean (SD) or n(%)**	**Dichotomised version n(%)**
Fear-avoidance beliefs questionnaire (physical activity scale)	14.73 (5.6)	Low fear avoidance= 243 (40.6%) High fear avoidance= 342 (57.1%) Missing = 14(2.3%)
Beliefs about neck exercises following whiplash injury	4.95(2.7)	Agree = 416 (69.4%) Unsure/disagree=182 (30.4%) Missing = 1(0.2%)
Pain Catastrophising Scale	17.85 (12.8)	Low catastrophising = 451(75.3%) High catastrophising = 117 (19.5%) Missing = 31 (5.2%)
Expected time for their recovery	2 weeks = 10(1.7%) 2-8 weeks = 160(26.7%) 2-6 months = 237(39.6%) 6-12 months = 91(15.2%) More than a year = 18(3%) Not sure I will recover = 76(12.7%) Missing = 7 (1.2%)	≤ 6 months = 407 (67.9%) > 6 months or unsure they will recover = 185 (30.9%) Missing = 7 (1.2%)
Treatment preference	Advice session = 24(4%) No preference = 295 (49.2%) Physiotherapy = 277 (46.2%) Missing = 3 (0.5%)	
Treatment preference and treatment received	Wanted advice – got advice = 14(2.3%) Wanted advice – got physio = 10(1.7%) No preference – got advice = 41(23.5%) No preference – got physio = 154(25.7%) Wanted physio – got physio = 134(22.4%) Wanted physio – got advice = 143(23.9%) Missing = 3 (0.5%)	Got preferred treatment/had no preference = 443 (74%) Did not get preferred treatment = 153 (25.5%) Missing = 3 (0.5%)
Predicted benefit of treatment	7.12 (2.4)	High expectations of treatment benefit = 395(65.9%) Low expectations =201 (33.6%) Missing = 3 (0.5%)
Perceived ability to cope with neck problem	3.68 (1.7)	Able to cope = 363(60.6%) Unsure/unable to cope = 234 (39.1%) Missing = 2 (0.3%)
Coping Strategy Questionnaire passive coping subscale	3.79(3.5)	Low use of passive coping = 371 (61.9%) High use of passive coping = 220 (36.7%) Missing = 8 (1.3%)
Coping Strategy Questionnaire active coping subscale	12.77 (5.5)	Low use of active coping =371 (61.9%) High use of active coping =219 (37.1%) Missing = 9 (1.5%)

Table 30: Treatment factors (n=599)

Treatment factors	**n(%)**	**Dichotomised version n(%)**
Treatment allocation	Advice session with physio = 299(49.9%) Course of physiotherapy = 300(50.1%)	Advice session with physio = 299(49.9%) Course of physiotherapy = 300(50.1%)
Attendance	Completed treatment = 434 (72.5%) Partially completed treatment = 45 (7.5%) Attended for assessment only = 26 (4.3%) Did not attend any sessions = 94 (15.7%)	Attended treatment = 434 (72.5%) Did attend treatment = 165 (27.5%)

5.2.2.1 Baseline characteristics of responders and non-responders

The percentages of participants who returned the NDI at each time point are presented in Table 31.

Table 31 Percentage of participants who returned the NDI at each follow up point

Follow up point	**Follow up rate**
4 month follow up (n=499)	83.3%
8 month follow up (n=495)	82.6%
12 month follow up (n=473)	79.0%

The baseline characteristics of responders and non-responders to follow up showed across all follow up points that non-responders were younger and reported higher levels of fear avoidance and catastrophising compared to responders (Table 32). The differences between other baseline variables were not as consistent with non responders reporting at baseline, higher disability, higher pain intensity, lower ratings of their ability to cope and greater use of active coping strategies at two of the follow up points compared to responders (Table 32). At 12 months follow up, non-responders reported greater use of passive coping strategies, higher GHQ scores and less agreement that exercises were helpful at baseline compared to responders (See Table 32). Baseline variables where no difference existed between responders and non-responders are not included in Table 32.

Table 32 Mean baseline characteristics of non-responders (NR) and responders(R) to follow up (SD)

Baseline variable	4 months	8 months	12 months
FABQ	_NR= 16.06(5.6)*_ _R= 14.46 (5.5)_	_NR= 16.66(5.2)*_ _R=14.33(5.6)_	_NR=16.54(5.2)*_ _R=14.25(5.6)_
PCS	_NR=21.11(13.9)*_ _R=17.22(12.5)_	_NR=21.36(13.9)*_ _R=17.03(12.5)_	_NR=21.81(13.4)*_ _R=16.81(12.5)_
Age	_NR=35.62(13.0)*_ _R=40.72(13.0)_	_NR=35.41(12.1)*_ _R=40.81(13.1)_	_NR=34.86(11.7)*_ _R=41.21(13.09)_
Pain intensity	_NR=60.64(15.9)*_ _R = 56.65(17.8)_	_NR=61.30(14.6)*_ _R=56.48(13.1)_	NR =59.95(16.0) R=56.62(17.9)
NDI	NR=44.15(16.1) R=41.30(16.2)	_NR=46.04(15.6)*_ _R=40.89(16.2)_	_NR=45.32(16.2)*_ _R=40.87(16.1)_
Ability to cope	NR=3.49(1.9) R=3.71(1.6)	_NR=3.26(20.)*_ _R=3.76(1.6)_	_NR=3.28(1.8)*_ _R=3.78(1.7)_
Active coping subscale - PCQ	NR=12.43(5.5) R=12.84(5.52)	_NR= 11.55(5.4)*_ _R= 13.03(5.5)_	_NR=11.41(5.5)*_ _R=13.14(5.5)_
Endorsement that exercises help recovery	NR=5.06(1.2) R=4.93(1.3)	NR=4.78(1.4) R=4.99(1.3)	_NR=4.75(1.3)*_ _R=5.00(1.3)_
Passive coping subscale - PCQ	NR=4.23(3.9) R=3.71(3.4)	NR=4.37(3.8) R=3.67(3.4)	_NR=4.81(3.6)*_ _R=3.52(3.4)_
GHQ	NR=6.22(3.9) R=6.36(3.9)	NR=6.83(3.9) R=6.23(3.9)	_NR=6.97(4.0)*_ _R=6.17(3.8)_

*The difference between NR and R was statistically significant p<0.05

5.2.2.2 Step 1 participants randomised to Step 2 compared to those not randomised

Participants in Step 2 of MINT (and this prospective cohort study) were also included in Step 1 of MINT. The baseline characteristics of the participants randomised to Step 2 were compared to those who were not randomised (Table 33). A lower proportion of males were observed amongst those randomised. There were a greater proportion of participants classified as having sustained a WAD II and WAD III. This indicated that those who sought physiotherapy treatment through Step 2 of MINT had sustained a more severe injury than those who did not. Similarly, those randomised had lower SF-12 scores indicating lower health related quality of life.

Table 33 Step 1 participants randomised to Step 2 compared to those not randomised

	Randomised	**Not randomised**
Number of patients	599	3,277
Sex – Males (%)	221 (37%)	1,456 (44%) (missing data=50)
Age in years, Mean (SD)	40 (13)	36 (13)
Had previous neck pain (%)	77 (13%) (missing data=40)	334 (10%) (missing data=115)
WAD grade		
WAD I	275 (46%)	1,823 (56%)
WAD II	299 (50%)	1,375 (42%)
WAD III	25 (4%)	79 (2%)
SF-12		
Mental component score, Mean (SD)	36 (12) (missing data=108)	42 (13) (missing data=692)
Physical component score, Mean (SD)	36 (7)	41 (9) (missing data=692)

5.3 Treatments received by participants

Participants in this prospective cohort study received physiotherapy treatment as part of MINT.

5.3.1 Physiotherapy package

Attendance rates for participants who received the physiotherapy package are displayed in Table 34.

Table 34 Attendance rates for treatment

	Physiotherapy Package (n=300)	**Advice session (n=299)**
Failed to attend any appointments	34 (11%)	60 (20%)
Attended for assessment only*	26 (9%)	N/A
Partial completion of treatment	45 (15%)	N/A
Completed treatment*	201 (67%)	239 (80%)

*Six patients attended the assessment session and no further treatment was deemed necessary; these patients are therefore included in both categories.

The mean number of treatment sessions attended by participants who received the physiotherapy package was 3 (SD=2.7). Fourteen (4.7%) participants received greater than the recommended six treatment sessions. Assessment sessions were between 40 and 60 minutes long, and treatment sessions were between 20 and 30 minutes. On average, participants commenced the physiotherapy package 47 days (SD=17) after their attendance at the ED. The average time from commencing to finishing the physiotherapy package was 55 days (SD=51) although there was considerable variability amongst participants.

Information about the content of the treatments received by participants was available for 259 of the 266 patients who attended at least one appointment (Table 35). Seven of the 26 patients who attended only the assessment session patients were assessed but did not receive any treatment. Psychological strategies and self-management advice were used with the majority of patients (246/259, 95%), and almost all received guidance on some form of exercises (246/259, 95%). The most common form of exercises was cervical ROM exercises. Manual therapy was used to a somewhat lesser degree (211/259, 81%) with soft tissue techniques and Maitland cervical mobilisations being used most frequently. The majority of patients (73%) received a combination of manual therapy, exercises and psychological strategies.

5.3.2 Control intervention – advice session

Attendance rates for participants who received the control intervention are also displayed in Table 34. The advice session provided for these participants was 30 to 60 minutes in duration. On average, participants attended for this advice session 50 days (SD=17) after their attendance at the ED. 163 participants received advice based on the Whiplash Book and 136 received advice based on the usual leaflet issued at ED they attended. The contents of the advice session is presented in Table 36.

Table 35 Types of treatments delivered in the physiotherapy package

Type of treatment delivered		**Number of patients receiving the treatment (%)**
Combinations of treatments		**n = 259**
	Manual therapy, exercises and psychological strategies	190 (73%)
	Exercises and psychological strategies	45 (17%)
	Manual therapy and psychological strategies	10 (4%)
	Manual therapy and exercises	9 (3%)
	Manual therapy only	2 (1%)
	Exercises only	2 (1%)
	Psychological strategies only	1 (0%)
Manual therapy techniques		**n = 211**
	Soft tissue techniques	123 (58%)
	Maitland cervical mobilisations	123 (58%)
	NAGS and SNAGS (cervical or thoracic)	86 (41%)
	Maitland thoracic mobilisations	71 (34%)
	Other manual therapy	42 (20%)
	Shoulder mobilisations	15 (7%)
	Thoracic manipulation	5 (2%)
Exercises		**n=246**
	Cervical ROM exercises	244 (99%)
	Cervical or scapular stability exercises	118 (48%)
	Thoracic ROM exercises	106 (43%)
	Shoulder ROM exercises	88 (36%)
	Other exercises	69 (28%)
	Proprioception exercises	28 (11%)
Psychological strategies and self-management advice		**n=246**
	Advice re: posture and positioning	194 (79%)
	Reassurance	194 (79%)
	Pain education	144 (59%)
	Advice re: return to work or activities	145 (59%)
	Goal setting or pacing	119 (48%)
	Advice re: medication and symptomatic control	87 (35%)
	Relaxation	56 (23%)
	Advice re: travel anxiety	27 (11%)
	Referral to GP/Psychologist for stress reaction	10 (4%)

Table 36 Contents of advice session

Contents of advice session	**Number of patients receiving the advice n=239 (%)**
Assessed ROM	232 (97)
Neurological Examination	87 (36.5)
Referred on due to serious complication	2 (0.8)
Reviewed exercises given in the ED	228 (95)
Progressed exercises within the guidelines of the whiplash book[1]	108 (45)
Postural or positioning advice	200 (83.5)
Advice re: collar	56 (22)
Advice re: pain control or medication use	185 (77.5)
Advice re: graded return to activities, return to work or staying active[1]	119 (50)
Relaxation techniques[1]	82 (34.5)
Reassurance[1]	119 (50)
Reinforced the “hurt does not equal harm” message[1]	121 (50.5)
Advised to see their GP if they had ongoing problems	220 (92)
Other advice	25 (8.4)

[1] Whiplash Book centres only

5.4 Course of recovery

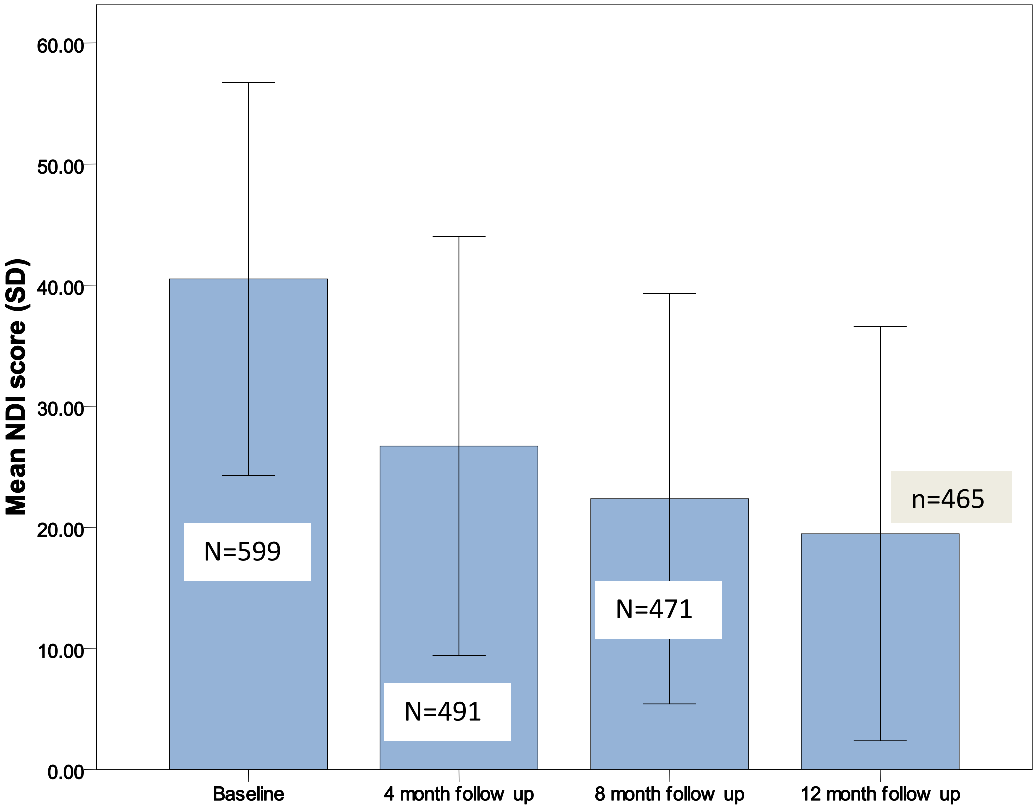
5.4.1 NDI scores

The NDI scores at follow up are in Table 37. The mean NDI score reduced at each follow up point indicating a reduction in mean disability of participants over time (Figure 13). A steep reduction in NDI scores is observed in the first four months following injury. Less improvement was seen between 4 and 8 months follow up with very little change occurring between 8 and 12 months. A small number of participants returned the NDI with missing data so that a total NDI could not be calculated. However, they completed the relevant questions to allow their recovery status to be classified.

Table 37 NDI scores at follow up

	Neck Disability Index Scores
4 month follow up (n=499)	Mean (SD) = 27.9(17.6) Participants without total NDI score = 8
8 month follow up (n=495)	Mean (SD) = 22.9(17.6) Participants without total NDI score = 16
12 month follow up (n=473)	Mean (SD) = 20.5 (17.8) Participants without total NDI score = 8

Figure 13 Mean NDI scores (SD) over time



NDI scores for each participant were also categorised into the 5 categories proposed by Vernon and Mior (208) and are presented in Figures 14-17. Generally there was a reduction in the number of participants classified as moderate, severe and completely disabled over time. However, approximately 30% of participants fall into these categories at 12 months follow up indicating considerable ongoing disability for these individuals.

Figure 14 Distribution of NDI at baseline (n=599)

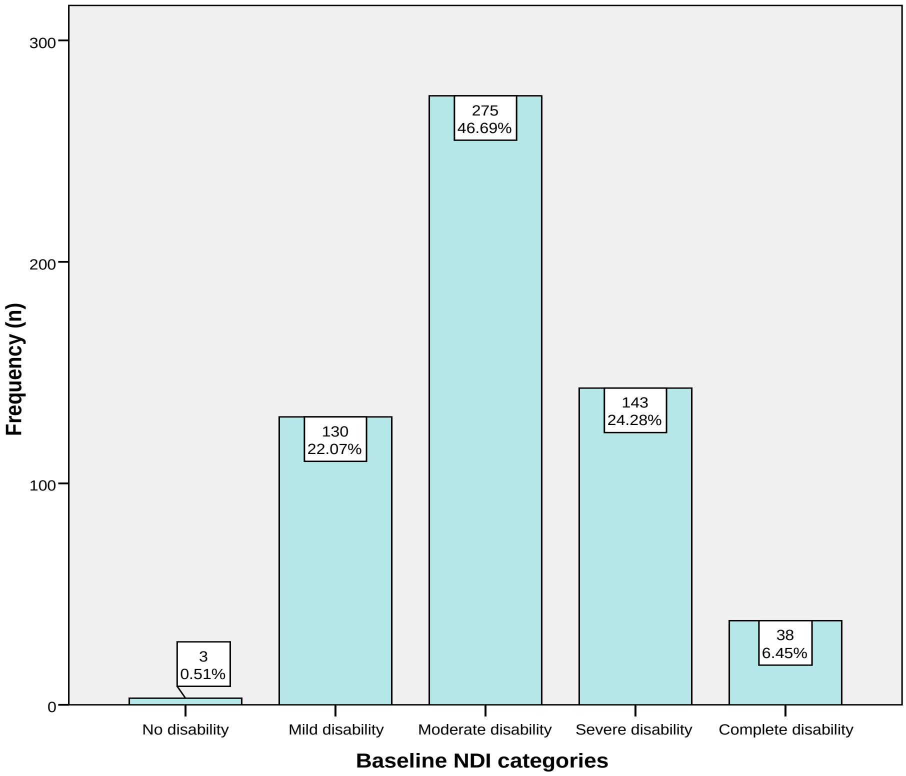


Figure 15 Distribution of NDI at 4 month follow up (n=491)

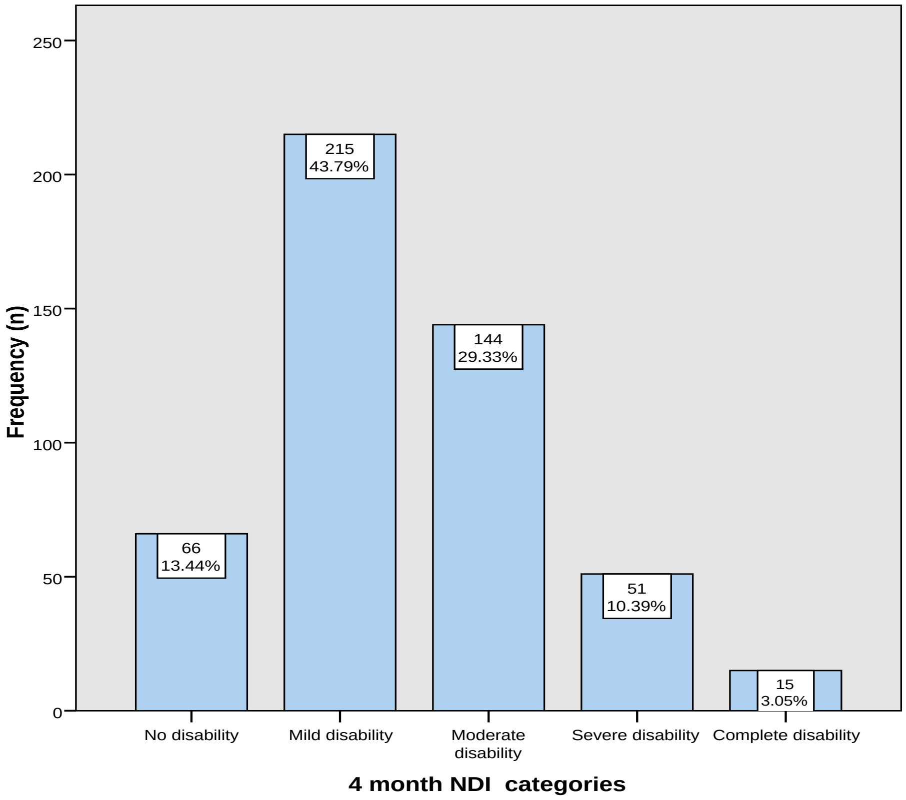


Figure 16 Distribution of NDI at 8 month follow up (n=479)

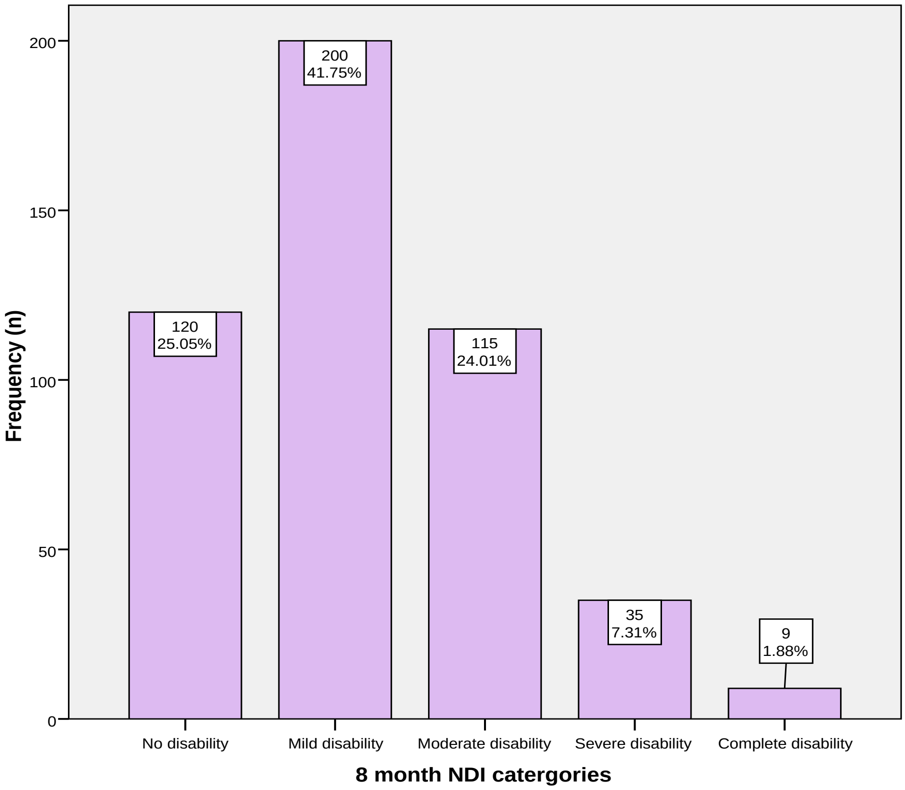
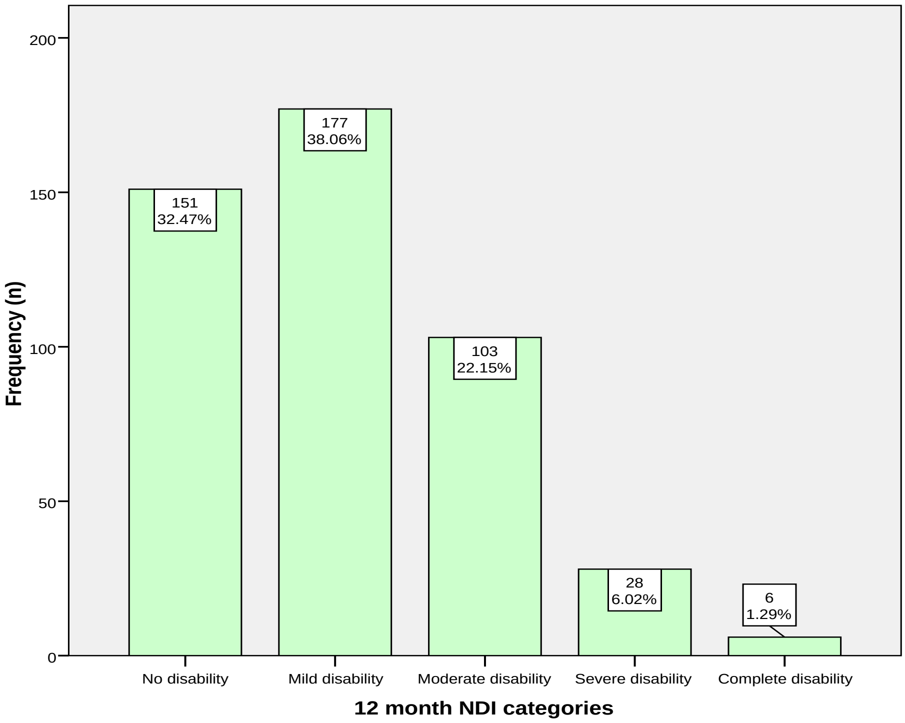


Figure 17 Distribution of NDI at 12 month follow up (n=465)



5.4.2 Participant rated improvement

Participant rated improvement at each follow up point is presented in Table 38 and Figures 18-20. The majority of participants rated themselves as improved (much better or better) at the 4 month follow up. A lesser proportion of participants rated themselves improved (better or much better) at the 8 month and 12 month follow up. These findings reflect those based on the NDI scores where the greatest change in NDI scores were seen between baseline and 4 month follow up. The proportion of participants who reported that they were the same increased over time which also reflects a reduction of improvement as seen in the NDI scores at 8 and 12 months follow up. The proportion of participants reporting that their condition had worsened increased at each time point. This rose from 5% at 4 month follow up to approximately 10% at 8 months follow up with little change seen at 12 month follow up.

Table 38 Participant rated improvement at follow up (n(%))

	4 month follow up (n=485)	**8 month follow up (n=489)**	**12 month follow up (n=471)**
Much better	126(26)	119(24.3)	113(24)
Better	247(50.9)	196(40.1)	164(34.8)
Same	88(18.1)	127(26)	149(31.6)
Worse	18(3.7)	45(9.2)	44(9.3)
Much worse	6(1.2)	2(0.4)	1(0.2)

Figure 18 Participant rated improvement at 4 month follow up (n=485)

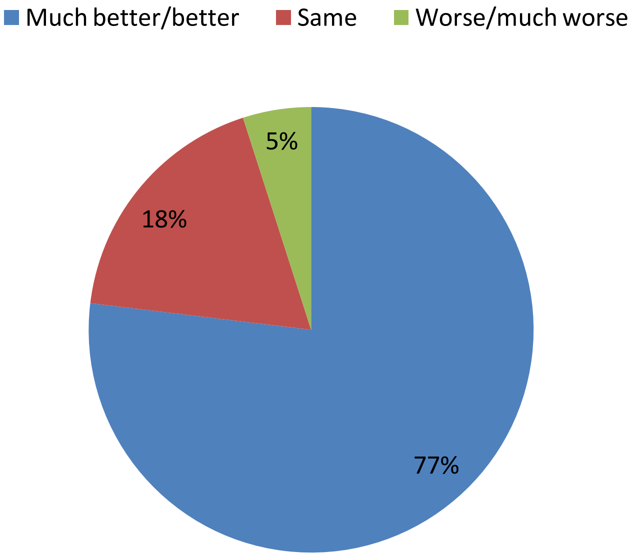


Figure 19 Participant rated improvement at 8 month follow up (n=489)

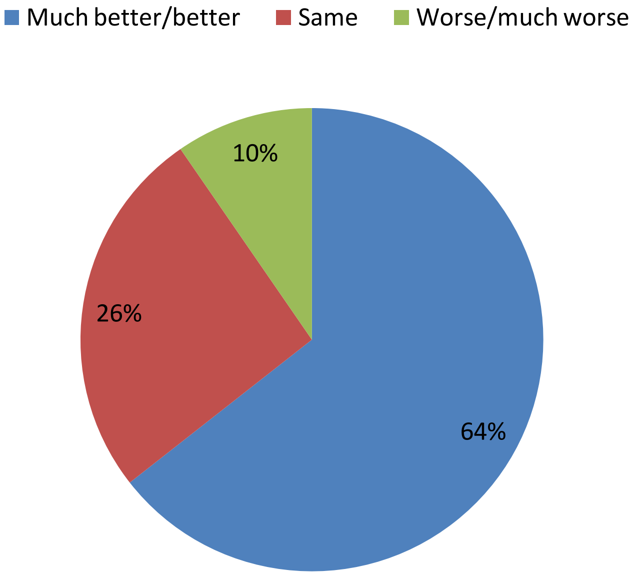
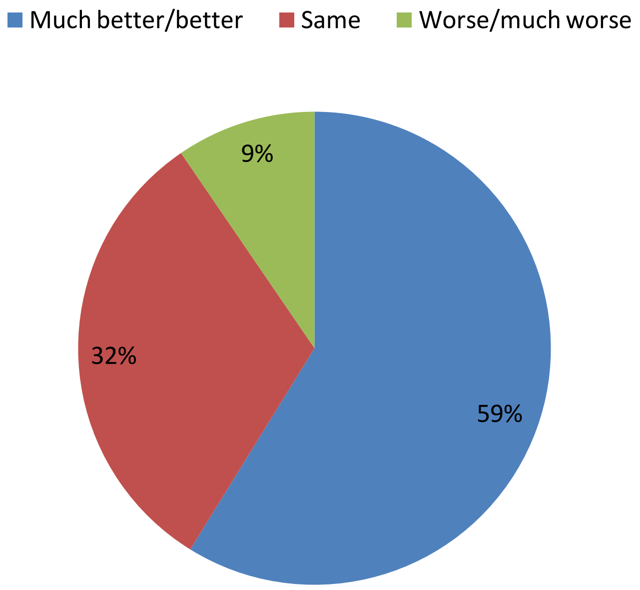


Figure 20 Participant rated improvement at 12 month follow up (n=471)



All possible combinations of participant rated improvement overtime were examined for participants who had provided data at each follow up point (n=394). Patterns of participant rated improvement were extremely variable with 26 combinations present in the cohort (Table 39 (p177)). The most common pattern of participant rated improvement was that the participant rated themselves as improved at all 3 time points (approximately 42%). Approximately 13% of participants reported improvement up until 8 months but no further improvement was reported at 12 months. Less frequently participants reported improvement at 4 months but no further improvement after this time point (8.4%). There were also a proportion of participants that reported different combinations of improvement and no change (14.5%), those that reported different combinations of improvement and worsening (6%) and those that reported improvement, no change and worsening in varying order over the follow up period (6.3%). These participants demonstrate the fluctuating nature of the condition in approximately 27% of participants.

No participants reported a worsening of symptoms at all time points but approximately 9% of participants did not report perceived improvement at any time point. These participants presented with a variety of combinations of no change and worsening of symptoms and represent a group of participants whose condition was resistant to improvement. Baseline differences were examined between those participants who did not improve at any time point and the rest of the cohort. Those who did not improve at any time point reported statistically significant ($p<0.05$) higher levels of fear avoidance (mean FABQ score (SD) = 16.3(5.7)) and greater pain severity ratings (mean pain severity ratings (SD)=63.0(15.1)) than other participants (mean FABQ score (SD)=13.7(5.7)); mean pain severity (SD)=55.7(18.2)). A greater proportion of those who did not improve at any time point also predicted their recovery would take > 6 months or were unsure they would recover compared to other participants (44% compared to 28%, $p<0.05$).

Table 39 Combinations of participant rated improvement over time (n=394)

4 month follow up	8 month follow up	12 month follow up	Number of participants presenting with this combination (%)
+	+	+	166(42.1)
+	+	=	50(12.7)
+	=	=	33(8.4)
+	=	+	25(6.4)
=	+	+	20(5.1)
=	=	=	17(4.3)
+	-	=	10(2.5)
+	=	-	9(2.3)
+	-	+	9(2.3)
+	+	-	8(2.0)
=	+	=	7(1.8)
=	=	+	5(1.3)
=	=	-	5(1.3)
=	-	=	5(1.3)
+	-	-	4(1.0)
=	+	-	3(0.8)
-	=	=	3(0.8)
=	-	-	2(0.5)
-	+	+	2(0.5)
-	+	=	2(0.5)
-	=	+	2(0.5)
-	=	-	2(0.5)
-	-	=	2(0.5)
=	-	+	1(0.3)
-	+	-	1(0.3)
-	-	+	1(0.3)

Improved (much better or better) +; No change =; Worsened (worse or much worse) -

5.4.3 Recovery status

Recovery status at baseline and follow up are presented in Table 40. The majority of participants were classified as non-recovered at baseline with a small proportion classified as recovered by the time they were assessed. However, these participants were still experiencing symptoms as demonstrated by their NDI scores. A similar pattern of recovery was observed to that based on NDI scores with the greatest change in recovery status occurring between baseline and four months and very little change observed between 8 and 12 months. The mean NDI scores for those classified as recovered were significantly lower than those classified as non-recovered or with LWS at all time points (p=<0.001). Frequencies and mean NDI scores for each category are displayed in Table 40.

Table 40 Recovery status at baseline and follow up

	Recovered	Non-recovered/LWS
Baseline (n=599) **Mean NDI scores (SD)**	99/599(16.5%) 22.0(7.9)	500/599(83.5%) 45.7(14.5)
4 month follow up (n=499) **Mean NDI scores(SD)**	229/499(45.9%) 14.9 (9.9) Missing data n=3	270/499(54.1%) 38.9 (14.9) Missing data n=5
8 month follow up (n=495) **Mean NDI scores(SD)**	n=292/495(59.0%) 12.4(9.9) Missing data n=5	203/495(41.0%) 38.5(14.9) Missing data n=11
12 month follow up (n=473) **Mean NDI scores (SD)**	n=288/473(60.9%) 9.86 (9.23) Missing data n=2	185/473(39.1%) 37.42 (14.68) Missing data n=6

The recovery status of participants over time was also examined and is presented in Table 41. The recovery status at all 3 follow up points was available for 410 participants. Around a third of participants were classified as recovered at all 3 time points with approximately one quarter of participants being non-recovered/LWS at all 3 time points. Another pattern of recovery to be observed was participants that followed an expected sequence of recovery and progressed from being non-recovered at 4 months follow up to recovered by the 12 month follow up point (21.2%). The remaining participants fell into several different combinations of recovery and non-recovery but all was classified as having LWS after being classified as recovered indicating a relapse at some point over the follow up period (17.5%).

Table 41 Recovery status over time (n=410)

4 month	**8 months**	**12 months**	**Number of participants (%)**
√	√	√	150(36.6)
X	X	X	101(24.6)
X	√	√	58(14.1)
X	X	√	29(7.1)
X	√	X	23(5.6)
√	X	√	18(4.4)
√	X	X	17(4.1)
√	√	X	14(3.4)

√=recovered, X=non-recovered/LWS

5.4.4 The relationship between participant perceived improvement and NDI scores at follow up

The relationship between participant ratings of improvement and NDI scores at each follow up was examined (Table 42). A moderate level of correlation was seen between the two scores which was statistically significant at each follow up point. The mean NDI scores were also significantly different between the three groups. Those who rated themselves as much better or better had the lowest NDI scores and those who rated themselves as worse or much worse had the highest NDI scores at each follow up point. However, as demonstrated in Figures 21-23, a large degree of variability was present. This indicates that, although, a statistically significant association between participant rated improvement and NDI score was observed, on an individual level there was not a close fit.

Table 42 The correlation between participant rated improvement and NDI scores and change in NDI scores.

	Correlation between participant rated improvements and NDI score	Correlation between participant rated improvements and change in NDI score
4 months	0.42* (n=471)	-0.36* (n=464)
8 months	0.43* (n=470)	-0.35* (n=429)
12 months	0.47* (n=457)	-0.29* (n=416)

* spearman's correlation p<0.01

Figure 21 Mean NDI scores (SD) stratified by participant rated improvement at 4 months follow up (n=471)

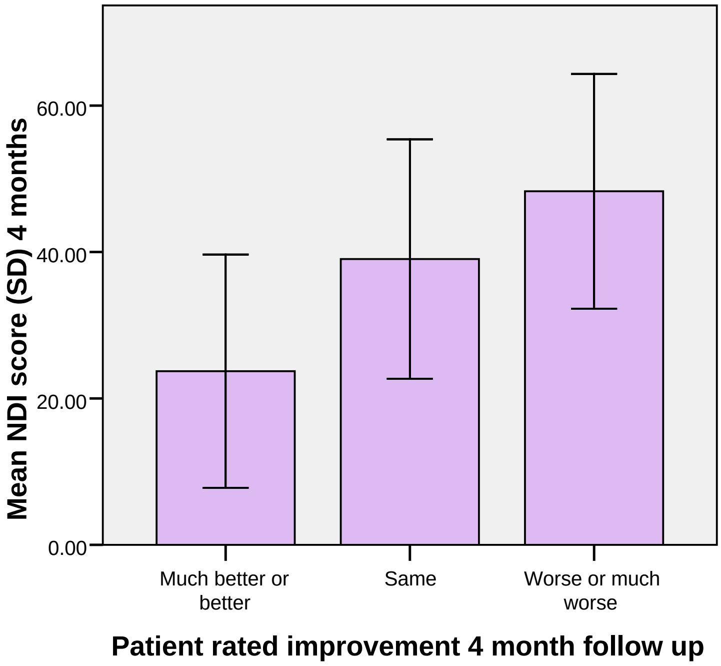


Figure 22 Mean NDI scores (SD) stratified by participant rated improvement at 8 months follow up (n=470).

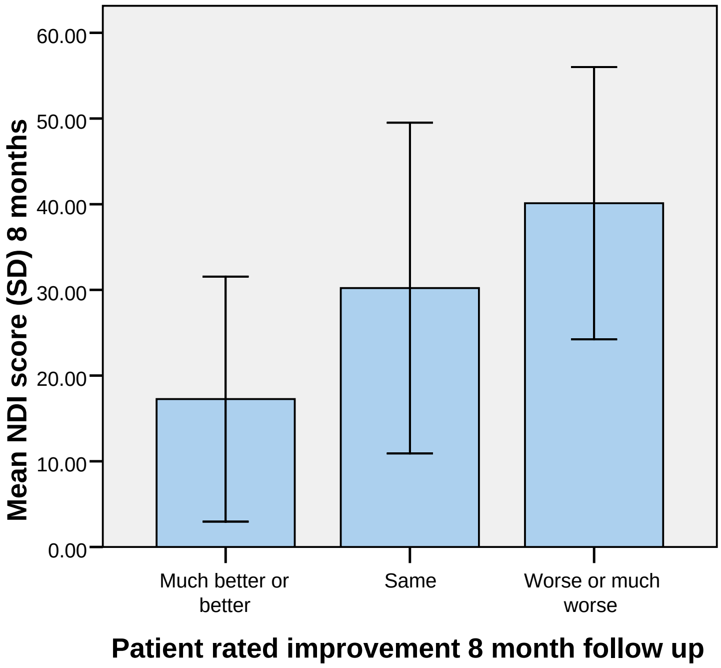
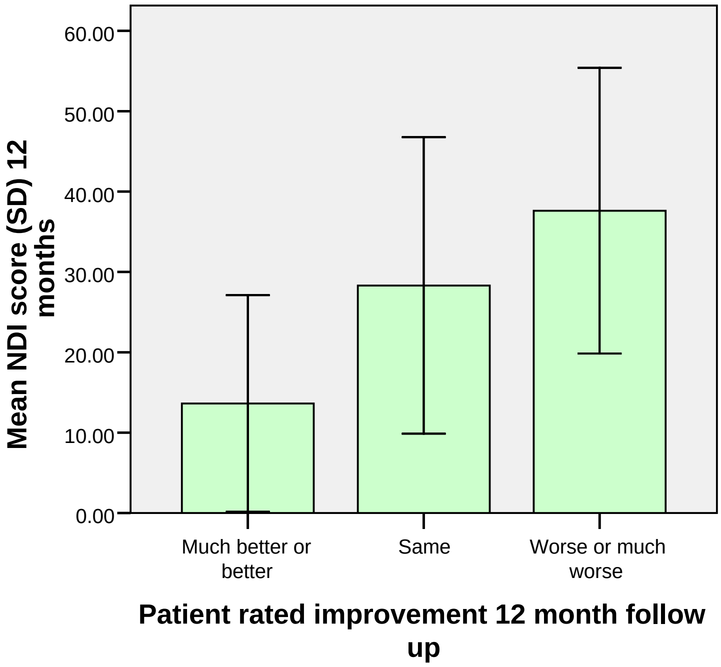


Figure 23 Mean NDI scores (SD) stratified by participant rated improvement at 12 months follow up (n=457).



Comparisons were also made between the participant rated improvement and the mean change in the NDI scores between follow up points. The reason for this was that the participant rating of improvement was based on their perceived improvement from one follow up point to the next. There was a significant correlation between the two scores but the amount of correlation was lower than compared to the actual NDI scores described above (Table 42). Those who were much better or better experienced a mean reduction in their NDI score at all 3 time points (Figures 24-26). For those that rated themselves as the same or worse there was less agreement between the types of outcomes. Those that rated themselves as the same, on average, experienced a 5 point reduction in their NDI score at the 4 month follow up. This would be considered a clinically important improvement in their NDI. Better agreement between the two measures was observed at 8 and 12 months when very little change in mean NDI scores was observed. Those who were much worse or worse experienced very little change in their mean NDI scores between baseline and 4 months which actually suggests they were the same at 4 months follow up. The two measures were in greater agreement at 8 and 12 months where on average these participants experienced an increase in their NDI scores of around 5 and 6 point respectively. Once again, a wide range of scores was observed indicating that although a statistically significant relationship between participant rated improvement and change in NDI was observed, the data were not a good fit on an individual level.

Figure 24 Change in mean NDI scores (SD) stratified by participant rated improvement at 4 months follow up (n=464)

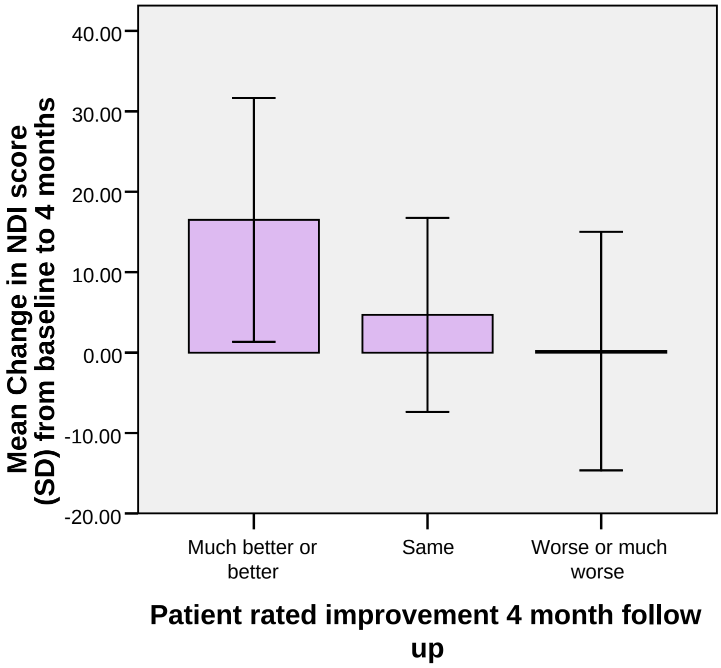


Figure 25 Change in mean NDI scores (SD) stratified by participant rated improvement at 8 months follow up (n=429)

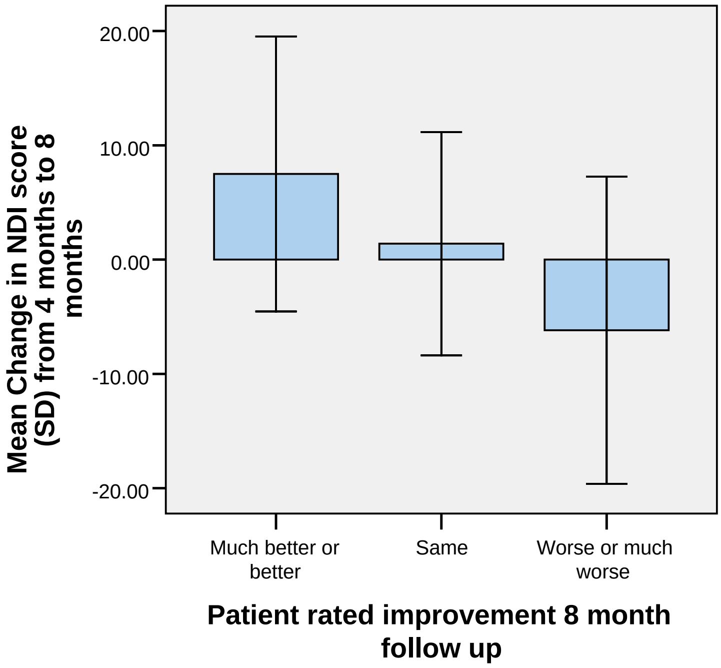
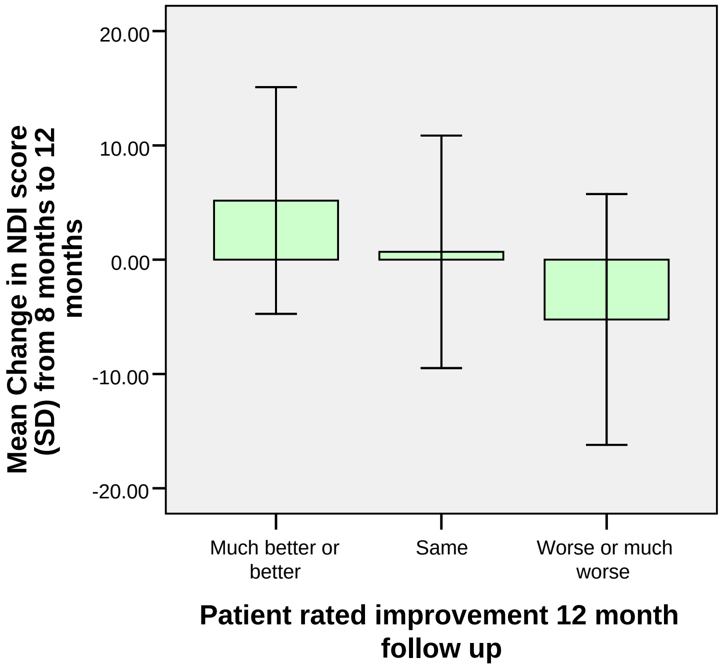


Figure 26 Change in mean NDI scores (SD) stratified by participant rated improvement at 12 months follow up (n=416)



5.4.5 The relationship between participant ratings of improvement and recovery status

Participant rated improvement and recovery status at follow up was also examined. There was a significant correlation between the two scores but it was moderate to low at all 3 follow up points. The proportion of participants classified as being non-recovered/LWS was least in those who were better or much better and greatest in those who were worse or much worse (Table 43). The differences between the 3 groups were statistically significant. This indicates some level of agreement but also discrepancies between the two measures. In particular, they demonstrate that some participants despite rating their improvement as worse were still classified as recovered.

Table 43 Participant rated improvement and recovery status

	Patient rated improvement	**Recovery status (n(%)**	**Correlation between participant rated improvements and recovery status**
4 months (n=479)	Much better or better (n=369)	Recovered=192(52.0) Non-recovered=177(48.0)*	0.24**
	Same (n=86)	Recovered=23(26.7) Non-recovered=63 (73.3)*	
	Worse or much worse (n=24)	Recovered=4(16.7) Non-recovered=20(83.3)*	
8 months (n=485)	Much better or better (n=313)	Recovered=218(69.6)* LWS=95(30.4)*	0.29**
	Same (n=126)	Recovered=54(42.9) LWS=72(57.1)	
	Worse or much worse(n=46)	Recovered=15(32.6) LWS=31(67.4)*	
12 months (n=465)	Much better or better (n=273)	Recovered=206(75.5) LWS=67(24.5)*	0.37**
	Same(n=147)	Recovered=64(43.5) LWS=83(56.5)*	
	Worse or much worse (n=45)	Recovered=13(28.9) LWS=32(71.1)*	

* p<0.01 Kruskall Wallis test ; ** spearman's correlation p<0.01

5.4.6 Participant prediction of recovery

For those participants who supplied data at each follow up point, recovery status over time was examined in relation to their predicted recovery time (Table 44 (p187)). The data were examined to see if participants were able to predict the time to their own recovery. However, it was difficult to evaluate this accurately due to the different time frames represented by the two types of data (i.e. the time frames for predicting outcome include in the next 2 weeks and 2-8 weeks but the first follow up point was 4 months). Also, some participants were classified as having LWS after being classified as recovered at an earlier time point.

To simplify this, the first four categories displayed in Table 44 were examined in more detail. For participants who were recovered by 4 months and remained recovered (category 1), recovery occurred at some point between baseline data collection and the 4 month follow up. However, it is impossible to identify an exact time of recovery. Approximately 33% of participants provided a predicted time to recovery that was well before the 4 month follow up time point (within 8 weeks). Around 42% suggested they would take 2-6 months which fell within the time frame where recovery occurred. The remaining participants in this category (25%) were incorrect in their predictions and appeared to recover more quickly than they anticipated.

For those who failed to recovery by 12 months (category 2 - Table 44), 23% of participants gave correct predictions as they predicted it would take more than a year to recover or they were unsure they would recover. The remaining participants in this category (77%) all expected to be recovered by 12 months if not much earlier so were incorrect in their predictions.

The third category was those that were recovered at the 8 month follow up and remained recovered at 12 months (Table 44). These participants recovered at some point between the 4 and 8 month follow up. 69% of participants in this group provided a prediction that may have fallen within this time frame (2-6 months or 6-12 months). Around 24% of participants in this group were incorrect and predicted a more rapid recovery than they experienced. A small proportion of participants (7%) had a better recovery than expected. Overall, 31% of participants in this category were incorrect in their prediction.

The fourth category was those participants who were recovered at the 12 month follow up (Table 44). These participants recovered at some point between the 8 and 12 month follow up. The majority of participants in this category (75%) were incorrect and predicted shorter recovery times than they experienced. Around 25% of participants in this category predicted a recovery time that fell within the time frame when they would have recovered (6-12 months).

These findings demonstrate a degree of variability in the participants' ability to predict their recovery time. However, one pattern did emerge. It appeared that a greater proportion of those that recovered more quickly (recovered by 4 or 8 months) predicted time frames that fell within the time frame in which their recovery occurred compared to those that took longer to recover (recovered by 12 months) or did not recover.

Table 44 Recovery status over time and participant predicted time to recovery (n=404)

Recovery status over time				**Patient predicted time to recovery (n(%))**			
Category	**4 month**	**8 months**	**12 months**	**Within the next 2 weeks or 2-8 weeks**[1]	**2-6 months**	**6-12 months**	**More than a year or I am not sure I will recovery**[1]
1	√	√	√	50 (33.8)	62(41.9)	23(15.5)	13(8.8)
2	X	X	X	25(25)	36(36)	16(16)	23(23)
3	X	√	√	14(24.1)	32(55.2)	8(13.8)	4(6.9)
4	X	X	√	9(32.2)	12(42.9)	6(21.4)	1(3.6)
5	X	√	X	9(40.,9)	7(31.8)	4(18.2)	2(9.2)
6	√	X	√	7(41.2)	5(29.4)	2(11.8)	3(17.6)
7	√	X	X	2(11.8)	6(35.3)	5(29.4)	4(23.5)
8	√	√	X	4(28.6)	6(42.9)	3(21.4)	1(7.1)

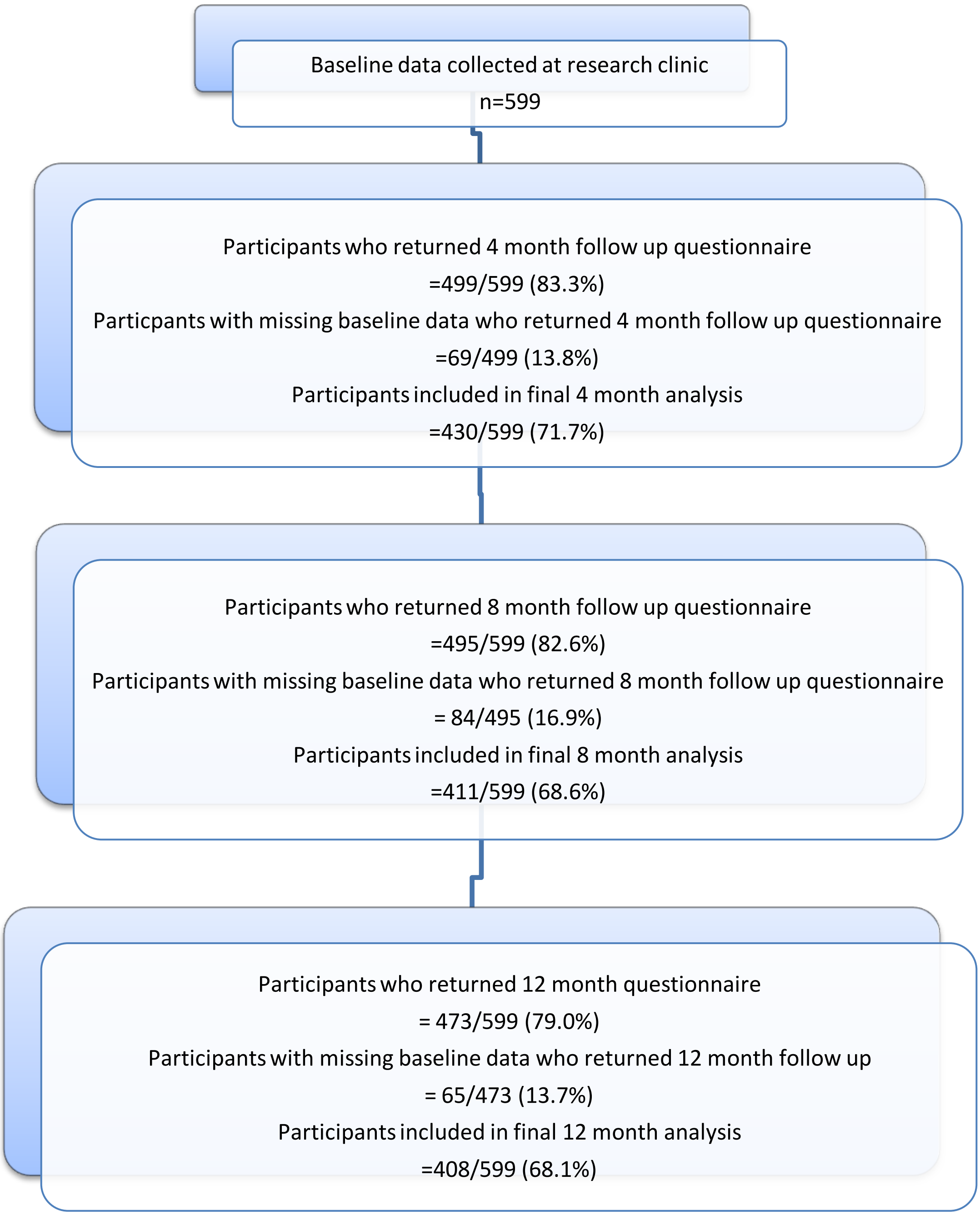
√=recovered; X=non-recovered/LWS

[1] combined two categories here

5.5 Participants included in multivariable analysis

Only participants with complete data at baseline and follow up were included in the multivariable analysis. Figure 27 shows the flow of participants through the trial and the number of participants included in the final step of the main logistic regression analysis at each follow up point.

Figure 27 Consort diagram for prospective cohort study



5.6 Logistic regression analysis - predictors of recovery status at 4 month follow up

5.6.1 Univariate analysis

The results of chi squared analysis between dichotomised baseline factors and recovery status at 4 month follow up are contained in Table 45.

Table 45 Univariate association between baseline factors and recovery status at 4 month follow up.

Baseline Factor (n)	Chi squared	P value
Injury severity factors		
Baseline NDI (n=499)	23.60	<0.001
Pain severity (n=461)	16.01	<0.001
No. of symptoms (n=495)	16.01	<0.001
WAD grade in ED (n=499)	0.83	0.36
WAD grade at randomisation (n=499)	3.63	0.06
Total cervical ROM (n=496)	14.12	<0.001
Belief factors		
Predicted recovery time (n=493)	1.82	0.17
FABQ (n=486)	3.54	0.06
Ability to cope (n=497)	14.74	<0.001
Beliefs about neck exercises after neck injury (n=498)	0.03	0.86
PCS (n=477)	6.56	0.01
Use of passive coping strategies (n=492)	15.09	<0.001
Use of active coping strategies (n=491)	0.21	0.64
Treatment preference (n=496)	4.52	0.003
Predicted benefit of treatment (n=496)	2.86	0.09
Psychological factors		
IES (n=476)	19.78	<0.001
GHQ (n=495)	25.93	<0.001
Pre-existing factors		
Age (n=499)	4.45	0.04
Sex (n=499)	0.12	0.73
Chronic widespread pain (n=492)	2.21	0.14
Previous neck pain (n=487)	0.40	0.53
Social support (n=488)	2.27	0.13
Treatment factors		
Treatment allocation (n=499)	0.49	0.48
Treatment attendance (n=499)	1.99	0.16

5.6.2 Logistic regression – injury severity factors

The 5 injury severity factors that had significant univariate associations of $p<0.25$ with recovery status at 4 months follow up were entered into a logistic regression model. Three 3 factors were retained to be entered into the final model (Table 46)

Table 46 Dichotomised injury severity factors predictive of non-recovery at 4 month follow up – logistic regression analysis (n=482)

Baseline Factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% CI**
Baseline NDI	0.81	0.23	<0.001	2.24	1.43-3.50
Cervical ROM	0.55	0.22	0.01	1.73	1.13-2.64
No. of symptoms	0.62	0.20	0.002	1.86	1.25-2.76
Constant	-0.44	0.14	0.001	0.64	

R^2= 0.08(Cox and Snell), 0.11(Nagelkerke); Model x^2 =41.67 p =<0.001

5.6.3 Logistic regression – psychological response factors

Dichotomised versions of the GHQ and IES were entered into a logistic regression model and both were retained to go into the final model (Table 47).

Table 47 Dichotomised psychological factors predictive of non-recovery at 4 month follow up – logistic regression analysis (n=473)

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
GHQ	0.87	0.22	<0.001	2.39	1.57-3.64
IES	0.78	0.25	0.002	2.19	1.34-3.55
Constant	-0.62	0.18	<0.001	0.54	

R^2= 0.08(Cox and Snell), 0.10(Nagelkerke); model x^2=37.05 p =<0.001

5.6.4 Logistic regression – pre-existing factors

Three pre-existing factors were entered into a logistic regression model but none were significantly associated with recovery status at 4 months and were not retained for the final model.

5.6.5 Logistic regression – treatment factors

Treatment attendance was entered into a logistic regression model and was not significantly associated with non-recovery and was not retained for the final model.

5.6.6 Logistic regression – final model

Factors retained from the initial logistic regression models described in sections 5.6.2 - 5.6.5 were entered into Block 1 of the final model. All belief factors with a univariate association with recovery status ($p<0.25$) were then entered into Block 2 of this analysis.

Block 1: Injury severity factors: baseline NDI, Total number of symptoms, Cx ROM; Psychological factors: IES, GHQ

Block 2: Patient beliefs: FABQ, PCS, Ability to cope, CSQ – passive coping subscale, treatment preferences and treatment received, predicted time to recover, predicted benefit of treatment

Factors found to be predictive of non-recovery at 4 month follow up are in Table 48.

Table 48 Dichotomised baseline factors predictive of non-recovery at 4 month follow up – logistic regression analysis (n=430)

Baseline Factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Baseline NDI	0.54	0.25	0.03	1.73	1.06-2.81
No. of symptoms	0.51	0.22	0.02	1.67	1.09-2.56
IES	0.60	0.27	0.03	1.82	1.07-3.07
GHQ	0.60	0.24	0.01	1.83	1.14-2.92
Ability to cope	0.51	0.22	0.02	1.67	1.08-2.58
Constant	-0.88	0.20	<0.001	0.41	

R^2= 0.12 (Cox and Snell), 0.16 (Nagelkerke), Model x^2 = 53.23 p =<0.001

VIF, tolerance and collinearity diagnostics (eigenvalues, condition index and variance proportions) were examined and all were within the recommended limits described in Section 4.14.2.4 indicating that there was no multicollinearity present.

Model fit was also examined as described in Section 4.14.2.3. Cook's distance, leverage, standardized residuals and DFBeta were within the recommended values indicating good model fit.

The following baseline factors were identified as being associated with increased risk of non-recovery at 4 months follow up:

1. High baseline NDI (≥50)
2. High number of symptoms (≥6)
3. High GHQ score (≥4)
4. Severe score on IES (>44)
5. Unable/unsure rating on ability to cope question

5.6.7 Recovery status according to individual risk factors

The proportion of participants classified as recovered and non-recovered according to each risk factor are presented in Table 49. For each identified risk factor a greater proportion of those with the risk factor were classified as non-recovered compared to those without the risk factor.

Table 49 Proportion of participants classified as recovered and non recovered according to each risk factor (n(%))

Baseline Factor		Are they classified as non-recovered at 4 months follow up?		Total
		No	Yes	
Baseline NDI	none/mild/mod disabled	185(53.16)	163(46.84)	348(100)
	Severe/complete disabled	42 (29.16)	102(70.84)	144(100)
Number of symptoms	Low number of symptoms	161(52.96)	143(47.04)	304(100)
	High number of symptoms	66(34.55)	125(65.45)	191(100)
GHQ	GHQ <4	93(63.70)	53(35.30)	146(100)
	GHQ 4 or more	135(38.68)	214(61.32)	349(100)
IES	Mild <44	188(51.37)	178(48.63)	366(100)
	Severe >/= 44	30(27.27)	80(72.73)	110(100)
Ability to cope	Yes	162(52.60)	146(47.40)	308(100)
	No/unsure	66(34.92)	123 (65.08)	189(100)

5.6.8 Recovery status according to the number of risk factors

The number of each risk factors present at baseline for each participant was calculated (Table 50) and as the number of risk factors increases the proportion of participants classified as non-recovered increases.

Table 50 Recovery status according to the number of risk factors present at baseline from 4 month analysis (n=599)

Number of risk factors present at baseline	**Number of participants (%)**	**Recovery status at 4/12 follow up**		
		Non recovered	**Recovered**	**Missing**
0	89(14.9)	20 (22.5)	58 (65)	11(12.5)
1	126(21.0)	48(38.2)	57(45.2)	21 (16.6)
2	150(25.0)	68 (45.3)	53 (35.3)	29(19.3)
3	102(17.0)	58 (56.9)	32(31.4)	12 (11.7)
4	65(10.9)	40 (61.5)	12 (18.5)	13 (20)
5	23(3.8)	16(69.5)	2(8.7)	5(21.8)
Missing baseline data	44(7.3)			
Total	599 (100)			

There is an accumulative effect of increasing numbers of risk factors present at baseline. Risk ratios were calculated using no risk factors present at baseline as the reference category. As the number of risk factors present at baseline increased so did the risk of non-recovery at 4 month follow up (Table 51).

Table 51 Relative risk of non-recovery with each additional risk factor at 4 month follow up

Number of risk factors present at baseline	**Risk ratio for non-recovery at 4 month follow up (95%CI)**
1 risk factor	1.8(1.3-4.6)
2 risk factors	2.2(1.5-3.3)
3 risk factors	2.5(1.7-3.8)
4 risk factors	3.0(2.0-4.5)
5 risk factors	3.5(2.3-5.2)

5.7 Logistic regression analysis - predictors of recovery status at 8 month follow up

5.7.1 Univariate analysis

The results of chi squared analysis between dichotomised baseline factors and the recovery status at 8 month follow up are contained in Table 52.

Table 52 Univariate associations between baseline factors and recovery status at 8 month follow up

Baseline Factor (n)	**Chi squared**	**P value**
Injury severity factors		
Pain severity (n=495)	16.02	<0.001
No. of symptoms (n=493)	8.59	0.003
WAD grade at randomisation (n=495)	2.65	0.10
WAD grade ED (n=495)	2.60	0.11
Total cervical ROM (n=493)	21.77	<0.001
Baseline NDI (n=495)	42.81	<0.001
Belief factors		
Predicted benefit of treatment (n=492)	8.32	0.004
Predicted recovery time (n=489)	13.84	<0.001
FABQ (n=483)	12.47	<0.001
Ability to cope (n=493)	8.90	0.003
Endorsement of exercises following neck injury (n= 494)	0.56	0.46
PCS (n=472)	15.90	<0.001
Use of passive coping strategies (n=488)	33.63	<0.001
Use of active coping strategies (n=487)	2.30	0.13
Treatment preference (n=496)	1.43	0.23
Psychological factors		
IES (n=476)	19.78	<0.001
GHQ (n=489)	37.37	<0.001
Pre-existing factors		
Age (n=495)	14.86	<0.001
Previous neck pain (n=483)	4.96	0.023
Widespread chronic pain (n=488)	10.51	0.001
Social support (n=488)	2.27	0.13
Sex (n=495)	0.12	0.73
Treatment factors		
Treatment allocation (n=495)	0.28	0.60
Treatment attendance (n=495)	3.48	0.06

5.7.2 Logistic regression – injury severity factors

All six injury severity factors that had significant univariate associations of p<0.25 with non-recovery at 8 months follow up and were entered into a logistic regression model. Three factors were retained to be entered into the final model (Table 53).

Table 53 Dichotomised injury severity factors predictive of LWS at 8 month follow up – logistic regression analysis (n=479)

Baseline factor	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Baseline NDI	0.93	0.25	<0.001	2.54	1.56-4.15
Pain severity	0.57	0.25	0.02	1.77	1.08-2.90
Total Cervical ROM	0.58	0.22	0.007	1.77	1.17-2.71
Constant	-0.98	0.14	<0.001	0.37	

R^2= 0.0.08(Cox and Snell), 0.15(Nagelkerke); model x^2=56.89 p =<0.001

5.7.3 Logistic regression – psychological response factors

Dichotomised versions of the GHQ and IES were entered into a logistic regression model and both were retained to go into the final model (Table 54).

Table 54 Dichotomised psychological response factors predictive of LWS at 8 month follow up – logistic regression analysis (n=467)

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
GHQ	1.21	0.24	<0.001	3.35	2.08-5.39
IES	0.50	0.23	0.03	1.65	1.04-2.61
Constant	-1.41	0.21	<0.001	0.25	

R^2= 0.08(Cox and Snell), 0.11(Nagelkerke); model x^2=41.05 p =<0.001

5.7.4 Logistic regression – pre-existing factors

The four pre-existing factors with significant univariate relationship ($p<0.25$) were entered into a logistic regression model with three being retained for the final model (Table 55).

Table 55 Dichotomised pre-existing factors predictive of LWS at 8 month follow up – logistic regression analysis (n=466)

Baseline factor	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Social support	0.42	0.21	0.04	1.51	1.01-2.26
Age	0.72	0.20	<0.001	2.05	1.39-3.03
Chronic widespread pain	1.82	0.80	0.02	6.20	1.29-29.71
Constant	-0.84	0.15	<0.001	0.43	

R^2= 0.05(Cox and Snell), 0.07(Nagelkerke); model x^2=28.28 p =<0.001

5.7.5 Logistic regression – treatment factors

Treatment attendance was entered into a logistic regression model and was not significantly associated with non-recovery and was not retained for the final model.

5.7.6 Logistic regression – final model

Factors retained from the initial logistic regression models described in sections 5.7.2-5.7.5 were entered into Block 1 of the final model. All belief factors with a univariate association with recovery status ($p<0.25$) were then entered into Block 2 of this analysis.

Block 1: Injury severity factors: baseline NDI, Pain severity, Cx ROM; psychological factors: IES, GHQ ; pre-existing factors: age, chronic widespread pain, social support

Block 2: Patient beliefs: FABQ, PCS, Ability to cope, Coping strategy questionnaire (CSQ) – passive coping subscale, CSQ- active coping subscale, treatment preferences and treatment received, predicted time to recover, predicted benefit of treatment

Factors found to be predictive of LWS at 8 month follow up are in Table 56. Surprisingly, a history of chronic widespread pain was not predictive of outcome despite being associated with a 6 fold increase in the odds of developing LWS in the initial analysis (Section 5.7.4). This is probably due to the fact that these participants also reported high baseline disability so when this was taken into consideration a history of CWP was no longer associated with outcome.

Table 56 Dichotomised baseline factors predictive of LWS at 8 month follow up – logistic regression analysis (n=411)

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Baseline NDI	1.09	0.25	<0.001	2.98	1.83-4.87
GHQ	1.17	0.28	<0.001	3.22	1.86-5.57
Age	0.97	0.23	<0.001	2.64	1.68-4.16
Predicted time to recovery	0.56	0.24	0.02	1.76	1.09-2.82
Predicted benefit of treatment	0.61	0.24	0.01	1.84	1.16-2.93
Constant	-2.33	0.30	<0.001	0.10	

R^2= 0.20(Cox and Snell), 0.27(Nagelkerke); model x^2=90.93 p =<0.001

VIF, tolerance and collinearity diagnostics (eigenvalues, condition index and variance proportions) were examined and all were within the recommended limits described in Section 4.14.2.4 indicating that there was no multicollinearity present.

Model fit was also examined as described in Section 4.14.2.3. Cook's distance, leverage, standardized residuals and DFBeta were within the recommended values indicating good model fit. A small number of the standardised residuals (n=5, 0.9%) were outside +/-2.58 but this number was still within the acceptable number of cases (<1%). These cases were checked for any anomalies with their data but none were found.

The following baseline factors were identified as being associated with increased risk of LWS at 8 months follow up:

1. High baseline NDI (≥50)
2. High GHQ score (≥4)
3. Older age(≥45)
4. Low expectations of treatment benefit (≤6)
5. Predicted time to recover >6 months or unsure they will recover

5.7.7 Recovery status according to individual risk factors

The proportion of participants classified as recovered or LWS at 8 month follow up according to each risk factor are presented in Table 57. For each identified risk factor a greater proportion of those with the risk factor were classified as developed LWS compared to those without the risk factor.

Table 57 Proportion of participants classified as having recovered or LWS according to each risk factor at 8 month follow up (n(%)).

Baseline Factor		Have they developed LWS at 8 months follow up?		Total
		No	Yes	
Baseline NDI	none/mild/mod disabled	238(68.39)	110(31.61)	348(100)
	Severe/complete disabled	48(34.78)	90(65.22)	138(100)
GHQ	GHQ <4	118(79.73)	30(20.27)	148(100)
	GHQ 4 or more	171(50.15)	170(49.85)	341(100)
Age	Age < 45	201(65.69)	105(34.31)	306(100)
	Age > = 45	91(48.14)	98(51.86)	189(100)
Predicted benefit of treatment	High	211(63.36)	122(36.64)	333(100)
	Low	79(49.69)	80(50.31)	159(100)
Predicted time to recovery	< 6/12	219(64.60)	120(35.40)	339(100)
	6/12 or more	70(46.67)	80(53.33)	150(100)

5.7.8 Recovery status according the number of risk factors

The number of each risk factors present at baseline was calculated (Table 58) and as the number of risk factors increases proportion of participants classified as having LWS increases.

Table 58 Recovery status according to the number of risk factors at present at baseline from 8 month analysis (n=599)

Number of risk factors present at baseline	Number of participants (%)	Recovery status at 8/12 follow up		
		LWS	Recovered	Missing at follow up
0	63(10.5)	3(4.7)	51(81)	9(14.3)
1	138(23)	28(20.3)	85(61.6)	25(18.1)
2	181(30.2)	62(34.3)	89(49.2)	30(16.5)
3	126(21)	63(50)	39(31)	24(19)
4	58(9.7)	32(55.2)	13(22.4)	13(22.4)
5	8(1.2)	5(62.5)	2(25)	1(12.5)
Missing baseline data	25(4.2)			
Total	599 (100)			

There was an accumulative effect of increasing numbers of risk factors. Risk ratios were calculated using no risk factors present at baseline as the reference category. As the number of risk factors present at baseline increased so did the risk of LWS at 8 month follow up (Table 59). When these are compared to the 4 months findings, the RR associated with the presence of increasing number of risk factors is much larger at 8 months. However, it should be noted that the risk factors are different in the two analyses which might explain the difference.

Table 59 Relative risk of LWS with each additional risk factor at 8 month follow up

Number of risk factors present at baseline	**Relative risk of LWS at 8 months follow up (95% CI)**
1 risk factor	4.5(1.4-14.0)
2 risk factors	7.4(2.4-22.6)
3 risk factors	11.1(3.7-33.7)
4 risk factors	12.8(4.2-39.0)
5 risk factors	12.9(3.9-42.5)

5.8 Logistic regression analysis - predictors of recovery status at 12 month follow up

5.8.1 Univariate analysis

The results of chi squared analysis between dichotomised baseline factors and recovery status at 12 month follow up are contained in Table 60.

Table 60 Univariate associations between baseline factors and recovery status at 12 month follow up.

Baseline Factor (n)	**Chi squared**	**P value**
Injury severity factors		
Pain severity (n=470)	31.49	<0.001
No. of symptoms (n=471)	21.21	<0.001
WAD grade at randomisation (n=473)	4.55	0.03
WAD grade ED (n=473)	3.93	0.05
Total cervical ROM (n=470)	19.04	<0.001
Baseline NDI (n=473)	52.91	<0.001
Belief factors		
Predicted benefit of treatment (n=470)	1.98	0.16
Participant predicted recovery time(n=467)	15.21	<0.001
FABQ (n=463)	9.30	0.002
Ability to cope (n=471)	9.40	0.002
Beliefs about neck exercises following neck injury (n=472)	0.88	0.35
PCS (n=450)	12.14	<0.001
Use of passive coping strategies (n=466)	27.47	<0.001
Use of active coping strategies (n=466)	2.62	0.11
Treatment preference (n=470)	3.81	0.05
Psychological factors		
IES (n=454)	10.84	0.001
GHQ (n=467)	25.26	<0.001
Pre-existing factors		
Age (n=473)	11.07	0.001
Sex (n=473)	0.49	0.49
Previous neck pain (n=460)	2.14	0.14
Widespread chronic pain (n=465)	8.23	0.004
Social support (n=462)	0.10	0.76
Treatment factors		
Treatment allocation (n=473)	1.60	0.21
Treatment attendance (n=473)	0.57	0.45

5.8.2 Logistic regression – injury severity factors

All six injury severity factors that had significant univariate associations of $p<0.25$ with non-recovery at 12 months follow up and were entered into a logistic regression model. Three factors were retained to be entered into the final model (Table 61).

Table 61 Dichotomised injury severity factors predictive of LWS at 12 month follow up – logistic regression analysis (n=479)

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Baseline NDI	1.24	0.24	<0.001	3.45	2.18-5.48
Total Cervical ROM	0.46	0.22	0.04	1.58	1.02-2.44
No. of symptoms	0.60	0.21	0.005	1.82	1.21-2.77
Constant	-1.26	0.16	<0.001	0.30	

R^2= 0.13(Cox and Snell), 0.17(Nagelkerke); model x^2=61.95 p =<0.001

5.8.3 Logistic regression – psychological factors

Dichotomised versions of the GHQ and IES were entered into a logistic regression model and only the GHQ score was retained to go into the final model (Table 62). Unlike the 4 and 8 months analyses, the IES score was not associated with recovery status in this analysis.

Table 62 Dichotomised psychological response factors predictive of LWS at 12 month follow up – logistic regression analysis (n=449)

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
GHQ	1.12	0.23	<0.001	3.07	1.95-4.83
Constant	-1.23	0.20	<0.001	0.29	

R^2= 0.056(Cox and Snell), 0.076(Nagelkerke); model x^2=25.87 p =<0.001

5.8.4 Logistic regression – pre-existing factors

The three pre-existing factors with significant univariate relationship ($p<0.25$) were entered into a logistic regression model with two being retained for the final model (Table 63). Once again, a history of CWP was associated with a large increase in the odds of developing LWS.

Table 63 Dichotomised pre-existing factors predictive of LWS at 12 month follow up – logistic regression analysis (n=452)

Baseline factor	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Age	0.58	0.20	0.004	1.78	1.20-2.64
Chronic widespread pain	1.42	0.68	0.04	4.12	1.09-15.66
Constant	-0.74	0.13	<0.001	0.48	

R^2= 0.03(Cox and Snell), 0.05(Nagelkerke); model x^2=15.12 p =0.001

5.8.5 Logistic regression – treatment factors

Treatment allocation was entered into a logistic regression model and was not significantly associated with LWS at 12 months and was not retained for the final model.

5.8.6 Logistic regression – final model

Factors retained from the initial logistic regression models described in sections 5.8.2-5.8.5 were entered into Block 1 of the final model. All belief factors with a univariate association with recovery status ($p<0.25$) were then entered into Block 2 of this analysis.

Block 1: Injury severity factors: baseline NDI, No. of symptoms, Cx ROM; Psychological response: GHQ ; pre-existing factors: age, chronic widespread pain

Block 2: Patient beliefs: FABQ, PCS, Ability to cope, Coping strategy questionnaire (CSQ) – passive coping subscale, CSQ- active coping subscale, treatment preferences and treatment received, patient predicted time to recover, patient rated benefit of treatment

Factors found to be predictive of LWS at 12 months follow up are in Table 64.

Table 64 Dichotomised baseline factors predictive of LWS at 12 month follow up – logistic regression analysis (n=408)

Baseline factor	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Baseline NDI	1.13	0.25	<0.001	3.10	1.91-5.03
No. of symptoms	0.57	0.23	0.01	1.77	1.13-2.78
GHQ	0.77	0.27	0.004	2.17	1.27-3.70
Age	0.55	0.23	0.01	1.74	1.12-2.72
Predicted time to recovery	0.61	0.24	0.01	1.84	1.16-2.93
Constant	-1.97	0.27	<0.001	0.14	

R^2= 0.16(Cox and Snell), 0.22(Nagelkerke); model x^2=70.60 p =<0.001

VIF, tolerance and collinearity diagnostics (eigenvalues, condition index and variance proportions) were examined and all were within the recommended limits described in Section 4.14.2.4 indicating that there was no multicollinearity present.

Model fit was also examined as described in Section 4.14.2.3. Cook's distance, leverage, standardized residuals and DFBeta were within the recommended values indicating good model fit.

The following baseline factors were identified as being associated with increased risk of LWS at 12 months follow up:

1. High baseline NDI (≥50)
2. High number of symptoms (≥6)
3. High GHQ score (≥4)
4. Older age (≥45)
5. Predicted time to recover >6 months or unsure they will recover

5.8.7 Recovery status according to individual risk factors

The proportion of participants classified as recovered or LWS at 12 month follow up according to each risk factor are presented in Table 65.

Table 65 Proportion of participants classified as recovered or LWS at 12 month follow up according to each risk factor (n(%))

Baseline factors		**Have they developed LWS at 12 months follow up?**		**Total**
		No	Yes	
Baseline NDI	none/mild/mod disabled	238(71.47)	95(28.53)	333(100)
	Severe/complete disabled	47(35.07)	87(64.93)	134(100)
Total number of symptoms	Low number of symptoms	201(68.84)	91(31.16)	292(100)
	High number of symptoms	85(47.49)	94(52.51)	179(100)
GHQ	GHQ <4	113(77.93)	32(22.07)	145(100)
	GHQ 4 or more	172(53.42)	150(46.58)	322(100)
Age	Age < 45	192(66.90)	95(33.10)	287(100)
	Age > = 45	96(51.61)	90(48.39)	186(100)
Time to recovery	< 6/12	216(66.67)	108(33.33)	324(100)
	6/12 or more	68(47.55)	75(52.45)	143(100)

5.8.8 Recovery status according to the number of risk factors

The number of each risk factors present at baseline was calculated for each participant (Table 66) and as the number of risk factors increases the proportion of participants classified as having LWS increases.

Table 66 Recovery status according to the number of risk factors present at baseline from 12 month analysis (n=599)

Number of risk factors present at baseline	**Frequency(%) Percent**	**Recovery status at 12 months follow up N(%)**		
		LWS	**Recovered**	**Missing follow up data**
0	71(11.9)	8(11.3)	49(69)	14(19.7)
1	129(21.5)	18(14)	84(65.1)	27(20.9)
2	167(27.9)	50(29.9)	83(49.7)	34(20.4)
3	127(21.2)	55(43.3)	42(33)	30(23.6)
4	66(11.0)	40(60.6)	14(21.2)	12(18.2)
5	12(2.0)	7(58.3)	4(33.3)	1(8.3)
Missing baseline data	2(4.5)			
Total	599(100.0)			

Risk ratios were calculated using no risk factors present at baseline as the reference category (Table 67). The presence of one risk factor at baseline did not increase the relative risk of LWS at 12 month follow up. However, participants with 2 or more risk factors at baseline were at increased risk of LWS at 12 month follow up compared to those with no risk factors present at baseline. Once again, the findings do differ to those from the 4 and 8 month analyses but different risk factors are included in this analysis.

Table 67 Relative risk of LWS with each additional risk factor

Number of risk factors present at baseline	**Relative risk of LWS at 12 month follow up (95% CI)**
1 risk factor	1.3(0.6-2.7)
2 risk factors	2.7(1.4-5.3)
3 risk factors	4.0(2.1-7.9)
4 risk factors	5.3(2.7-10.2)
5 risk factors	4.5(2.1-9.9)

5.9 Linear regression analysis – predictors of NDI scores at 4 month follow up

5.9.1 Univariate analysis

The strength of association between ordinal or interval baseline variables and NDI score at 4 months follow up is presented in Table 68.

Table 68 Correlation between baseline factors and NDI score at 4 month follow up

Injury severity factors	**Correlation co-efficient[1]**	**P value**
Baseline NDI(n=484)	0.53	<0.001
Pain severity (n=487)	0.43	<0.001
Number of symptoms (n=487)	0.30	<0.001
Cervical ROM (n=488)	-0.30	<0.001
Belief factors		
Predicted time to recovery (n=485)	0.23	<0.001
FABQ (n=478)	0.16	0.001
Ability to cope (n=489)	-0.20	<0.001
Beliefs about exercises following neck injury (n=490)	-0.03	0.51
PCS (n=470)	0.40	<0.001
Use of passive coping strategies (n=485)	0.34	<0.001
Use of active coping strategies (n=483)	0.03	0.56
Predicted benefited of treatment (N=488)	-0.12	0.011
Psychological factors		
IES (n=468)	0.35	<0.001
GHQ(n=487)	0.37	<0.001
Pre-existing factors		
Age (n=479)	0.19	<0.001
Social support (n=469)	-0.02	0.71

[1] Strengh of association measured by Pearson's correlation co-efficient for CxROM, Spearman's rho for all others

The univariate relationship between categorical baseline factors and 4 month NDI scores are presented in Table 69. The mean NDI scores at 4 month follow up for each category are compared for each baseline factor.

Table 69 Univariate relationship for categorical baseline variables at 4 months

Baseline factors	**Categories**	**Mean NDI score at 4 month follow up**	**P value[1]**
Injury severity factors			
WAD grade ED	1 (n=229)	26.2	0.19
	2 (n=239)	28.9	
	3(n=23)	34.0	
WAD grade @ randomisation	1 (n=73)	20.9	<0.001
	2 (n=359)	28.5	
	3 (n=59)	32.8	
Belief factors			
Treatment preference and treatment received	Got preferred treatment (n=120)	28.5	0.01
	Did not get preferred treatment (N=127)	31.1	
	No preference (N=244)	25.9	
Pre-existing factors			
Sex	Male (n=176)	26.7	0.38
	Female (n=315)	28.6	
Previous neck pain	Yes (n=40)	31.3	0.20
	No (n=439)	27.5	
Chronic widespread pain	Yes (n=11)	36.7	0.11
	No (n=473)	27.7	
Treatment factors			
Treatment allocation	Advice session (n=249)	27.6	0.75
	Physiotherapy package (n=242)	28.2	
Treatment attendance	Completed treatment (n=370)	27.0	0.08
	Partially completed treatment (n=36)	33.5	
	Attended for assessment only (n=19)	25.3	
	Did not attend any sessions (n=66)	30.3	

[1]The difference between categories was tested for statistical significant using a Mann Whitely U test or Kruskall-Wallis Test.

5.9.2 Injury severity factors

All 6 injury severity factors were entered into a linear regression model (forward stepwise) to determine which factors would be retained for the final model. 3 factors were shown to be predictive of the 4 month NDI score explaining 36% of the variance (Table 70). It is not unexpected that baseline NDI explained the majority of this as this is often the case when the same scale is used as a predictor variable and outcome.

Table 70 Linear regression – baseline injury severity factors predictive of 4 month NDI score (n=474)

Model	Factors	B	SE B	β	Adjusted R^2
1	Constant	1.51	1.77		
	NDI score	0.63	0.04	.59*	0.34
2	Constant	-0.01	1.87		
	NDI score	0.60	0.04	.55*	
	Number of symptoms	0.62	0.25	.10*	0.35
3	Constant	-3.06	2.25		
	NDI score	0.51	0.06	.40*	
	Number of symptoms	0.62	0.24	.10*	
	Pain severity	0.12	0.05	.12*	0.36

*$p<0.05$

5.9.3 Psychological factors

GHQ and IES both showed a significant univariate relationships with 4 month NDI and were entered into a linear regression model (forward stepwise) to determine which factors would be retained for the final model. Both factors were shown to be predictive of outcome explaining 18% of the variance (Table 71).

Table 71 Linear regression – baseline psychological factors predictive of 4 month NDI score (n=465)

Model	**Factors**	**B**	**SE B**	**β**	**Adjusted R²**
1	Constant	16.66	1.44		
	GHQ	1.73	0.19	.39*	0.15
2	Constant	14.09	1.52		
	GHQ	1.16	0.23	.26*	
	IES	0.22	0.05	.23*	0.18

*p<0.05

5.9.4 Pre-existing factors

Factors with significant univariate relationships with 4 month NDI were entered into a linear regression model (forward stepwise) to determine which factors would be retained for the final model: social support, age, history of chronic pain, history or previous neck pain. Only age was shown to be predictive of outcome explaining 2% of the variance (Table 72).

Table 72 Linear regression – pre-existing factors predictive of 4 month NDI score (n=462)

Model	**Factors**	**B**	**SE B**	**β**	**Adjusted R²**
1	Constant	19.19	2.70		
	Age	0.21	0.06	.15*	0.02

*p<0.05

5.9.5 Treatment factors

Treatment attendance was associated with 4 month NDI scores so was included in the regression analysis but did not significantly predict outcome in this analysis.

5.9.6 Final model

Factors retained from the initial linear models described in sections 5.9.2-5.9.5 were entered into Block 1 of the final model. All belief factors with a univariate association with recovery status (p<0.25) were then entered into Block 2 of this analysis.

Block one: Baseline NDI, Number of symptoms, pain intensity, GHQ, IES and age

Block two: FABQ, ability to cope, PCS, Passive coping, predicted benefit of treatment, predicted time to recover, treatment preferences and treatment received

Five factors were identified that were predictive of NDI scores at 4 month follow up (Table 73):

1. Baseline NDI
2. Total Impact of Events Scale
3. Age at randomisation
4. Total number of symptoms
5. Predicted time to recovery

These factors explained 39% of the variance, although, baseline NDI explained the majority of this (35%). The remaining factors explained around 4% of the model variance between them. This suggests that baseline disability is the most important factor but these other factors still represent potentially important clinical factors when considering treatment strategies.

Table 73 Final linear regression model: baseline factors predictive of 4 month NDI scores (n=423)

Model	**Factors**	**B**	**SE B**	**β**	**Adjusted R^2**
1	Constant	1.38	1.88		0.35
	NDI score	0.64	0.04	.60*	
2	Constant	0.29	1.89		
	NDI score	0.58	0.05	.54*	
	IES	0.13	0.04	.14*	0.37
3	Constant	-4.90	2.74		
	NDI	0.58	0.05	.53*	
	IES	0.12	0.04	.13*	0.38
	Age	0.14	0.05	.10*	
4	Constant	-5.88	2.77		
	NDI	0.55	0.05	.50*	
	IES	0.12	0.04	.12*	
	Age	0.13	0.05	.09*	
	Number of symptoms	0.54	0.26	.09*	0.381
5	Constant	-9.16	3.01		
	NDI	0.53	0.05	.49*	
	IES	0.11	0.04	.11*	
	Age	0.12	0.05	.09*	
	Number of symptoms	0.53	0.26	.08*	
	Predicted time to recovery	1.40	0.53	.10*	0.39

*p<0.05

5.10 Linear regression – predictors of NDI score at 8 month follow up

5.10.1 Univariate analysis

The strength of association between ordinal or interval baseline variables and NDI score at 8 months follow up is presented in Table 74.

Table 74 The correlation between baseline variables with NDI scores at 8 month follow up

Injury severity factors	**Correlation coefficient**[1]	**P value**
Baseline NDI(n=470)	0.51	<0.001
Pain severity (n=475)	0.39	<0.001
Number of symptoms (n=477)	0.28	<0.001
Cervical ROM (n=477)	-0.261	<0.001
Belief factors		
Predicted time to recovery (n=475)	0.21	<0.001
FABQ (n=467)	0.14	0.003
Ability to cope (n=477)	-0.15	0.001
Beliefs about exercises following neck injury (n=478)	-0.02	0.75
PCS (n=456)	0.39	<0.001
Use of passive coping strategies (n=472)	0.35	<0.001
Use of active coping strategies (n=472)	0.03	0.49
Predicted benefited of treatment (N=476)	-0.14	0.002
Psychological factors		
IES(n=457)	0.34	<0.001
GHQ (n=474)	0.34	<0.001
Pre-existing factors		
Age (n=479)	0.19	<0.001
Social support (n=469)	-0.02	0.71

[1] Strengh of association measured by Pearson's correlation co-efficient for CxROM, Spearman's rho for all others

The univariate relationship between categorical baseline factors and 8 month NDI scores are presented in Table 75. The mean NDI scores at 8 month follow up for each category are compared for each baseline factor.

Table 75 Univariate relationship for categorical baseline variables at 8 months

Baseline factors	**Categories**	**Mean NDI score at 8 month follow up**	**P value**[1]
Injury severity factors			
WAD grade ED	1 (n=222)	21.0	0.13
	2 (n=238)	24.1	
	3 (n=23)	29.5	
WAD grade @ randomisation	1 (n=72)	16.9	0.003
	2 (n=349)	23.5	
	3 (n=58)	26.5	
Belief factors			
Treatment preference and treatment received	Got preferred treatment (n=118)	24.4	0.09
	Did not get preferred treatment (n=122)	23.9	
	No preference (n=236)	21.6	
Pre-existing factors			
Sex	Male (n=171)	21.3	0.16
	Female (n=308)	23.7	
Previous neck pain	Yes (n=42)	28.2	0.04
	No (n=426)	22.5	
Chronic widespread pain	Yes (n=13)	42.9	0.002
	No (n=460)	22.2	
Treatment factors			
Treatment allocation	Advice session (n=235)	21.7	0.22
	Physiotherapy package (n=244)	24.0	
Treatment attendance	Completed treatment (n=352)	22.1	0.24
	Partially completed treatment (n=345	28.1	
	Attended for assessment only (n=21)	19.3	
	Did not attend any sessions (n=71)	25.1	

[1]The difference between categories was tested for statistical significant using a Mann Whitely U test or Kruskall-Wallis Test.

5.10.2 Injury severity factors

All 6 baseline injury severity factors were entered into a linear regression model (forward stepwise) to determine which factors would be retained for the final model. Two factors were shown to be predictive of outcome explaining 32% of the variance (Table 76).

Table 76 Linear regression – baseline injury severity factors predictive of 8 month NDI score (n=462)

Model	**Factors**	**B**	**SE B**	**β**	**Adjusted R^2**
1	Constant	-2.09	1.83		
	NDI score	0.61	0.04	.56*	0.31
2	Constant	-3.43	1.93		
	NDI score	0.57	0.05	.53*	
	Number of symptoms	0.54	0.26	.09*	0.32

*p<0.05

5.10.3 Psychological factors

GHQ and IES both showed a significant univariate relationships with 4 month NDI and were entered into a linear regression model (forward stepwise) to determine which factors would be retained for the final model. Both factors were shown to be predictive of outcome explaining 16% of the variance (Table 77).

Table 77 Linear regression – baseline psychological factors predictive of 8 month NDI score (n=452)

Model	**Factors**	**B**	**SE B**	**β**	**Adjusted R^2**
1	Constant	12.77	1.412		
	GHQ	0.36	0.04	.36*	0.13
2	Constant	9.95	1.54		
	GHQ	0.23	0.05	.24*	
	IES	1.01	0.24	.22*	0.16

*p<0.05

5.10.4 Pre-existing factors

Four pre-existing factors were entered into a linear regression model (forward stepwise) to determine which factors would be retained for the final model: age, widespread chronic pain, previous neck pain and sex. Age and a history of chronic pain were shown to be predictive of outcome explaining 6% of the variance (Table 78).

Table 78 Linear regression – pre-existing factors predictive of 8 month NDI score (n=461)

Model	**Factors**	**B**	**SE B**	**β**	**Adjusted R^2**
1	Constant	22.37	0.82		
	Chronic widespread pain	21.65	5.07	.20*	0.04
2	Constant	14.18	2.64		
	Chronic widespread pain	18.84	5.08	.17*	
	Age	0.21	0.06	.15*	0.06

*p<0.05

5.10.5 Treatment factors

Treatment allocation and attendance were entered into a linear regression model (forward stepwise) to determine which factors would be retained for the final model. Neither factor was significantly associated with the 8 month NDI so were not included in the final model.

5.10.6 Final model

Factors retained from the initial linear models described in sections 5.10.2- 5.10.5 were entered into Block 1 of the final model. All belief factors with a univariate association with recovery status (p<0.25) were then entered into Block 2 of this analysis.

Block one: Baseline NDI, Number of symptoms, GHQ, IES, history of chronic pain and age

Block two: FABQ, ability to cope, PCS, Passive coping, predicted benefit of treatment, predicted time to recover, treatment preferences and treatment received

Six factors were identified that were predictive of NDI scores at 8 month follow up explaining 38% of the variance (Table 79):

1. Baseline NDI
2. Age
3. Total IES
4. History of chronic widespread pain
5. Predicted benefit of treatment
6. Predicted time to recover

The results were similar to the 4 month findings in that the baseline NDI explained the most variance in the model (33%) and the remaining factors explained a small but clinically important proportion of the variance (around 5%).

Table 79 Final linear regression model: baseline factors predictive of 8 month NDI scores (n=407)

Model	Factors	B	SE B	β	Adjusted R²
1	Constant	-2.45	1.96		
	NDI score	0.62	0.04	.57*	0.33
2	Constant	-10.17	2.88		
	NDI score	0.61	0.04	.56*	0.34
	Age	0.20	0.06	.14*	
3	Constant	-10.58	2.86		
	NDI score	0.57	0.05	.51*	
	Age	0.19	0.06	.14*	
	IES	0.11	0.04	.11*	0.35
4	Constant	-9.58	2.89		
	NDI score	0.55	0.05	.51*	
	Age	0.17	0.06	.12*	
	IES	.109	.043	.11*	
	Chronic widespread pain	9.66	4.45	.09*	0.36
5	Constant	-3.52	3.70		
	NDI score	0.54	0.05	.50*	
	Age	0.17	0.06	.12*	
	IES	0.11	0.04	.11*	
	Chronic widespread pain	9.61	4.42	.09*	
	Expectations of treatment benefit	-0.80	0.31	-.10*	0.37
6	Constant	-7.33	4.04		
	NDI score	0.52	0.05	.48*	
	Age	0.17	0.06	.12*	
	IES	.098	0.04	.10*	
	Chronic widespread pain	9.61	4.40	.09*	
	Expectations of treatment benefit	-0.71	0.31	-.09*	
	Predicted time to recovery	1.29	0.56	.09*	0.38

*p<0.05

5.11 Linear regression analysis – predictors of NDI scores at 12 months follow up

5.11.1 Univariate analysis

The strength of association between ordinal or interval baseline variables and NDI score at 12 months follow up is presented in Table 80.

Table 80 The correlation between baseline variables with NDI scores at 12 month follow up

Injury severity factors	**Correlation coefficient[1]**	**P value**
Baseline NDI(n=459)	0.48	<0.001
Pain severity(n=462)	0.37	<0.001
Number of symptoms	0.34	<0.001
Cervical ROM (n=462)	-0.30	<0.001
Belief factors		
Predicted time to recovery (n=459)	0.27	<0.001
FABQ (n=455)	0.11	0.016
Ability to cope (n=463)	-0.16	0.001
Beliefs about exercises following neck injury (n=464)	0.30	0.57
PCS (n=443)	0.34	<0.001
Use of passive coping strategies (n=458)	0.33	<0.001
Use of active coping strategies (n=458)	0.06	0.19
Predicted benefited of treatment (n=462)	-0.10	0.03
Psychological factors		
IES (n=446)	0.28	<0.001
GHQ (n=459)	0.31	<0.001
Pre-existing factors		
Age (n=465)	0.20	<0.001
Social support (n=454)	0.02	0.67

[1] Strengh of association measured by Pearson's correlation co-efficient for CxROM, Spearman's rho for all others

The univariate relationship between categorical baseline factors and 12 month NDI scores are presented in Table 81. The mean NDI scores at 12 month follow up for each category are compared for each baseline factor.

Table 81 Univariate relationship for categorical baseline variables at 12 months

Baseline factors	**Categories**	**Mean NDI score at 12 month follow up**	**P value**[1]
Injury severity factors			
WAD grade ED	1 (n=212)	19.1	0.09
	2 (n=234)	20.9	
	3 (n=19)	30.0	
WAD grade @ randomisation	1 (n=68)	14.4	0.001
	2 (n=340)	20.5	
	3 (n=57)	27.4	
Belief factors			
Treatment preference and treatment received	Got preferred treatment (n=109)	22.1	0.08
	Did not get preferred treatment (n=144)	22.0	
	No preference (n=239)	19.1	
Pre-existing factors			
Sex	Male (n=163)	18.7	0.06
	Female (n=302)	21.4	
Previous neck pain	Yes (n=38)	25.4	0.07
	No (n=414)	20.1	
Chronic widespread pain	Yes (n=13)	37.8	0.005
	No (n=444)	19.9	
Treatment factors			
Treatment allocation	Advice session (n=233)	19.2	0.17
	Physiotherapy package (n=232)	21.8	
Treatment attendance	Completed treatment (n=352)	19.9	0.15
	Partially completed treatment (n=34)	25.5	
	Attended for assessment only (n=18)	20.1	
	Did not attend any sessions (n=61)	21.2	

[1] The difference between categories was tested for statistical significant using a Mann Whitely U test or Kruskall-Wallis Test.

5.11.2 Injury severity factors

All 6 baseline injury severity factors were entered into a linear regression model (forward stepwise) to determine which factors would be retained for the final model. Two factors were shown to be predictive of outcome explaining 30% of the variance (Table 82).

Table 82 Linear regression – baseline injury severity factors predictive of 12 month NDI score (n=450)

Model	**Factors**	**B**	**SE B**	**β**	**Adjusted R^2**
1	Constant	-3.27	1.89		
	NDI score	0.58	0.04	.54*	0.29
2	Constant	-5.24	1.96		
	NDI score	0.52	0.05	.48*	
	Number of symptoms	0.86	0.26	.14*	0.30

*p<0.05

5.11.3 Psychological factors

GHQ and IES both showed a significant univariate relationships with 12 month NDI and were entered into a linear regression model (forward stepwise) to determine which factors would be retained for the final model. Both factors were shown to be predictive of outcome explaining 12% of the variance Table 83.

Table 83 Linear regression – baseline psychological factors predictive of 12 month NDI score (n=440)

Model	**Factors**	**B**	**SE B**	**β**	**Adjusted R^2**
1	Constant	11.37	1.51		
	GHQ	1.50	0.21	.32*	0.10
2	Constant	9.67	1.61		
	GHQ	1.08	0.25	.23*	
	IES	0.15	0.05	.16*	0.12

*p<0.05

5.11.4 Pre-existing factors

Four pre-existing were entered into a linear regression model (forward stepwise) to determine which factors would be retained for the final model: age, widespread chronic pain, previous neck pain and sex. Age and a history of chronic pain were shown to be predictive of outcome explaining 5% of the variance (Table 84).

Table 84 Linear regression – pre-existing factors predictive of 12 month NDI score (n=443)

Model	Factors	B	SE B	β	Adjusted R^2
1	Constant	9.36	2.75		
	Age	0.27	0.06	.20*	0.04
2	Constant	10.26	2.75		
	Age	0.24	0.07	.18*	
	Chronic widespread pain	15.68	5.15	.14*	0.05

*p<0.05

5.11.5 Treatment factors

Treatment allocation and attendance were entered into a linear regression model (forward stepwise) to determine which factors would be retained for the final model. Neither factor was significantly associated with the 12 month NDI so were not included in the final model.

5.11.6 Final model

Factors included in the final model:

Block one: Baseline NDI, Number of symptoms, GHQ, IES, history of chronic pain and age

Block two: FABQ, ability to cope, PCS, Passive coping, predicted benefit of treatment, predicted time to recover, treatment preferences and treatment received

Four factors were identified that were predictive of NDI scores at 12 month follow up explaining 36% of the variance (Table 85):

1. Baseline NDI
2. Number of symptoms
3. Age
4. Predicted time to recover

Once again the NDI explained the most variance in the model (29%) although this is less compared to the 4 and 8 months findings. The remaining 3 factors explained slightly more in the 12 month model explaining 7% between them.

Table 85 Final linear regression model: baseline factors predictive of 12 month NDI scores (n=396)

Model	**Factors**	**B**	**SE B**	**β**	**Adjusted R^2**
1	Constant	-3.58	2.051		0.29
	NDI score	0.60	.046	.54*	
2	Constant	-5.85	2.133		0.31
	NDI score	0.53	.050	.48*	
	Number of symptoms	0.98	.290	.16*	
3	Constant	-12.50	3.00		0.33
	NDI score	0.51	0.05	.47*	
	Number of symptoms	0.91	0.29	.14*	
	Age	0.18	0.06	.13*	
4	Constant	-19.51	3.24		0.36
	NDI score	0.47	0.05	.43*	
	Number of symptoms	0.86	0.28	.14*	
	Age	0.18	0.06	.13*	
	Predicted time to recovery	2.76	0.57	.20*	

*$p<0.05$

5.12 Type and combinations of symptoms present at baseline and influence on outcome

A high number of symptoms were predictive of recovery status at 4 and 12 months follow up. Similarly the number of symptoms explained a small but significant amount of the variance of NDI scores at 4 and 12 months follow up. It was also possible the type of symptoms or particular combinations of symptoms were risk factors for poor outcome and were potentially more important risk factors than the actual number of symptoms. The analyses reported in the previous sections 5.6-5.11 were re-run to examine this.

Firstly, the regression analyses examining the injury severity factors were re-run including the types of symptoms and combinations of symptoms found to have significant univariate analysis with the outcome. The number of symptoms was also included in this analysis. The types of symptoms and the combinations of symptoms were not predictive of outcome. This indicated that while some types of symptoms and combinations of symptoms may have a univariate relationship with outcome, the number of symptoms was a better predictor of outcome. No further analysis was conducted.

Secondly, the regression analyses examining the injury severity factors were re-run including the types of symptoms and combinations of symptoms found to be have significant associations with the outcome instead of the number of symptoms. Those symptoms or combinations of symptoms found to be related to outcome were then included in the final models which were re-run.

In the logistic regression analysis the results were as follows:

- The type of symptoms or combinations of symptoms did not predict recovery status at 4 and 8 months.
- The presence of neurological symptoms at baseline increased the odds of LWS at 12 months by 1.74. This was almost identical to the increased odds associated with a high number of symptoms at baseline (OR=1.77).
- However, participants with neurological symptoms had a high numbers of symptoms.

In the linear regression analysis the results were as followed:

- Symptom combination 1 (proximal pain + arm pain + headaches + neurological symptoms) was significantly associated with NDI score at 4 months explaining approximately 1% of the variance. This was the same amount of variance explained by the number of symptoms.
- The type of symptoms or combinations of symptoms did not predict NDI scores at 8 months.
- The presence of neurological symptoms at baseline was significantly associated with NDI score at 12 months explaining approximately 2% of the variance. This was the same as the amount of variance explained by the number of symptoms.
- However, participants with symptom combination 1 or neurological symptoms also have a high number of symptoms.

In summary, the types or combinations of symptoms did not predict outcome when the number of symptoms was included in the analysis. When the number of symptoms was not included, neurological symptoms and symptom combination 1 (proximal pain + arm pain + headaches + neurological symptoms) did predict outcome at some follow up points. This is most likely related to the fact that these categories were both associated with a high number of baseline symptoms. These findings suggested that the number of symptoms rather than the type or combination of symptoms was the best way to identify those at risk of poor outcome.

5.13 Moderator analyses

5.13.1 Were the effects of belief factors moderated by other belief factors?

5.13.1.1 4 month moderator analysis – belief factors

1) The participant rated ability to cope was found to be predictive of recovery at 4 month follow up. Four baseline variables were found to be associated with the participant rated ability to cope in a cross-sectional analysis (Table 86).

Table 86 Baseline belief factors found to predict baseline ability to cope (n=541)

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Time to recovery	0.49	0.20	0.02	1.64	1.10-2.44
Endorsement of exercises	-1.04	0.20	<0.001	.35	0.24-0.53
Use of passive coping strategies	1.10	0.20	<0.001	3.00	2.03-4.42
Use of active coping strategies	-0.42	0.20	0.04	0.65	0.44-0.97
Constant	-0.82	0.38	0.03	0.44	

R^2= 0.16(Cox and Snell), 0.22(Nagelkerke); model x^2=70.60 p =<0.001

Belief factors associated with an increased risk of the participant rating their ability to cope as unsure/unable:

1. Participant rated recovery time of ≥6 months or unsure they will recover
2. High use of passive coping strategies

Belief factors associated with a reduced risk of the participant rating their ability to cope as unsure/unable:

1. High level of endorsement of the use of exercises to help recovery after a neck injury
2. High use of active coping strategies

2) The four factors identified above were then entered into step two of a logistic regression model described in the final model for the 4 months analysis as interactions with ability to cope.

Step 1: Injury severity factors: baseline NDI, Total number of symptoms, Cx ROM; Psychological response: IES, GHQ

Step 2: Patient beliefs: FABQ, PCS, Ability to cope, Coping strategy questionnaire (CSQ) – passive coping subscale, treatment preferences and treatment received, predicted time to recover, active coping subscale, endorsement of exercises, ability to cope*predicted time to recover, ability to cope*passive coping subscale, ability to cope*endorsement of exercises, ability to cope*active coping subscale

The results remain the same as those presented in the final model for the 4 month logistic regression model (See Section 5.7.6) except that ability to cope is replaced by an interaction between ability to cope and the use of passive coping strategies (Table 87). The amount of variance explained by the model remains the same as for the main analysis.

Table 87 4 month moderator analysis (n=428)

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Baseline NDI	0.54	0.25	0.03	1.72	1.05-2.80
Number of symptoms	0.49	0.22	0.02	1.64	1.07-2.51
IES	0.57	0.27	0.04	1.77	1.04-3.00
GHQ	0.57	0.24	0.02	1.77	1.11-2.84
Ability to cope*use of passive coping	0.33	0.14	0.02	1.40	1.06-1.84
Constant	-0.83	0.20	<0.001	0.43	

R^2= 0.12(Cox and Snell), 0.15(Nagelkerke); model x^2=52.46 p =<0.001

The possible combinations of the interaction between ability to cope and use of passive coping were examined (Table 88). The number of participants (n(%)) classified as recovered and non-recovered were compared in each of the interaction groups. A significant association between interaction and recovery status was seen (x^2=23.16 p=<0.001) with those participants who were unsure or unable to cope and had high use of passive coping being most likely to be non-recovered. Those participants who were able to cope and had low use of passive coping were most likely to be recovered.

Table 88 Ability to cope*Use of passive coping and recovery status at 4 months

Are they classified as non-recovered at 4 months follow up?	Unsure/unable to cope with high use of passive coping	Unsure/unable to cope with low use of passive coping	Able to cope with high use of passive coping	Able to cope with low use of passive coping	Total
No	29/99 (29.3%)	37/88 (42%)	32/80 (40%)	127/224 (56.7%)	225/491 (45.8%)
Yes	70/99 (70.7%)	51/88 (58%)	48/80 (60%)	97/224 (43.3%)	266/491 (54.2%)
Total	99/491 (20.2%)	88/491 (17.9%)	80/491 (16.3%)	224/491 (45.6%)	491/491 (100%)

5.13.1.2 8 month moderator analysis – belief factors

1) Patient predicted time to recovery and expectations of treatment benefit were both predictive of LWS at 8 months follow up. One baseline variable, treatment preference, was found to be associated with expectations of treatment benefit (cross-sectional analysis) (Table 89). Receiving your preferred treatment or having no treatment preference was associated with reduced risk of the participant having low expectations of treatment benefit.

Table 89 Baseline belief factors found to predict expectations of treatment at baseline (n=541)

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Treatment preference and treatment received	-1.64	0.21	<0.001	0.19	0.129-0.293
Constant	0.49	0.17	0.005	1.63	

R^2= 0.11(Cox and Snell), 0.16(Nagelkerke); model x^2=64.73 p =<0.001

Four variables were associated with participant predicted time to recovery (Table 90). Beliefs associated with an increased risk of a participant predicting their recovery time as >6 months or unsure if they would recover:

1. Ability to cope rated as unsure/unable
2. High level of catastrophic thinking
3. High use of passive coping strategies
4. High use of active coping strategies

Table 90 Baseline belief factors found to predict participant rated time to recovery at baseline (n=541)

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Ability to cope	0.51	0.20	0.01	1.67	1.12-2.47
PCS	0.67	0.27	0.01	1.96	1.15-3.35
Use of passive coping	0.55	0.24	0.03	1.73	1.07-2.78
Use of active coping	0.40	0.20	0.05	1.49	1.01-2.21
Constant	-2.46	0.42	<0.001	0.09	

R^2= 0.09(Cox and Snell), 0.12(Nagelkerke); model x^2=47.79 p =<0.001

2) Factors were then entered into a logistic regression analysis in the following steps:

Block 1: Injury severity factors: baseline NDI, Pain severity, Cx ROM; Psychological response: IES, GHQ ; pre-existing factors: age, chronic widespread pain, social support

Block 2: Patient beliefs: FABQ, PCS, Ability to cope, Coping strategy questionnaire (CSQ) – passive coping subscale, CSQ- active coping subscale, treatment preferences and treatment received, predicted time to recover, predicted benefit of treatment, predicted benefit of treatment*treatment preferences and treatment received, predicted time to recover*Ability to cope, predicted time to recover*PCS, predicted time to recover*passive coping, predicted time to recover*active coping

The results remain the same as those presented in the final model for the 8 month logistic regression model (See Section 5.7.6) except that participant predicted time to recovery is replaced with an interaction between time to recovery and the use of passive coping strategies (Table 91). The amount of variance explained by the model is slightly increased with this analysis.

Table 91 8 month moderator analysis (n=411)

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Baseline NDI	1.03	0.25	<0.001	2.80	1.71-4.60
GHQ	1.15	0.28	<0.001	3.17	1.83-5.50
Age	0.98	0.23	<0.001	2.66	1.69-4.20
Predicted benefit of treatment	0.59	0.24	0.01	1.81	1.13-2.88
Time to recovery*Use of passive coping strategies	0.41	0.15	0.01	1.51	1.12-2.04
Constant	-2.31	.30	<0.001	.10	

R^2= 0.20(Cox and Snell), 0.27(Nagelkerke); model x^2=92.95p =<0.001

The possible combinations of the interaction between time to recovery and use of passive coping were examined (Table 92). The number of participants (n(%)) classified as recovered and non-recovered were compared in each of the interaction groups. A significant association between interaction and recovery status was seen (x^2=40.54 p=<0.001) with participants who predicted they would take >6/12 or unsure they would recovery and reported high use of passive coping strategies being more likely to have LWS at 8 months. Participants who predicted they would take < 6 months to recovery and reported low use of passive coping were most likely to be recovered at 8 months.

Table 92 Time to recovery*Use of passive coping and recovery status at 8 months

Have they developed LWS at 8 months follow up?	**> 6/12 to recover with high use of passive coping**	**> 6/12 to recover with low use of passive coping**	**< 6/12 to recover with high use of passive coping**	**< 6/12 to recover with low use of passive coping**	**Total**
No	25/77 (32.5%)	44/71 (62%)	48/97 (49.5%)	169/238 (71%)	286/483 (59.2%)
Yes	52/77 (67.5%)	27/71 (38%)	49/97 (50.5%)	69/238 (29%)	197/483 (40.8%)
Total	77/483 (15.9%)	71/483 (14.7%)	97/483 (20.1%)	238/483 (49.3%)	483/483 (100%)

5.13.1.3 12 month moderator analysis – belief factors

1) The only belief factor predictive of LWS at 12 months follow up was participant predicted time to recovery. The associations between participant predicted time to recovery and other baseline beliefs are in the section above.
2) Factors were entered into the next model of the logistic regression analysis in the following blocks:

Block 1: Injury severity factors: baseline NDI, No. of symptoms, Cx ROM; Psychological response: GHQ ; pre-existing factors: age, chronic widespread pain

Block 2: Patient beliefs: FABQ, PCS, Ability to cope, Coping strategy questionnaire (CSQ) – passive coping subscale, CSQ- active coping subscale, treatment preferences and treatment received, predicted time to recover, predicted benefit of treatment, predicted time to recover*Ability to cope, predicted time to recover*PCS, predicted time to recover*passive coping, predicted time to recover*active coping

The results remain the same as those presented in the final model for the 12 month logistic regression model (See Section 5.8.6) main analysis except that participant predicted time to recovery is replaced with an interaction between time to recovery and the use of passive coping strategies (Table 93). The amount of variance explained by the model is slightly increased with this analysis.

Table 93 12 month moderator analysis (n=408)

Baseline factors	B	S.E.	Sig.	Exp(B)	95.0% C.I.
Baseline NDI	1.06	0.25	<0.001	2.89	1.78-4.70
GHQ	0.76	0.27	0.01	2.14	1.26-3.64
Age	0.58	0.23	0.01	1.79	1.15-2.80
No. of symptoms	0.54	0.23	0.02	1.72	1.09-2.69
Time to recovery*use of passive coping strategies	0.43	0.15	0.003	1.54	1.15-2.05
Constant	-1.95	0.27	<0.001	0.14	

R^2= 0.18(Cox and Snell), 0.24(Nagelkerke); model x^2=70.63 p =<0.001

The possible combinations of the interaction between time to recovery and use of passive coping were examined (Table 94). The number of participants (n (%)) classified as recovered and non-recovered were compared in each of the interaction groups. A significant association between interaction and recovery status was seen (x^2=34.64 p=<0.001) with participants who predicted they would take >6/12 or unsure they would recovery and reported high use of passive coping strategies being more likely to have LWS at 12 months. Participants who predicted they would take < 6 months to recovery and reported low use of passive coping were most likely to be recovered at 12 months.

Table 94 Time to recovery*Use of passive coping and recovery status at 12 months

Have they developed LWS at 8 months follow up?	**> 6/12 to recover with high use of passive coping**	**> 6/12 to recover with low use of passive coping**	**< 6/12 to recover with high use of passive coping**	**< 6/12 to recover with low use of passive coping**	**Total**
No	25/71 (53.2%)	42/70 (60%)	44/86 (51.2%)	168/234 (71.8%)	279/461 (60.5%)
Yes	46/71 (64.8%)	28/70 (40%	42/86 (48.8%)	66/234 (22.8%)	182/461 (39.5%)
Total	71/461 (15.4%)	70/461 (15.2%)	86/461 (18.7%)	234/461 (50.8%)	461/461 (100%)

5.13.2 Were the effects of beliefs moderated by treatment?

To investigate if beliefs were moderated by treatment a logistic regression analysis was run that included interaction variables between the treatment allocation and some of the belief factors. The three belief factors that were identified in the main analysis and use of passive coping strategies (identified as important in the previous moderation analysis) were chosen to be included in the analysis. Therefore, the following interactions were included in the analysis at each time point.

Time to recovery*Treatment allocation

Ability to cope*Treatment allocation

Use of passive coping *Treatment allocation

Expectations of treatment* Treatment allocation

The interactions were included in block two of a forward stepwise logistic regression analysis. Block one included the injury severity, psychological and pre-existing factors found to be significant in the main analyses. The dependent variable was non-recovery/LWS.

5.13.2.1 4 month moderator analysis – treatment allocation

The following factors were entered into the logistic regression analysis to investigate whether treatment allocation interacted with the belief factors above to predict non-recovery at 4 months:

Block one: Baseline NDI, Number of symptoms, IES and GHQ

Block two: Treatment allocation, Time to recovery, Use of passive coping, expectations of treatment, ability to cope, Time to recovery*Treatment allocation, Ability to cope*Treatment allocation, Use of passive coping *Treatment allocation, Expectations of treatment* Treatment allocation

None of the interactions were found to be significantly associated with non-recovery at 4 months indicating that there was no interaction between the treatment allocation and the belief factors chosen.

5.13.2.2 8 month moderator analysis – treatment allocation

The following factors were entered into the logistic regression analysis to investigate whether treatment allocation interacted with the factors above to predict LWS at 8 months:

Block one: Baseline NDI, Number of symptoms and GHQ

Block two: Treatment allocation, Time to recovery, Use of passive coping, expectations of treatment, ability to cope, Time to recovery*Treatment allocation, Ability to cope*Treatment allocation, Use of passive coping *Treatment allocation, Expectations of treatment* Treatment allocation

Baseline NDI, GHQ and age were once again significantly associated with the development of LWS in line with the final model for the 8 month logistic regression model (See Section 5.10.6). However, differing from the previous analysis, high use of passive coping emerged as a risk factor for LWS and time to recovery was no longer significant. An interaction was also seen between expectations of treatment and treatment allocation that was significantly associated with the development of LWS (Table 95).

Table 95 Investigating treatment allocation interactions at 8 months (n=465)

Baseline factors	**B**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Baseline NDI	0.91	<0.001	2.47	1.53-3.98
GHQ	0.99	<0.001	2.70	1.63-4.49
Age	0.80	<0.001	2.23	1.46-3.40
Use of passive coping	0.58	0.01	1.79	1.14-2.83
Expectations of treatment*Treatment allocation	0.53	0.002	1.71	1.22-2.38
Constant	-2.11	0.00	0.12	

The possible combinations of the interaction between expectations of treatment and treatment allocation were examined further (Table 96). The number of participants (n (%)) classified as recovered and non-recovered were compared in each of the interaction groups. A significant association between the interaction and recovery status was seen (x^2=14.25 p=0.003) with participants with low expectations of treatment who were allocated to physiotherapy being more likely to have LWS at 8 months. Participants who had high expectations of treatment and were allocated to advice were most likely to be recovered at 8 months. However, these results should be interpreted cautiously due to the small number of participants in the low expectations of treatment and physiotherapy (n=34) and may be a spurious finding.

Table 96 Expectations of treatment*treatment allocation and recovery status at 8 months

Have they developed LWS at 8 months follow up?	**High expectations and Physio**	**High expectations and Advice**	**Low expectations and Physio**	**Low expectations and Advice**	**Total**
No	133/215 (61.9%)	78/118 (66.1%)	11/34 (32.4%)	68/125 (54.4%)	290/492 (58.9%)
Yes	82/215 (38.1%)	40/118 (33.9%)	23/34 (67.6%)	57/125 (45.6%)	202/492 (41.1%)
Total	215/492 (43.7%)	118/492 (24.0%)	34/492 (6.9%)	125/492 (25.4%)	492/492 (100%)

5.13.2.3 12 month moderator analysis – treatment allocation

The following factors were entered into the logistic regression analysis to investigate whether treatment allocation interacted with the factors above to predict LWS at 12 months:

Step one: Baseline NDI, Number of symptoms, GHQ and age

Step two: Treatment allocation, Time to recovery, Use of passive coping, expectations of treatment, ability to cope, Time to recovery*Treatment allocation, Ability to cope*Treatment allocation, Use of passive coping *Treatment allocation, Expectations of treatment* Treatment allocation

None of the interactions were found to be significantly associated with LWS at 12 months indicating that there was no interaction between the treatment allocation and the belief factors chosen.

5.14 Predictors of participant perceived improvement - logistic regression analysis

A second logistic regression analysis was conducted to identify risk factors for poor outcome using participant perceived improvement as the outcome variable. As this is a secondary analysis the final models for each follow up point are presented.

5.14.1 Predictors of participant perceived improvements at 4 months follow up

Preliminary logistic regression analysis was carried out to select factors related to injury severity, psychological response, pre-existing and treatment factors (not shown). Dichotomised versions of each variable were included in this analysis. Those factors that were significantly associated with participant perceived outcome were entered into Block 1 of the final model. Surprisingly, the GHQ or the IES scores (psychological response factors) were not associated with outcome in the preliminary analysis so were not included in the final model. Also, the baseline NDI score, was no longer associated with outcome.

Belief factors that had a significant univariate relationship with outcome ($p<0.25$) were entered into Block 2 of the model. The final was model was as follows:
Block 1: Injury severity factors: pain severity; Pre-existing factors: age; Treatment factors: allocation
Block 2: Patient beliefs: FABQ, PCS, Ability to cope, CSQ – passive coping subscale, CSQ – active coping subscale, treatment preferences and treatment received, predicted time to recovery, predicted benefit of treatment
Factors found to be predictive of non-recovery at 4 month follow up are in Table 97.

Table 97 Dichotomised baseline factors predictive of perceived improvement at 4 months follow up (n=434).

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Pain severity	0.51	0.25	0.04	1.67	1.02-2.75
Predicted time to recovery	0.83	0.24	0.001	2.30	1.42-3.70
Predicted benefit of treatment	0.73	0.26	0.006	2.07	1.24-3.45
Constant	-1.37	0.46	0.003	0.26	

R^2= 0.08 (Cox and Snell), 0.12(Nagelkerke), Model x^2 = 36.67 p =<0.001

The following baseline factors were identified as being associated with increased risk of perceived improvement being rated as the same or worse at 4 month follow up:

1. High pain severity (>67/100)
2. Predicted time to recovery (>6 months or unsure I will recover)
3. Low expectations of treatment benefit (<6/10)

5.14.2 Predictors of participant perceived improvements at 8 months follow up

Preliminary logistic regression analysis was carried out to select factors related to injury severity, psychological response, pre-existing and treatment factors (not shown). Dichotomised versions of each variable were included in this analysis. Those factors that were significantly associated with participant perceived outcome were entered into Block 1 of the final model. Only one factor was entered into Block 1 of the final model as a history of previous neck pain was the only factor from the preliminary logistic regression analyses that was retained for the final model. No injury severity, psychological response or treatment factor were shown to be related to participant perceived improvement.

Belief factors that had a significant univariate relationship with outcome (p<0.25) were entered into Block 2 of the model. The final was model was as follows:

Block 1: Pre-existing factors: History of previous neck pain

Block 2: Patient beliefs: Ability to cope, CSQ – active coping subscale, predicted time to recovery, predicted benefit of treatment

Factors found to be predictive of non-recovery at 8 month follow up presented in Table 98.

Table 98 Dichotomised baseline factors predictive of perceived improvement at 8 months follow up (n=461).

Baseline factors	B	S.E.	Sig.	Exp(B)	95.0% C.I.
A history of previous neck pain	0.87	0.34	.02	2.18	1.12-4.21
Use of active coping strategies	0.46	0.20	.02	1.58	1.07-2.35
Constant	-1.284	0.20	.000	0.27	

R^2= 0.01 (Cox and Snell), 0.02(Nagelkerke), Model x^2 = 6.56 p =0.01

The following baseline factors were identified as being associated with increased risk of perceived improvement being rated as the same or worse at 8 month follow up. However, this only explained 1-2% of the variance in the model.

1. A history of pervious neck pain
2. High use of active coping strategies (>15/30)

5.14.3 Predictors of participant perceived improvements at 12 months follow up

Preliminary logistic regression analysis was carried out to select factors related to injury severity, psychological response, pre-existing and treatment factors (not shown). Dichotomised versions of each variable were included in this analysis. However, none of these factors were shown to be associated with outcome in the 12 month analysis. Therefore, only belief factors were entered into the final model. Those with significant univariance relationship with perceived improvement of p<0.25 were entered into a forward step logistic regression model in one block: predicted time to recovery, PCS, CSQ – active coping subscale, treatment preferences and treatment received.

Only one factor was found to be predictive of outcome. Participant predicted recovery time of > 6 months or unsure I will recover was associated with increased odds of a participant perceived improvement rating of the same or worse at 12 months follow up. This only explained 2% of the variance of the model (Table 99).

Table 99 Dichotomised baseline factors predictive of perceived improvement at 12 months follow up (n=438).

Baseline factors	**B**	**S.E.**	**Sig.**	**Exp(B)**	**95.0% C.I.**
Predicted time to recovery	0.54	0.21	0.01	1.72	1.14-2.58
Constant	-0.44	0.12	<0.001	0.65	

R^2= 0.02 (Cox and Snell), 0.02(Nagelkerke), Model x^2 = 6.71 p =<0.001

5.15 Summary

This chapter has provided a detailed description of the clinical presentation and course of recovery of individuals who present for physiotherapy treatment following an acute whiplash injury. Individuals presented with both physical and psychological symptoms. The biggest reduction in neck pain related disability was observed between baseline and 4 months follow up with far less change occurring at subsequent follow ups. A substantial proportion of participants experienced ongoing disability 12 months after their injury.

Participant perceived improvement was also reported. A similar pattern of improvement was observed with the most participants reporting improvement in the initial 4 months. However, there was a group of participants that failed to improve at any point over the 12 months follow up. Participant perceived improvement showed low to moderate correlation with recovery status and NDI scores. There was wide individual variation indicating substantial mismatch between participant perceived improvement and recovery status and NDI scores.

The factors predictive of outcome are summarised Table 100 (p243). Baseline NDI score was the most consistent predictor of recovery status and NDI. However, there was no association with participant perceived improvement. Predicted time to recovery and age were consistently reported as predictive of recovery status and NDI in all analyses except that based on recovery status at 4 months suggesting they are both important factors. Predicted time to recovery was also predictive of participant perceived improvement at 4 and 12 months follow up.

The number of symptoms was predictive of recovery status and NDI at 4 and 12 months but not at 8 months. It was not associated with participant perceived improvement.

Predicted benefit of treatment was predictive of recovery status and NDI scores at 8 months as well as participant perceived improvement at 4 months.

The GHQ was consistently predictive of recovery status but not NDI scores. This may be an effect of using a dichotomised score rather than the total score. The IES was predictive of both recovery status and NDI score at 4 months but only NDI score at 8 months. Surprisingly, neither of these psychological response factors were related to participant perceived improvement.

There were several factors that were only predictive of either recovery status, NDI score or participant perceived improvement at one follow up time point (pain intensity, chronic widespread pain, history of neck pain, ability to cope and use of active coping).

Risk factors for recovery status and NDI scores showed greater similarities generally compared to those for participant perceived improvement. This further emphasises the mismatch between recovery status and NDI scores with participant perceived improvement.   A much larger amount of variance was explained in the models based on recovery status and NDI compared to those based on participant perceived improvement.

As the number of risk factors present at baseline increases so does the risk of non-recovery/LWS .

The use of passive coping strategies may moderate the effect of predicted time to recovery and ability to cope on outcome.

These findings will be discussed in the following chapter.

Table 100 Summary of findings (√ = baseline factor predictive of outcome, X= baseline factor not predictive of outcome)

	4 months			8 months			12 months		
	Recovery status	**NDI score**	**Participant rated improvement**	**Recovery status**	**NDI score**	**Participant rated improvement**	**Recovery status**	**NDI score**	**Participant rated improvement**
Injury severity factors									
NDI	√	√	X	√	√	X	√	√	X
Number of symptoms	√	√	X	X	X	X	√	√	X
Pain severity	X	X	√	X	X	X	X	X	X
Psychological response factors									
GHQ	√	X	X	√	X	X	√	X	X
IES	√	√	X	X	√	X	X	X	X
Pre-existing factors									
Age	X	√	X	√	√	X	√	√	X
Chronic widespread pain	X	X	X	X	√	X	X	X	X
History of neck pain	X	X	X	X	X	√	X	X	X
Belief factors									
Ability to cope	√	X	X	X	X	X	X	X	X
Predicted time to recovery	X	√	√	√	√	X	√	√	√
Predicted benefit of treatment	X	X	√	√	√	X	X	X	X
Use of active coping	X	X	X	X	X	√	X	X	X

6.0 Prospective cohort study discussion

This chapter will discuss:

1. The potential implications for patient management based on the results of this study.
2. The findings in relation to other published research.
3. Methodological issues related to the study.

6.1 The primary outcome

The primary outcome of this study was recovery status with the aim of this research being to identify risk factors for late whiplash syndrome. LWS was a term coined by Balla (11) and has gone on to be used frequently within the whiplash literature. The time period specified by Balla (11) as the point when whiplash symptoms become chronic is 6 months. This is in contrast to the definition of chronic pain provided by the British Pain Society (321) who define chronic pain as "continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery." This study demonstrated that the biggest change in the proportion being classified as non-recovered was seen between baseline and 4 months. A further 13% of participants recovered between 4 and 8 months suggesting that recovery was still ongoing during this time. From 8 months on very little change was seen in the proportion of participants who recovered suggesting that chronic symptoms are established by this time point. These finding suggest that there was still capacity to recover from a whiplash injury between 4 and 8 months although to establish the exact point when recovery ceases would require the collection of outcomes at more time points than this study allowed. Therefore, the cut off of 6 months as the point where symptoms have become chronic and are unlikely to change may be more appropriate than the traditional view of chronic pain of 3 months. Findings from other prospective cohort studies support this view (184).

The presence of LWS was defined using questions from the NDI. As discussed previously these questions indicated that the neck pain experienced interfered with normal function. Face validity was given to this method of categorising recovery status by the fact that those classified as having developed LWS had much higher total NDI scores than those who were recovered. For example at 12 months the mean NDI for those with LWS was 37.4 compared to a mean of 9.8 in those that had recovered.

6.2 The course of recovery following a whiplash injury

A whiplash injury represents a complex clinical picture of both physical and psychological symptoms. Although, neck pain was the most commonly reported symptom, the majority of participants also presented with additional symptoms including headaches, arm pain, neurological symptoms and swallowing difficulties. These additional symptoms result in higher levels of disability and psychological morbidity on initial presentation. The psychological impact of injury was evident even early on after injury. A high level of psychological morbidity was observed at baseline with a large proportion of participants considered to have elevated scores on the GHQ-12 at baseline. A smaller proportion of participants experienced a severe stress reaction to their injury as demonstrated by their IES scores. Fear of movement and re-injury was also observed amongst over half of participants.

A trend was seen for participants to experience an improvement in neck related disability over the twelve months follow up. However, the biggest reduction occurred from baseline to four month follow up with more moderate improvements seen between 4 and 8 months. Very little change occurred between 8 and 12 months. At 8 and 12 months follow up approximately 40% of participants were classified as having LWS indicating that a substantial number of participants were still suffering from the effects of their injury. Rates of non-recovery for this study fall within the range reported by previous smaller UK ED based studies which report persistent symptoms at least one year post injury ranging from 16%-48% (12, 53, 276-278). Although, different definitions of persistent symptoms made direct comparisons difficult, it suggests that these findings are generalisable to patients presenting to UK EDs following a whiplash injury. The age and sex of participants were also similar to the previous UK studies.

It is not unexpected that the most improvement should occur in the early phase of the follow up period as participants experienced an acute injury. Other authors have also suggested that the greatest period of improvement following a whiplash injury is in the first few months following injury. A meta-analysis of prospective cohort studies found that the greatest reductions in pain and disability occurred in the first three months post injury with very little improvement occurring from 6 months onwards (184).

Some participants would have experienced a rapid improvement in symptoms early on. This may explain why a proportion of participants were classified as recovered at the baseline point for this study. Baseline data were collected on average 32 days post ED presentation and some participants would have made rapid improvements in this time. However, as the inclusion criteria required the presence of neck symptoms 24 hours prior to assessment, all participants were still experiencing some degree of neck symptoms when baseline data were collected.

Although many participants showed improvements some participants failed to experience a reduction in their symptoms over the follow up period. From the participant rated benefit data there was a proportion of participants (9%) whose symptoms were resistant to any perceived improvement over the 12 month period and often experienced perceived worsening of symptoms. Participants experienced ongoing problems despite being provided with physiotherapy treatment as part of MINT. This suggests that current methods of physiotherapy management are ineffective in preventing the development of LWS in a proportion of patients. New treatment strategies need to be considered to reduce the impact of whiplash injuries on patients. Identifying risk factors for LWS can potentially assist with this.

6.3 Initial injury severity

This prospective cohort study confirms the findings of published systematic reviews that the initial level of reported symptoms and disability are consistently predictive of disability following whiplash injury (19-21, 183, 184). The NDI explained the majority of the variance of the linear regression models that predicted NDI scores suggesting that it was the most important factor. This finding is not unexpected as when the same scale is used as a predictor variable and outcome they are highly likely to be associated. However, other factors did contribute small but significant amounts to these models indicating that they are also important and should not be discounted.

The number of symptoms was also predictive of recovery status and NDI scores. The reported symptoms were explored to see if it was possible to identify types of symptoms or combinations of symptoms that put participants at risk of poor outcome. However, it was found that the number of symptoms was the best way to identify these individuals.

6.3.1 Potential implications for patient management

The NDI and the symptoms subscale of the CSOQ could be used to identify patients at risk of ongoing disability following a whiplash injury. Disability was measured using a validated questionnaire but this still depends on the participant’s perceptions of the physical impact of their injury. When considering ways to improve outcomes following a whiplash injury then minimising perceived disability early on after injury may be an important factor. A possible way to do this would be to ensure that adequate pain relief is achieved in the immediate post injury phase so that patients are able to move and stay active. Providing pain relief in the form of simple analgesics (such as paracetamol or ibuprofen) is recommended as part of the early treatment of whiplash injuries (279). For patients struggling with pain early on after injury, reviewing and modifying pain relief may be an important part of the medical management to improve long term outcome. Physiotherapists are able to advise patients on the regular use of pain medication to control symptoms or advise patients to see their GP if their current medication regime appears inadequate.

6.4 Psychological response to a whiplash injury

Sustaining a whiplash injury impacted on psychological well being early on after injury. The presence of psychological distress measured by the GHQ-12 was a predictor of recovery status at all time points. The systematic literature review concluded that psychological distress was not associated with LWS based on moderate strength evidence. A variety of tools have been used to measure psychological state in whiplash populations so it is best to make direct comparisons with the study by Atherton et al (40) who also used the GHQ-12 in an ED population. The main outcome used in this study was the symptomatic report of neck pain rather than disability. The GHQ-12 predicted outcome in the univariate analysis but not when injury severity factors were included in a multivariable analysis controlling for age and sex. Although, the authors of this study actually report that psychological distress measured by the GHQ-12 is a risk factor for poor outcome, the risk ratios presented do not support these recommendations. The differences between the study by Atherton et al (40) and this prospective cohort study is probably due to the different outcome used. They also split the GHQ-12 scores differently which may impact on findings.

Although, a high GHQ-12 score predicted recovery status in this study, the actual GHQ-12 scores did not predict NDI score at any follow up point. This may indicate that the relationship between the GHQ-12 and NDI scores is not linear. The cut-point used was that recommended for a UK population as the best for identifying psychological distress (247). Therefore, once this cut point is passed (i.e. GHQ-12 score of 4) indicating the presence of psychological distress, further increases in the score did not equate with increasing levels of disability. This was most obvious at the 8 months follow up where an elevated GHQ-12 score (dichotomised version) was the risk factor associated with the greatest increase in odds of developing LWS. See Figure 28 and Figure 29.

Figure 28 Mean NDI scores (SD) at 8 month follow up versus baseline GHQ-12 scores (n=489)

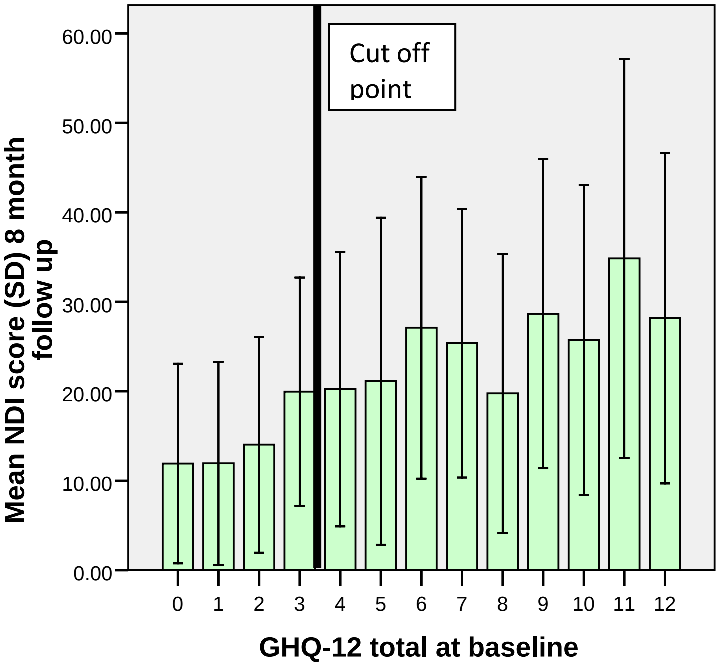
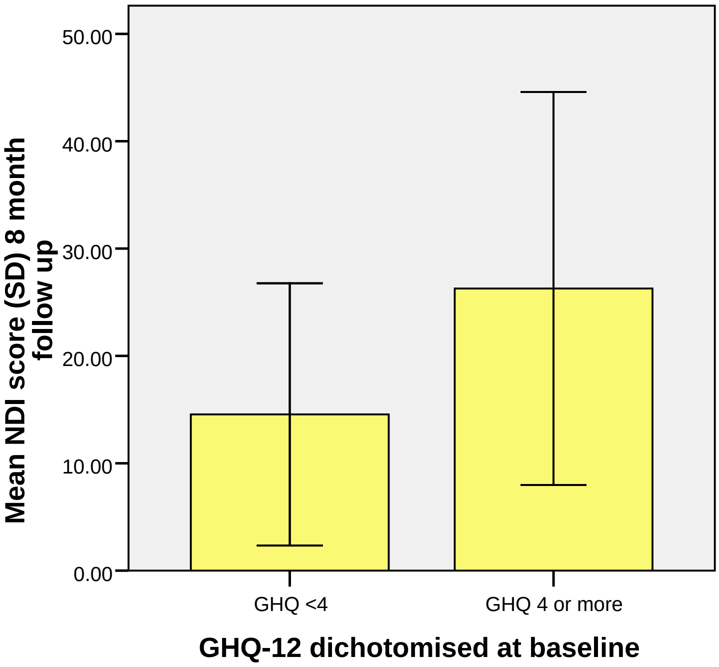


Figure 29 Mean NDI scores (SD) at 8 month follow up versus dichotomised baseline GHQ-12 scores (n=489)



An elevated post traumatic stress reaction was predictive of recovery status at 4 months and with higher levels of disability at 4 and 8 months. It appeared that the influence of an elevated post traumatic stress reaction at baseline reduced over time as the IES was predictive of neither outcome at 12 months. It is possible that over time the post traumatic stress reaction resolved and no longer impacted on disability. However, as we did not collect the IES at the follow up points this is only speculation. Other studies have found this not to be the case and an elevated post traumatic reaction was found to be predictive of outcome when measured from 1-3 years post whiplash injury (41, 91, 95). The IES was used apart from the study by Buitenhuis (91) which used the Self Rating Scale for Post Traumatic Stress Disorder and only found the hyperarousal subscale to be predictive of outcome.

6.4.1 Potential implications for patient management:

In regards to the presence of psychological morbidity it is likely that this is at least partly related to the degree of symptoms and disability reported by the patient. As demonstrated earlier, participants with symptoms localised to the head, neck and shoulder tended to be less disabled and have less psychological distress compared to those with additional symptoms. Those with greater number of symptoms may be understandably more worried and anxious which would impact on their psychological wellbeing. Physiotherapists are able to provide reassurance to patients about their symptoms as well as provide strategies for reducing symptoms and facilitating return to activities. Resolution of symptoms and return to normal activities may well be enough to improve psychological well being. This has been demonstrated previously in a whiplash population where resolution of pain following nerve blocks was shown to substantially improve psychological distress (280). It is also possible that treatments designed to improve mood such as antidepressants or exercise would be of benefit for some patients but this needs further investigation.

Physiotherapists dealing with these patients should be aware of the potential psychological impact of a whiplash injury and refer on for appropriate management if indicated. Although, these findings suggest that the impact of an elevated IES on outcome did reduce over time, appropriate management of a stress reaction may help patients to recover more quickly. In addition, there is a small body of evidence supporting a longer term impact of an elevated post-traumatic reaction and poor outcome. Sterling (281) recommends that patients suspected of experiencing a post traumatic reaction should be referred on for specialist management, specifically, trauma-focussed cognitive behavioural therapy delivered by a psychologist. Although, at this point in time there appears to be no published evidence that this approach improves outcome in WAD.

6.5 Participant held beliefs about injury and recovery

Three different patient held beliefs emerged as predictors of outcome at different time points in this study. The first two risk factors to be identified are related to expectations of outcome. It is hypothosized that expectations of outcome can influence outcome through several mechanisms (as outlined in Chapter 2.0) which includes both neurophysiological mechanisms and behavioural mechanisms.

The strongest finding was that those participants who were less optimistic about recovery time were at greater risk of LWS at both 8 and 12 months follow up. Less optimistic recovery time was associated with higher NDI scores at all 3 time points. A study by Holm et al (90) also found that those participants who were less optimistic that they would recover were at risk of poor outcome. Expectations of recovery were measured using a VAS where 0 indicated it was unlikely they would recover and 10 indicated it was highly likely they would recover. Important factors such as previous neck pain, initial injury severity, sex and age were controlled for. Despite the differences in measurement of expectations the studies had similar findings. Two further studies reporting the same cohort were also identified but were ineligible for the literature review as the outcome used did not fulfil the criteria for LWS (282, 283). The outcome was time to recovery and did not provide information about which participants had ongoing problems 6 months after injury. However, these studies both investigated expectations of recovery and found that more optimistic expectations of recovery were associated with shorter recovery times after controlling for factors such as depression, pain intensity and post-collision health. These studies provide further weight to the finding that patient's expectations of recovery can influence outcome in WAD.

Attempts were made to examine whether participants could predict their own recovery time. This was difficult due to the different times frames used for predicting outcome and collecting follow up data. In retrospect, to allow accurate comparisons, the same time frame should have been used e.g. given participants a choice of 4, 8 and 12 months as the predicted times for their recovery. Another difficulty with determining the accuracy of predictions was that follow up data would not have been collected exactly at 4, 8 and 12 months depending on when the participant completed their form and returned it. According to the MINT follow up protocol, participants had 3 months to return their questionnaire before being considered a non-responder at that time point. However, despite these limitations, a trend was observed in the data. A greater proportion of those who recovered more quickly (at 4 and 8 months) predicted a recovery time that fell within the time frame of their recovery compared to those who took longer to recover or had failed to recover. Those who took longer to recover or who did not recover often predicted a much shorter recovery time than they experienced. This may appear to be in contrast to the findings of this prospective cohort study where a more optimistic outlook was associated with a better outcome. However, due to the limitations of the data collected this should be interpreted cautiously.

The second belief factor found to be predictive of ongoing disability related to expectations of outcome was expected benefit of treatment. Those participants who had lower expectations of treatment benefit were at greater risk of LWS and higher levels of disability at 8 month follow up. Expectations of treatment benefit have not been studied in a whiplash population before so these findings cannot be compared to any other studies.

The final factor identified was the participants rating of their ability to cope with their neck injury. Participants who were unable or unsure they were able to cope with their neck problem when it is painful were at increased risk of non-recovery in the short term as this was only evident in the 4 month logistic regression. When data was treated as continuous there was no relationship seen with the NDI scores at outcome. The participant rating of their ability to cope is a measure of self-efficacy. This study supports a relationship between self-efficacy and short term recovery status but not with longer term outcome. This is in contrast to two other studies that have demonstrated that low levels of self-efficacy are related to LWS (46, 49). The studies (46, 49) were much smaller than the study presented in this thesis but the populations included in the studies appear similar. One reason for the difference in findings is that this current study used a single question where as the previous studies have used the Self-Efficacy Scale which is a more extensive measure focusing on the patient's confidence to carry out a series of activities despite pain. The single question used in this study provided a global rating of their confidence to cope.

It is also important to consider some of the belief factors that were not identified as risk factors. Many consider fear avoidance beliefs to be an important factor in the development of disability but they did not emerge as a predictor of outcome in this study (69). A significant proportion of participants did have an elevated score on the FABQ at baseline. This demonstrated that is it common for individuals to be concerned about the effect of physical activity on their pain early after a whiplash injury. Fear avoidance levels were predictive of outcome in univariate relationships but not when other factors such as injury severity were controlled for in the model. These findings are in line with other studies in the systematic literature review who found that fear avoidance was not predictive of outcome in multivariable models (41, 50). It could be hypothesised that as symptoms improve and participants return to their normal activities then fear about movement also subsides. A similar finding was seen for catastrophising as measured by the PCS. In the systematic literature review, studies that presented univariate analysis tended to suggest a relationship between catastrophising and outcome (44, 49) but those who presented multivariable analysis suggested that no such relationship existed (62, 92). This study was in agreement with the later. It is important to emphasise that although these factors are not predictive of outcome it does not mean they do not play a role in maintenance of disability when it is established (130). However, these factors are not able to identify participants that are at risk of poor outcome so should not be used to screen patients for that purpose.

In an attempt to understand how the baseline factors interact and influence each other a moderator analysis was carried out. This analysis revealed that the use of passive coping strategies moderated the effect of participant rated ability to cope and predicted time to recover. The coping strategies used were not independently predictive of outcome which is in agreement with the systematic literature which concluded there was no associated between coping strategies and LWS (62, 90). Instead, these findings suggest that the high use of passive coping strategies is problematic when the participant was also unsure or unable to cope with their neck injury or was less optimistic about recovery. Passive coping strategies are often considered to be ineffective. It makes sense that an individual with a tendency to use them would not perceive themselves as coping well if the strategies they use are ineffective. Likewise, this could result in less optimism about recovery time. These findings should be interpreted cautiously as they were exploratory.

Treatment allocation was also observed to moderate the effect of expectations of treatment on recovery status. These findings suggested that those allocated to physiotherapy with low expectations of treatment benefit were at risk of LWS at 8 months only. The importance of this finding is unclear as it may be spurious due to the very small number of participants in the low expectations and physiotherapy group.

6.5.1 Potential implications for patient management

Assessing participants for the presence of these risk factors did not involve lengthy questionnaires but used simple questions that could easily be asked in a clinical situation. Clinicians could assess patients and identify those who hold potentially unhelpful beliefs about their ability to cope or their expectations of outcome. These questions would also provide a useful tool to open up discussion with the patient about how they are coping with their injury and their expectations for recovery. If participants hold unhelpful beliefs then focused interventions to modify patient's perceptions around these factors may prove helpful in reducing long term disability.

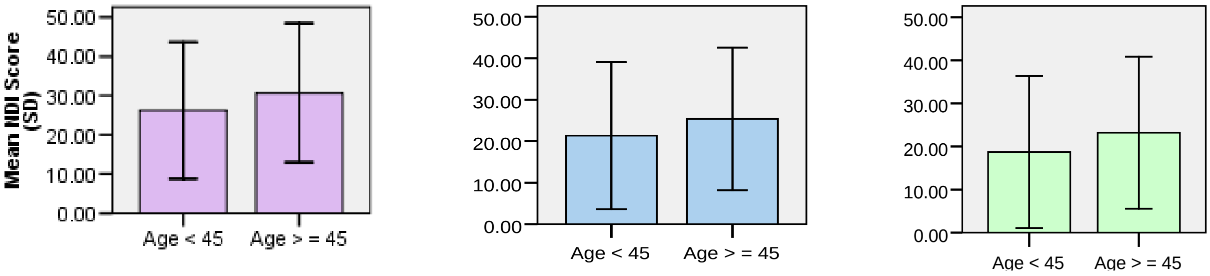
Half of these participants received a package of physiotherapy treatment that reflected a good quality physiotherapy intervention that is commonly delivered in an NHS setting. This package was primarily a physical intervention (manual therapy and exercises) with the additional of simple psychological and self management advice (203). However, no difference in long term disability was observed between those who had a package of physiotherapy and those who received a single advice session. A reason for this may be that this traditional physiotherapy package did not focus adequately on some of the factors that have been highlighted in this study. Interventions focused on improving the patient's ability to cope with their condition based on a cognitive behavioural (CB) approach have proved to be affective in conditions such as LBP (284, 285). A more focused approach such as a CB approach to improving coping skills (and discouraging the use of passive coping strategies) amongst patients following a whiplash injury may be of benefit.

Similarly, modification of patient expectations of outcome may also be of benefit. This may involve providing reassurance that patients will recover and promoting a positive attitude to their recovery. Discussing treatment options with patients and assessing patient expectations of treatment outcome could also be used to guide treatment choices. Especially as at this time when no superior treatment has been identified then this may be a useful strategy for improving patient outcomes.

6.6 Pre-existing factors

Published systematic reviews have been divided over whether older age is a risk factor for poor outcome (19, 20, 183-185). However, from this study, older patients appear to be at risk of LWS and greater disability at follow up. At each follow up point, participants over 45 years of age reported NDI scores that were on average 4 to 5 percentage points higher than younger participants (See Figure 30).

Figure 30 Mean NDI scores (SD) at follow up stratified by age



4 months

8 months

12 months

A history of chronic widespread pain (CWP) was also identified as a risk factor but this was not consistent. The criteria used were quite stringent so only a small number of participants fulfilled the criteria which may have influenced the findings. It was the same criteria used by Atherton et al (40) who reported it was a predictor of persistent neck pain at 12 months follow up. Another reason that it failed to be predictive of outcome in many of the analyses was that those participants with a history CWP also reported high levels of baseline disability. CWP was highly predictive in several of the initial multivariable models but when it was included in the final model with baseline disability it was no longer significant.

6.6.1 Potential implications for patient management

Age is not a modifiable risk factor. However, physiotherapists should be aware that older patients are at risk of greater levels of disability and possibly in need of greater support throughout the recovery phase.

Patients who present with a history of CWP are likely to present with a high level of disability and need extra encouragement to return to their activities. This may particularly be the case if they have developed unhelpful beliefs about pain (such as fear of movement) due to their previous experiences. In these cases then patients may benefit from a CB approach as discussed above.

6.7 The impact of increasing numbers of risk factors

The risk ratios associated with the number of risk factors present at baseline did differ somewhat between the 3 follow up points. One reason for the differences in RR ratios is that although, 5 risk factors were identified at each time point, they were not the same set of risk factors although there were similarities (e.g. baseline NDI was present at al 3 time points). However, a pattern of accumulation of risk was observed at each time point with increasing risk of poor outcome each additional risk factor present at baseline. Approximately 5% of participants with no risk factors were classified as non-recovered/LWS at 4 and 8 months and 11% had LWS at 12 months. This is in comparison to approximately 60% of participants with 4 or 5 risk factors being classified as non-recovered/LWS at follow up. The accumulative effect of increasing numbers of risk factors has been demonstrated previously. Atherton et al (40) demonstrated a similar accumulative effect. This study identified 5 risk factors for persistent neck pain at 12 months. 14% of participants with no risk factors developed persistent pain compared to 80% of those who had 4 out of 5 risk factors (no participants had all 5 risk factors).

It had been hoped to be able to identify the combinations of risk factors that were most likely to result in poor outcome. However, this was not possible as there were so many possible combinations, many with very small numbers of participants, which made it difficult to analyse in a meaningful manner. For example, when considering the 4 month results there were 26 possible combinations of the 5 identified risk factors present amongst the cohort.

6.7.1 Potential implications for patient management

As the NHS faces the ongoing challenge of providing patient care with limited budgets, the number of risk factors could be used to guide clinical reasoning and treatment planning. Patients who present with none or a small number of risk factors (i.e. 1-2) may benefit from a less intensive treatment approaches such as the advice session provided in MINT. This advice session proved to be as effective as a package of physiotherapy care for participants in the trial. The advice session could be tailored depending on the risk profile of each participant. For participants with a greater number of risk factors present then more intensive treatments could be offered such as the CB approach described earlier.

6.8 Comparison between findings based on recovery status and NDI with participant perceived improvement

When participant perceived improvement was used as the outcome measure for logistic regression analyses the findings were considerably different to those based on recovery status or NDI scores. The 4 month analysis produced the most similar findings although there were some important differences. When participant perceived improvement was used as the outcome rather than a disability based outcome, the baseline NDI was no longer predictive of outcome. However, another injury severity factor was found to be predictive of participant perceived improvement suggesting that initial injury severity remains an important factor even when alternative methods of measuring outcome are used. However, this was only apparent at the 4 month follow up. Surprisingly no injury severity factors were identified as predictive of perceived improvement in either the 8 or 12 month analysis. Predicted time to recovery and benefit of treatment emerged as risk factors for poor outcome at 4 months which was in agreement with other analysis based on recovery status and NDI scores.

There was little consistency between the different analyses at 8 and 12 months. Previous neck pain and use of active coping were identified as risk factors for a patient perceived improvement rating of the same or worse at 8 months. Neither of these factors was identified in any previous analysis. The inclusion of previous neck pain as a risk factor may have a similar mechanism as a history of chronic widespread pain which was also identified as a risk factor based on the NDI scores. Those with a history of pain conditions may experience central sensitisation enhancing their pain experience as well as demonstrating established unhelpful beliefs and behaviours about pain. High use of active coping was also identified as a risk factor for poor outcome which was surprising as it has previously been suggested that the use of active coping strategies is advantageous (110) . The mean scores of the active subscale of the coping strategy questionnaire for each group (better versus same/worse) showed there was actually very little difference between the two groups with those that rated themselves better having a mean score of 12.56/30(SD=5.35) compared to those who were the same or worse having a mean sore of 13.74/30(SD=5.59). The mean difference between the two groups is statistically significant but the clinical importance of this is unclear.

When considering the 12 months analysis, it was surprising that only one factor was predictive of participant perceived improvement (predicted time to recovery) which was in agreement with analyses based on recovery status and NDI scores. However, due to the small amount of variance explained by the model it is unclear how important this factor is.

Generally the amount of variance explained by each model was small compared to that explained by the models based on recovery status or NDI scores. At 4 months, the identified risk factors explained between 8% and 12% of the variance in the model based on participant perceived improvement compared to the model based on recovery status where around 20% of the variance was explained. The amount of variance explained by the models based on participant perceived improvement at 8 and 12 months was very small explaining only 1-2% of the variance. The majority of the variance remained unexplained. One reason for this may be that the factors measured in this study were not the types of factors that are important when considering participant perceived improvement. If other factors had been chosen then risk factors explaining greater variance in the models could have been identified. However, it may also suggest that the outcome used was problematic. The participant perceived improvement measured the perceived change between one data collection point and another. This relied on the participant to accurately recall their symptoms 4 months previously. This type of measure will be subject to recall error. It may be postulated that this will be most accurate when asked at 4 months as the biggest change in symptoms would be expected in this time period and, therefore, more easily recalled by participants. As demonstrated by the NDI scores a much smaller change in symptoms was seen at the 8 and 12 months follow up which may make accurate recall difficult. This maybe why the most variance was explained by 4 month model compared to 8 and 12 months.

The relationship between participant perceived improvement and change in NDI score was examined and provided further evidence that participant perceptions of change may not be accurate. This data demonstrated that participant perceptions of change in their condition did not necessarily equate with changes in the NDI score. For example, at 4 months participants who rated themselves as worse showed on average a very small change in the NDI score which actually suggests they were the same. There was only low to moderate correlation between participant perceived improvement and change in NDI scores. In addition, the lack of agreement between participant perceived improvement and NDI scores or recovery status that was presented in the results section, provides an explanation for the different findings discussed. Generally these factors would suggest that the results based on participant perceived improvement should be interpreted cautiously.

6.9 Methodological issues

The setting in which the participants were recruited may limit the generalisability of the finding. Individuals presenting to an NHS ED will not reflect all individuals who sustain a whiplash injury. In particular, those that went onto seek physiotherapy through step 2 of MINT represent a subgroup of patients who had persistent symptoms 3 weeks post injury. This will not be the case for all individuals who have a whiplash injury. However, the participants included in this prospective cohort study are likely to reflect the type of patients that present to NHS physiotherapy departments making the findings and recommendations applicable to that setting.

Another limitation of the study is the amount of missing data which may have introduced some bias. Non responders tended to have slightly higher scores on FABQ and PCS which may be one reason that these factors failed to be predictive of outcome as these participants with higher scores were not included in the analysis. However, the sample size included in the analysis was always >400 participants which is an adequate sample size for the number of variables included in each model. The large sample size remains a strength of the study.

Another consideration is the time lag between injury and data collection for the study. As discussed earlier, patient symptoms may improve rapidly initially after injury so different results may have been seen if data collection was closer to the time of injury. However, the timing of data collection would be similar to the timing of physiotherapy treatment in the NHS so it reflects the situation in which these study results would be applied in clinical practice.

It should also be acknowledged that all possible factors that may influence outcome have not have been considered. This is demonstrated by the fact that proportion of the variance of the models remained unexplained. The models presented explained 20% and 40% of the variance in the logistic regression models and linear regression models respectively. The amount of variance of multivariable models that was reported by studies included in the systematic review ranged from approximately 20%-60% but this was not always reported (46, 47, 50, 52, 58, 62, 88, 92).The inclusion of other factors in the model may have improved the amount of variance explained. For example, the presence of cold hyperalgesia has been shown to be a risk factor for poor outcome (41, 286). However, the quantitative measurement of cold hyperalgesia requires the use of expensive equipment that was beyond the scope of this research. Some new evidence has emerged since the development of the study for which there is evidence of an association with LWS such as causal beliefs of whiplash and ratings of helplessness (89, 92). Despite this limitation, the factors included in the study were those based on the best evidence at the time which is another strength of this study.

A separate analysis was carried out using the outcome at each follow up time point. There are other ways that this data could have been analysed which may have yielded different results. For example, a recent paper by Sterling et al (322) identified 3 different trajectories of recovery following a whiplash injury and the baseline factors associated with membership of these different trajectories. Patterns of recovery were also presented in this thesis. Some important subgroups were identified within this cohort (e.g. those participants who did not improve at any time point) so further analysis could be carried out to identified the risk factors for membership of this subgroup.

Finally, this study was conducted within the context of a large clinical trial. The opportunity to carry out a thesis in this setting has a large number of advantages. Firstly, it provided access to a large number of participants enabling this study to have a large sample size often not afforded to PhD studies. Collecting data from 599 participants would have been impossible for one individual and assistance with data collection was provided by the other research staff working on the trial. Data was collected from 12 centres across the UK adding to the generalisability of findings to the UK population. There was also administrative support throughout data collection and follow up which ensured a good response rate to follow up.

There were also some challenges to carrying out this study within the restraints of large RCT. Any research carried out as part of this PhD needed to fit into the main trial protocol which dictated the timing of data collection for both baseline and follow up data. There were also limits to the amount of data that could be collected so as not to over burden trial participants. In particular, follow up data was limited to the outcomes collected for the main trial. However, the advantages more than outweighed these disadvantages.

6.10 Summary

The majority of participants who sought physiotherapy treatment following their injury presented with a complex picture of physical and psychological symptoms. Many participants experienced a reduction in neck related disability over the 12 month follow up. However, there was a group of participants whose symptoms were resistant to improvement. This suggests that current physiotherapy management was not effective for these participants.

This prospective cohort study supports previous research that baseline symptoms and disability are predictive of outcome in a whiplash population.

The psychological impact of a whiplash injury was demonstrated. There was further support that an elevated stress reaction had an adverse effect on recovery. However, effects were not as long term as suggested by other studies.

The literature is currently divided over whether psychological morbidity is a risk factor for poor outcome but this study provides support that it is an important factor to consider. The impact of age on outcome is also inconclusive based on previous studies but this study suggests it is an important factor to consider.

Beliefs about outcome also have the potential to impact of recovery. Beliefs about ability to cope may also influence outcome in the short term. These types of beliefs are potentially modifiable. The use of passive coping may moderate the impact of beliefs about outcome and coping on outcome.

Factors that are often suggested as risk factors for poor outcome such as fear avoidance and catastrophising were not found to be predictive of outcome. This suggests that measures of fear avoidance and catastrophising are not able to identify patients with poor prognosis.

Screening patients for risk factors early on after injury has the potential to guide the treatments offered to patients. Treatment strategies that could potentially improve patient outcomes include:

- ensuring adequate pain relief early on after injury so that patients can return to activities as soon as possible and reduce perceived disability
- provision of reassurance early on to reduce psychological morbidity especially in those patients who present with multiple symptoms
- refer patients exhibiting signs of an elevated stress reaction for the appropriate management

- address unhelpful beliefs about outcome and facilitate the use of effective coping strategies through a cognitive behaviour approach which has been shown to be effective in other conditions

7.0 An exploratory interview study investigating patient held beliefs about injury recovery following a whiplash injury: methods

7.1 The importance of qualitative research

Evidence based healthcare is driven by quantitative research with the randomised controlled trial advocated as the gold standard (287, 288). However, some argue that quantitative methods do not provide the best way to study the non-quantifiable aspects of patient care such as understanding clinical interactions or the emotional impact of illness (288-290). Qualitative methods offer a different perspective to researchers by allowing access to individual patients' experiences of living with a particular condition or to be in a particular situation (287, 288). This type of research has the potential to inform clinical practice alongside quantitative methods or to identify future research questions (287, 288, 290). Clinical evidence can be strengthened when findings from both quantitative and qualitative research are considered (sometimes referred to as triangulation) (288). In fact, qualitative research may have an important role to play in understanding the findings of quantitative research (289).

Despite the recognised importance of qualitative data in understanding patient experiences, there are very few qualitative studies in the field of whiplash injury (291). It was hoped that this qualitative study would supplement the quantitative measures that had been taken and possibly reveal aspects of patients beliefs that questionnaires failed to address.

7.2 Aims

The aims of this qualitative study were:

1. To explore beliefs about injury and recovery held by individuals following an acute whiplash injury.
2. To gain an understanding of factors that may potentially influence belief formation.
3. To compare the narratives of participants who were recovering well at interview and those that were not.
4. To compare the results of this interview study to the prospective cohort study (this is included in Chapter 10).

7.3 Methods

Semi-structured interviews were conducted with 20 participants following attendance for their physiotherapy treatments.

7.3.1 Sample

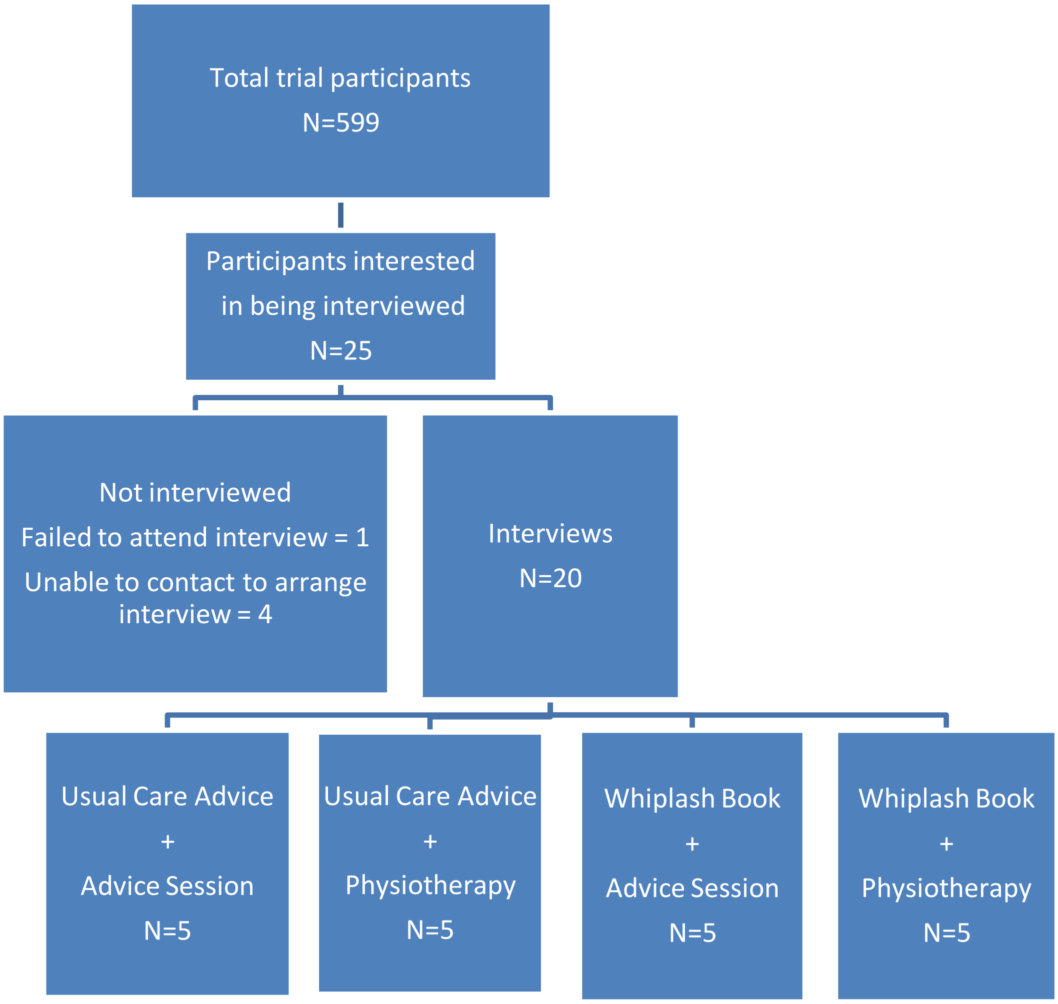
The interviewees were sampled purposively from five trusts local to the trial co-ordinating centre for pragmatic reasons of time and cost (University Hospital Birmingham NHS Trust, University Hospitals Coventry and Warwickshire NHS Trust, Heart of England NHS Trust, Worcestershire Acute Hospitals NHS Trust and South Warwickshire NHS Trust).
Sampling aimed for equal numbers from each of the 4 possible treatment combinations so as to cover the spectrum of experiences that were possible during participation in MINT (Figure 31). As the study progressed the gender and Neck Disability Index (NDI) scores of the participants were examined to ensure that the sample interviewed would reflect the pattern of gender and NDI scores of participants in the prospective cohort study. This was based on information from the first 500 recruits. If there was a choice of potential

interviewees we aimed to select those who were most appropriate based on their gender and NDI scores to ensure a similar profile to that of the main cohort study. NDI was chosen as this was the baseline factor with the most evidence that it was a risk factor for poor outcome. It was also felt it was important to interview both male and female participants to enhance generalisability of findings.

7.3.2 Participant recruitment

Participants attended the research clinic where they were assessed and then consented (if eligible) to take part into the Step Two of the trial. Potential interviewees were then invited to take part in a semi-structured interview to be conducted on completion of their treatment. Those who expressed an interest were provided with an additional information sheet about the interviews. 25 trial participants were approached and all expressed an interest in being interviewed. Attempts were made to contact all 25 potential interviewees on completion of their treatment. Twenty-one patients were successfully contacted. Interviewees were given a choice of venue for interview (e.g. home, ED department, physiotherapy department) to make it as convenient as possible for the interviewee. Of those successfully contacted one participant failed to attend for the interview with 20 participants attending for interview. Four potential interviewees were not contactable and they failed to respond to messages left asking them to contact the trial team.

Figure 31 Consort diagram for qualitative study



7.3.3 The interview

Semi-structured interviews were carried out. Semi-structured interviews are the most common way to collect data in qualitative research (292p7). In a semi-structured interview the main questions are fixed but the interviewer should improvise follow up questions to explore meanings and interesting topics that arise during the interview (292p7). The interview schedule was developed following consideration of the aims of the interview which in addition to the aims of the qualitative study for this thesis (See section 7.2) also included gaining feedback from participants on the MINT interventions. The interview schedule was reviewed by other members of the MINT research team. The schedule was then reviewed and piloted on the first participant. Some changes were made after this initial interview. The interviews explored the participant's experience of having a whiplash injury. Open questions were used whenever possible to encourage participants to talk freely about their experiences. Prompts were used to expand on questions to elicit personal experience and opinions surrounding their experiences. See Table 101. Some of the questions included do not relate to this thesis so are not reported on here. Interviewees provided informed written consent prior to the start of the interview which took no more than one hour and was recorded using a digital recorder (Olympus digital recorder (DM-10)).

Table 101 Interview schedule

As you know we are recording the interview today. If tell me anything that you don't wish to be included in the final recording then please let me know and we can discuss it at the end.

1. Today we are mainly talking about the problems you had with your neck but it helps to put your injury into perspective if I know a bit more about you. Would you mind telling me about yourself?

2. How did you injure your neck?

3. Tell me about the symptoms that you experienced following your accident.

4. Did you know anything about this type of injury before you experienced it yourself? Explain.

5. Initially when you had your injury how long did you expect it would take you to recover? Why did you think this?

6. You attended A&E with your neck injury. Will you tell me about that?

7. Would you pass on this advice/information to a friend if they had a similar injury? Why or why not?

8. You also went on to have a package of physiotherapy/advice session. Will you tell me about that?

9. Would you recommend the physiotherapy treatment you received to a friend if they had this sort of injury? Why or why not?

10. Have you seen anyone else about your neck problem?

11. Get patient to rate recovery – 0% = no better 100% = completely better

12. If not 100% recovered, what sort of problems are you still having?

13. What do you think is the key to getting over a whiplash injury?

14. What do you think your neck will be like a year from now? What is this based on?

15. Is there anything else you want to tell me about your injury or the treatment you received?

7.4 Ethical approval

Ethical approval for this study was given by the Trent Multicentre Research Ethics Committee (reference MREC/04/4/003) (See Appendix 6).

7.5 Analysis of interviews

Each interview was transcribed verbatim. Computer software (NVIVO version 7(293)) was used to assist in carrying out the analysis.

7.5.1 Interpretative Phenomenological Analysis

Analysis was done using Interpretative Phenomenological Analysis (IPA) (294). IPA is recommended as a suitable approach to investigate how an individual perceives a situation or to explore the meaning of particular events, experiences and states for the individual (295p51). It is thought to be particularly suited to exploring biopsychosocial theory that is integral to understanding how patients deal with injury or disease (287). This approach has been used successfully to describe the experiences of patients with musculoskeletal problems such as chronic low back pain (296). IPA does not require the testing of a hypothesis but allows the researcher to carry out exploratory work which reflects the aims of this study (Smith and Osborn, 2003 p 53). IPA also allows the examination of similarities and differences between participants which also suited the aims of this study (294p3).

IPA draws on different philosophical approaches. Firstly, phenomenology, which is concerned with experiences and how an individual perceives them (294p21). This study was concerned with the participants' experiences of managing or attempting to mange a whiplash injury. The participant provides an account of their experience and the researcher then attempts to attach meaning to the participant's account and so the process becomes interpretative. This is the second approach integral to IPA, hermeneutics, the theory of interpretation (294p21). In the case of IPA the researcher is interpreting the participant's interpretation of an event (294p35). A third consideration of IPA is idiography which is concerned with the particular (294p29). This means that IPA is committed to achieving an in-depth analysis of each individual interview as well as providing analytical procedures to move from the findings of single interviews to the collective findings of multiple interviews (294p32).

In line with an IPA approach the following procedure was following during the analysis (294, 295). The interview was listened to and the transcript was checked for correctness. The transcript was then uploaded to the NVIVO programme (293) which was used to manage the data. The transcript was then read through several times and preliminary codes were applied to the text using the "free nodes" function of NVIVO. These codes were then examined to look for connections between them and themes that were similar were clustered together using the "tree node" function of NVIVO. These tree nodes were then transferred into a table of themes which was used to assist in the analysis of subsequent transcripts and to which new themes were added as they emerged. The process was repeated for the remaining transcripts with ongoing reappraisal of the table of themes. On the completion of this analysis NVIVO was used to generate reports that produced counts of the themes identified as well as the supporting text from each participant. This information was then translated into a narrative account and links were made to the relevant literature to produce an interpretative account. This account included a description of the identified themes and was supported by verbatim quotes. Participants were given a pseudonym to protect their identity.

How themes were identified

Participants produced rich data that covered a multitude of possible themes. In line with the aims of this study the primary focus was on identifying themes related to patient held beliefs about their whiplash injury and how this influenced the ways they managed their injury. Themes that included the types of symptoms experienced and the impact of these symptoms on their lives were also included to give context to the study.

7.5.2 Classification of recovery status at interview

To enable comparisons to be made between participants recovering well and those recovering slowly participants were separated into two groups. Participants were asked to provide a rating of their recovery during the interview (0% recovered = no better and 100% = completely recovered). The original idea was to use these scores to separate participants into two groups (recovering well and recovering slowly). However, it soon became apparent that this was not straightforward. Participant ratings of recovery did not always equate with the narrative that they provided when discussing their injury. Therefore, when allocating the participants to the two groups their narratives about the continuing impact of symptoms on their daily lives was also taken into account.

7.5.3 Strategies for reducing bias in qualitative research

Qualitative research is often considered to be less rigorous than quantitative research (297). However, methods are afforded to qualitative research just as they are to quantitative research to reduce bias and maintain scientific rigor (288, 297). The following strategies were considered:

Transparency: A well documented analysis is essential to reduce bias and a systematic method of analysis should be used (297). IPA provides detailed guidelines to make the analytical process transparent and reduce potential bias (287). Theoretical frameworks that influence analysis should be spelled out (297).

Reflexity: Interpretation of data will be influenced by characteristics and experiences of the researcher (297). It is important that this is recognised and that the researcher reflects on these potential influences (287). The standpoint from which the researcher carried out this analysis was primarily as a physiotherapist with experience of working with patients with a variety of musculoskeletal conditions and with a strong interest in how patients manage their own condition. This experience will have resulted in the formation of beliefs about potentially helpful and unhelpful management strategies. If strong preconceived beliefs are held by the researcher then this may introduce bias with the researcher trying to identify themes that confirm these beliefs. Another potential influence was the results of the prospective cohort study where certain factors had been linked to outcome. The temptation to look specifically for the same themes that were investigated in prospective cohort study needed to be avoided. Although, it was hoped to compare the findings of one study to the other, if the themes were limited to those contained in the prospective cohort study then there was a risk of missing important findings. Bracketing or “putting to one side” is encouraged throughout analysis (287, 294p13). A concept developed by the phenomonologist Hesserl, it refers to the researcher’s attempt to put aside their own assumptions and preconceptions and make the participants’ accounts the primary focus (287, 294p14).

Counting: Detailed analysis is time consuming so relatively small numbers of participants are usually involved (294p3). The sample size of this qualitative study was relatively large in IPA terms. In larger samples, the reoccurrence of themes across the group is important and counting the occurrence adds validity to the findings (294p106). A potential source of bias in qualitative research is when a theme maybe very strongly represented in a couple of cases leading the researcher to presume that it is more important than it is (298p263). Counting up actual occurrence across all participants is one way to ensure that this does not occur (298p263). Although, direct counts were not reported routinely, they provided one indication of the relevant importance of one finding compared to others to help identify the most important findings.

Look for exceptions: It is tempting to ignore or smooth over cases that may contradict a particular finding (298p269). Ensuring that such cases are highlighted if present reduces the risk of bias and may also lead to new theories or explanations adding to the depth of analysis (298pp269-271).

7.5.4 Validity checks

IPA advocates a review of work by supervisors or colleagues to ensure that the account produced is a plausible or credible one as another way to reduce bias (290, 294p183). The aim of this peer review is not to produce consensus (such as inter-rater reliability in a quantitative framework) but checking that the themes make sense when the transcripts are examined (294p183-184). Another researcher will also approach the data from a different standpoint and so offer new perspectives to the interpretation which can add further depth to the analysis (297).

Preliminary themes and a brief summary of findings for two participants were examined by a colleague who had experience in carrying out qualitative research at doctoral level. The findings were found to be credible and suggestions were made about other potential interpretations. The main issue identified was that an unwieldy number of themes had been used. Ways to combine themes to make the data more manageable were discussed resulting in the reorganisation of themes. This feedback was considered further throughout the remaining analysis.

7.6 Summary

This chapter has described the methods of the qualitative study. The results are presented in the following chapter.

8.0 The results of the qualitative study

8.1 Participant Characteristics

Tables 102 and 103 present characteristics of the participants. The participants in the interview study appeared to broadly reflect the participants from the cohort study in the majority of baseline characteristics including age, sex, injury severity factors (including baseline NDI), psychological response factors and the majority of belief factors. Participants were given a disability severity rating which was based on the NDI (208) and there was a greater percentage of those in the interview group classified as severe compared to the main trial. The main trial had a greater percentage of those classified moderate. The remaining 3 categories were similar. There was a greater proportion of participants in the interview study who reported previous neck pain compared to the main cohort study (15% versus 7%). However, none of the interview participants were classified as having chronic widespread pain which was reported in approximately 7% of the main cohort study. There were some differences in treatment preferences observed between the two groups. Advice was the preferred treatment for a small percentage of participants in the main cohort study but not by any taking part in the interview study. However, a greater proportion of those taking part in the interview study had no treatment preference compared to those in the cohort study (60% versus 49%). There were also some differences observed between treatment preferences and treatment received between the two groups. More participants with no preference were randomised to advice in the interview study (35%) compared to those in the main cohort study (35% versus 23.5%) but less participants who wanted physiotherapy got advice compared to the main cohort study (15% versus 24%). Despite these differences, the participant ratings of predicted treatment benefit were very similar between the two groups.

Table 102 Baseline characteristics of participants in prospective cohort study and interview study.

Pre-existing factors:	**Prospective cohort study (n=599) Mean(SD) or n(%)**	**Interview study (n=20) Mean (SD) or n(%)**
Age	39.9(13.1)	42.5(11.7)
Sex	Female = 379 (63.3%) Male = 220 (36.7%)	Female = 12(60.0%) Male = 8(40.0%)
History of previous neck pain (in the month before injury)	Yes = 44(7.3%) No = 513(85.6%) Missing = 42(7.0%)	Yes=3(15.0%) No=17 (85.5%)
Full fills the Manchester definition of chronic widespread pain	Yes = 15 (2.5%) No = 576(96.2%) Missing = 8(1.3%)	Yes = 0(0%) No=20(100%)
Multidimensional Scale of Perceived Social Support	5.58 (1.3)	5.7(0.90)
Injury severity factors		
Neck Disability Index	41.8(16.2)	42.8(17.8)
Modified Von-Korff Pain Scale	57.31 (17.5)	56.7(15.9)
Disability severity (based on NDI scores)	No disability = 0 (0%) Mild disability = 5 (25%) Moderate disability = 7 (35%) Severe disability = 7 (35%) Complete disability = 1 (5%)	No disability = 3 (0.5%) Mild disability = 127 (21%) Moderate disability = 266 (44%) Severe disability = 155 (26%) Complete disability = 48 (8%)
Physical symptoms scale from the Cervical Spine Outcomes Questionnaire	5.37 (2.9)	5.65(2.7)
WAD grade at research clinic	WAD 1 = 84 (14%) WAD 2 = 442 (73.8%) WAD 3 = 73 (12.2%)	WAD I = 2 (10%) WAD II = 17 (85%) WAD III = 1 (5%)
Total active cervical ROM	232.53 (67.1)	215.20(68.9)
Psychological response factors		
Impact of Events Scale	28.4(18.5)	29.61(16.1)
General Health Questionnaire-12	6.3(3.9)	6.3(4.1)

Belief factors	**Prospective cohort study (n=599) Mean(SD) or n(%)**	**Interview study (n=20) Mean (SD) or n(%)**
Fear-avoidance beliefs questionnaire (physical activity scale)	14.73 (5.6)	15.65(4.9)
Beliefs about neck exercises following whiplash injury	4.95(2.7)	5.05(1.3)
Pain Catastrophising Scale	17.85 (12.8)	18.75(12.4)
Expected time for their recovery	2 weeks = 10(1.7%) 2-8 weeks = 160(26.7%) 2-6 months = 237(39.6%) 6-12 months = 91(15.2%) More than a year = 18(3%) Not sure I will recover = 76(12.7%) Missing = 7 (1.2%)	2 weeks = 1(5.0%) 2-8 weeks = 7(35.0%) 2-6 months = 7(35.0%) 6-12 months = 2(10.0%) More than a year = 1(5.0%) Not sure I will recover = 2(10.0%)
Treatment preference	Advice session = 24(4%) No preference = 295 (49.2%) Physiotherapy = 277 (46.2%) Missing = 3 (0.5%)	Advice session = 0(0%) No preference = 12 (60.0%) Physiotherapy = 8 (40.0%)
Treatment preference and treatment received	Wanted advice – got advice = 14(2.3%) Wanted advice – got physio = 10(1.7%) No preference – got advice = 141(23.5%) No preference – got physio = 154(25.7%) Wanted physio – got physio = 134(22.4%) Wanted physio – got advice = 143(23.9%) Missing = 3 (0.5%)	Wanted advice – got advice = 0(0%) Wanted advice – got physio = 0(0%) No preference – got advice = 7(35.0%) No preference – got physio = 5(25.0%) Wanted physio – got physio = 5(25.0%) Wanted physio – got advice = 3(15.0%)
Predicted benefit of treatment	7.12 (2.4)	7.00(1.9)
Perceived ability to cope with neck problem	3.68 (1.7)	3.45(1.7)
Coping Strategy Questionnaire passive coping subscale	3.79(3.5)	4.15(4.4)
Coping Strategy Questionnaire active coping subscale	12.77 (5.5)	12.4(5.8)

Table 103 Study participants: individual characteristics

Participants allocated to advice session				**Participants allocated to physiotherapy package**			
Name	**Age (years)**	**Initial NDI Score**	**Level of disability**	**Name**	**Age (years)**	**Initial NDI Score**	**Level of disability**
Maria	45	54	Severe	Connie	45	66	Severe
William	36	22	Mild	Louise	40	42	Mod
Lisa	24	16	Mild	Emma	24	74	Complete
Sam	40	46	Mod	Gary	45	58	Severe
Zach	41	22	Mild	Carol	44	66	Severe
Steve	37	30	Mod	Caroline	58	26	Mild
Catherine	35	54	Severe	Jane	31	38	Mod
George	35	32	Mod	John	50	34	Mod
Celia	45	58	Severe	Yvonne	44	36	Mod
Margaret	72	20	Mild	Thomas	42	56	Severe

8.1.1.1 Advice session participants:

All participants receiving the advice session attended with a mean wait of 18 days (SD=11) between randomisation and the physiotherapy advice session. Waiting times were similar to the main trial (mean =18 days, SD= 13.8). Mean time between ED presentation and attending the physiotherapy advice session was 50 days (SD =13.6), similar to the main trial (mean = 49.7 days, SD =17.47). Mean time between ED presentation and interview was 84 days (SD= 18).

8.1.1.2 Physiotherapy package participants:

For the group randomised to the physiotherapy package, seven of the ten participants (70%) interviewed completed their full course of treatment, two participants (20%) partially completed treatment and one (10%) attended the initial assessment only. This attendance pattern was similar to that of the main trial where 67% completed treatment, 15% partially completed and 9% only attended the assessment session. The mean number of treatments attended in addition to the assessment session was five (SD=3.7), somewhat larger than in the trial overall (mean = 3, SD=2.7). Mean wait from randomisation to first physiotherapy appointment was 13 days (SD=12.2), similar to the main trial (mean=15 days, SD=13.4). Mean time between ED presentation and starting treatment was 39 days (SD=18) which was shorter than those in the main trial (mean=47 days SD=17). Mean time between injury and interview was 120 days (SD= 28).

8.1.2 Timing and location of interviews

Interviews took place in a variety of locations (Interviewee's home n= 8 (40%), physiotherapy department n=9 (45%), Emergency Department n=2 (10%), work place n=1 (5%)). It had been hoped to interview participants on completion of their treatment and this was the case for 17 out of the 20 interviewees. Due to time restraints 3 interviewees (Louise, Emma, Thomas) who were receiving the physiotherapy package were interviewed towards the end of their attendance for treatment. Interviews were carried out between 54 and 167 days post injury (mean= 101.75).

8.1.3 Mechanism of injury

All but two participants had sustained their injuries during a road traffic accident. One participant (Sam) had sustained his injury in a work related fork lift collision and the other (Emma) had been jolted forward when the bus she was travelling on stopped suddenly.

8.2 The impact of sustaining a whiplash injury

8.2.1 Physical impact

The impact of physical symptoms was wide-ranging. Most of the participants reported the onset of their physical symptoms immediately or very soon after their injury (n=16). Of the four remaining participants, one participant reported their symptoms to have come on hours later on same day. Two participants reported the onset of their symptoms the following morning. One participant who had suffered neck pain previously (Margaret) reported that she did not really notice her symptoms were noticeably worse until she tried to return to activities she had not tried since the injury. This was also reinforced by completing the initial MINT questionnaire several weeks after her injury.

Throughout the course of the interview participants described the symptoms they had experienced from the time of injury until the time of the interview (i.e. not necessarily present at the time of interview). All participants had experienced neck pain at some point since their accident. A variety of other symptoms were also reported (Table 104).

Table 104 Range of symptoms experienced

Symptom	**Number reporting**
Neck pain	20
Shoulder pain	9
Headache/head pain	9
Leg pain	6
Low back pain	4
Arm pain	4
Chest pain	3
Paraesthesia/numbness in arm	3
Abdominal pain	1
Throat pain	1

These symptoms interfered with different aspects of the participants' lives and to varying degrees. It included minimal interference:

"It weren't a case where I was restricted as such. I was still doing my normal everyday activities but I weren't doing any heavy sort of work, lifting, I wasn't doing any weights as such so from that point of view I was still getting on with the work and driving as such."

William

More extensive interference with activities was described by other participants:

" I don't like… its very rare that I'm ill and when I am ill I try and keep going with things and so when I had the neck injury everything just stopped. Even doing my assignments for university, it was in my head so my daughter had to do some of the typing because I couldn't type for long periods of time because of the way you hold your hands to the keyboard. It was pulling my neck and even looking at the keyboard so I thought it would be about two weeks so I was a bit disappointed that it wasn't healing as fast as I thought it would be." Catherine

The types of activities that were affected included recreational activities (n=14), work or study (n=14), activities of daily living (n=11), family life (n=4), driving (n=3) and sleeping (n=2).

8.2.2 Psychological impact

The impact was psychological as well as physical. The majority of participants reported being affected psychologically by their injury in the immediate post injury period. Many participants found the experience of sustaining a whiplash injury upsetting. Although not asked specifically, the majority of the participants reported their psychological reactions immediately following their injury (n=16). Participants gave descriptions of being "fired up", "shocked and scared", "lost and confused", "feeling teary", "angry", "emotions running high" and "terrified".

The psychological impact continued after the immediate post injury period. Many participants experienced psychological symptoms during the recovery period. Feeling down or depressed at some point over the course of recovery was described by 11 participants. This was for variety of reasons including dealing with symptoms, insurance claims and being unable to do their usual activities.

" It does…well, I'd be lying if I said it didn't get you down a bit to start with, but it's not just the injury. It's everything else that goes with it as well.............You know, like claiming for the accident.." George

Other participants described being worried or anxious (n=10). This worry or anxiety was due to similar factors described above such as not being able to carry out their usual activities or because their symptoms continued longer than they expected.

"I was very worried and very concerned because I have two children and I am a teacher and I need to do my job properly." Connie

Other psychological responses reported less frequently included financial concerns (n=5), anger related to their accident (n=4) and feelings of frustration due to symptoms being ongoing or an inability to return to normal activities (n=3).

8.3 Situation at interview

8.3.1 Recovery status at interview

One of the aims of this interview study was to compare the beliefs about injury and recovery of those recovering well and those recovering slowly. These were primarily based on the participant's rating of recovery (See Table 105 (p290)). However, participant perceived ratings of recovery did not always equate with the narrative that they provided when discussing their injury. Lisa and John both rated themselves as 70% recovered but had returned to all their usual activities. In contrast, Connie and Celia's self-ratings of recovering were similar to Lisa and John. However, both described considerable difficulties with their activities. Such accounts within the narratives of participants were considered when separating participants into the two groups. This resulted in 12 participants classified as recovering well and 8 participants classified as recovering slowly. Apart from the exceptions discussed already, those recovering well rated their recovery as higher than those considered recovering slowly.

Those recovering well did not necessarily have complete resolution of symptoms or return to full activities but were making good progress. Therefore, a proportion of participants still reported difficulty carrying out activities at interview (n=12). However, only participants who were considered to be recovering well had returned to all their usual activities (n=8). Ongoing difficulties described by participants included difficulty with ADL and recreational activities. These ongoing problems were more likely to be described by those recovering slowly.

Information was offered about work status by some participants. Five participants who were all recovering well reported having returned to work and were able to do their normal job. Four other participants stated they had also returned to work or study but were finding it difficult due to their symptoms (recovering well=1, recovering slowly=3). Only two participants stated they were not currently at work (recovering well=1, recovering slowly=1). One was a teacher currently on summer holidays and planned to return in the new school year. The other had been redeployed as her job was too heavy for her to manage following her injury and she was due to start at her new job in the next few weeks.

It was common for participants to still experience some symptoms at interview even if they were recovering well. Symptoms were reported by 18 participants and ranged from occasional discomfort to more severe symptoms. Although, one participant who said he was symptom free was taking one tablet a day to prevent the symptoms returning.

Participants also had their recovery status classified in the prospective cohort study and these classifications are also included in Table 105.

Table 105 Recovery status of participants

Recovering well at interview	**Self rated recovery at interview**	**Cohort study classification system of recovery status**		
		Non-recovered at 4 month follow up (Yes/No)	**LWS at 8 month follow up (Yes/No)**	**LWS at 12 month follow up (Yes/No)**
Maria	“Back to normal”	No	No	No
William	95%	No	No	No
Catherine	85%	No	No	No
George	85%	No	No	No
Yvonne	95%	No	No	No
Lisa	70%	Yes	No	No
Jane	90%	Yes	No	No
John	70%	Yes	Yes	No
Steve	98%	Non-responder	No	Yes
Sam	95%	Yes	Yes	Yes
Gary	85%	Yes	Yes	Yes
Carol	85%	Yes	Yes	Yes
Recovering slowly at interview				
Connie	65-70%	Yes	Yes	Yes
Louise	50%	Yes	Yes	Yes
Emma	60%	Yes	Yes	Yes
Celia	75%	Yes	Yes	Yes
Thomas	60%	Yes	Yes	Yes
Caroline	50%	Yes	Yes	No
Zach	60%	Yes	No	No
Margaret	5%	Non-responder	No	No

The two classification systems were in agreement for some participants recovering well. 5 of the 12 participants (42%) considered to be recovering well at interview were classified as recovered at all 3 follow up points according to the prospective cohort study. Another two participants (16%) were recovered by the 8 month follow up point. Steve (n=1(8%) was also recovered by the 8 month follow up but appeared to relapse at 12 months. Interestingly, Steve had suggested in his narrative that his neck may cause him problems in the future due to a previous neck problem. One other participant (8%) classified as recovering well was recovered by the 12 months follow up. The remaining 3 participants (25%) were considered to be non-recovered or had LWS at all 3 follow up point. This is despite their estimation at interview of being 95%, 85% and 85% recovered respectively.

The two classification systems were also in agreement for some participants recovering slowly. 5 of the 8 participants (62%) considered to be recovering slowly at interview were classified as non-recovered or having developed LWS at all 3 time points. Another participant was non-recovered/had LWS at 4 and 8 month follow up but was recovered by the 12 month follow up. Of the remaining participants, one was recovered by 8 month follow up even though he rated his own recovery at interview as only 60%. The final participant was rated as recovered at 8 and 12 months (non-responder at 4 months) despite rating her improvement as only 5% at interview. This will be discussed in Chapter 10.

8.3.2 Psychological symptoms at interview

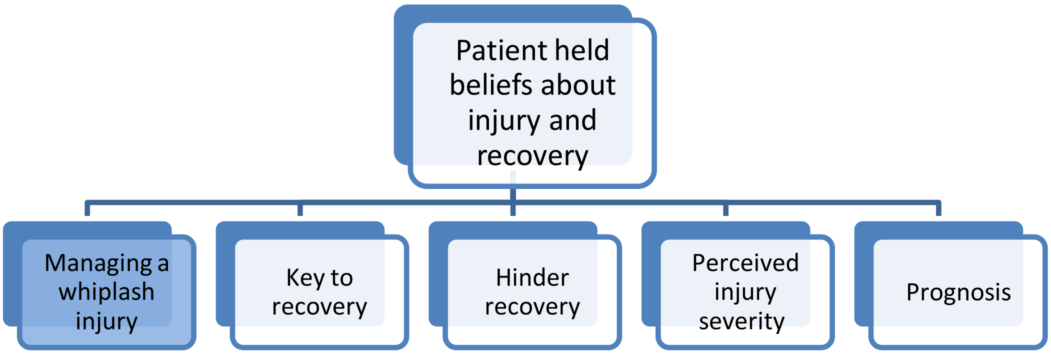
The psychological impact was ongoing for some participants and still apparent at the time of interview. Five participants reported ongoing psychological problems that they related directly to their accident and were possibly experiencing some degree of post traumatic stress reaction. Two reported driving anxiety, one was experiencing nightmares and sleep disturbance, another reported flashbacks and while the final participant began shaking when talking about the accident. There was no difference between those recovery well and those recovering slowly.

8.4 Patient held beliefs about injury and recovery

The main aim of the interview study was to identify patient held beliefs about injury and recovery and 6 major themes related to this were identified (Figure 32).

8.4.1 Managing a whiplash injury

Figure 32 Themes related to beliefs about injury and recovery: managing a whiplash injury



The first theme identified related to patient held beliefs was *“managing a whiplash injury”* (Figure 32). This theme incorporated any data related to participant beliefs about managing their whiplash injury or factors that influenced how they managed their injury. Within this theme there were five subthemes (See Table 106).

Table 106 Subthemes related to “managing a whiplash injury”

Subthemes **“Managing a whiplash injury”**
Attribution of recovery
Beliefs about activity
Self-efficacy
What is needed now
Personal situation

8.4.1.1 Attribution of recovery

Definition:
Anything the participants suggested as being helpful to their own personal recovery.

The participants described things that they believed had helped in their recovery. There was a range of factors identified by participants and even those recovering slowly suggested things that had helped them. All participants appeared to benefit from the provision of exercises further endorsing the importance of exercise in the management of whiplash injuries.

Both participants recovering well and those recovering slowly appeared to benefit from the physiotherapy interventions that were offered as part of the trial. All participants but one who received the physiotherapy package suggested it contributed to their recovery. This participant (Gary) only attended his initial appointment and then failed to attend any more appointments. The majority of participants who received the advice session (n=6/8) also suggested that it contributed to their recovery.

"… that helped a hell of a lot and the exercise they gave me, bending my head and holding my chin in, sitting up straight here and having them did help me."

John (Recovering well (W)) commenting on the physiotherapy package

"I knew bits and pieces about it but it was for someone to actually go through and spending a bit of time saying if you do this or have any concerns then you can start off with this basic exercise and then move onto to the next level so in that sense I thought it was fairly good."

William (W) commenting on the advice session

The importance of reassurance was more apparent in the narratives of those recovering slowly compared to those that were recovering well.

"I think it was, having that guidance and having someone there to say whether you are actually, it is reassuring for somebody to say oh yes, that's right that is how you should do it. Or, that's not quite right." Caroline (Recovering slowly (S))

In contrast, those recovering well were more likely to highlight the helpfulness of medication to control their symptoms early on suggesting that effective pain control is an important aspect of injury management.

""The pain was really bad. I mean, I had to have them tramadol and, um, they were brilliant. As long as I carried on taking them I could actually do my normal work. It was still slow but I could still do my normal work. I could actually move around. As soon as I stopped taking them the pain was really bad again." Maria (W)

8.4.1.2 Beliefs about activity

Definition:
Beliefs about exercises or activity and their role in the recovery process.

When considering beliefs about activity two themes that emerged were consistent with Vlaeyen's model of fear avoidance (See Figure 5): avoidant and confrontational beliefs and behaviours (Table 107). Participants were not always consistent in their beliefs and behaviours regarding activity. They often exhibited both avoidant and confrontational beliefs and behaviours depending on the situation. There was also evidence that beliefs and behaviours changed over time or in response to interaction with health professionals.

Table 107 Beliefs about activity

Avoidant beliefs and behaviours:	Any evidence of beliefs or behaviours that the individual is avoiding activity or movement.
Confrontational beliefs and behaviours:	Any evidence of beliefs or behaviours that the individual is confronting their injury by attempting to exercise or stay active.

There was evidence that some participants were avoidant of movement or exercise early on after injury. This was the case for both those recovering well and slowly.

"There was no way I could have done any form of exercise with my neck in those first days"

Jane (W)

Interviewer (I): Did you try any of the exercises from the book?
Respondent (R): I don't think I did because I didn't know whether I'd be doing the right thing or the wrong thing and I thought I'd give it time to settle before I tried it. I didn't try it straightaway. Louise(S)

Generally those participants who were recovering well demonstrated that they had overcome avoidant behaviours, although, not necessarily all. For example, Sam had tried the exercises and stopped as they were too painful. However, the physiotherapist advised him to gradually build up his exercises and he was then happy to do them.

"I did about say 3 sessions of the 10s and then I didn't do anymore until I see [physio] that time and [physio] said to drop them down to what you feel comfortable with and I did it that way" Sam(W)

At interview he had returned to the majority of activities although he was still avoidant of some specific activities (golf and swimming) as he was concerned trying them might set him back.

"I know it is awkward to get the motion that I want, that I need to get and I don't want it upsetting anything else and putting me back a week or two." Sam (W)

Avoidant beliefs and behaviours were more likely to be ongoing in those recovering slowly. These participants continued to report behaviours at interview that indicated they were continuing to avoid activities.

"I don't do…like changing beds because…and you know…stuff that I can't like pull up. I can't do it." Emma(S)

The biggest difference between those recovering well and those recovering slowly was seen when examining evidence of confronting behaviours. Those recovering well were much more likely to have started exercising or trying to stay active immediately following their injury.

R: You know, I sort of got on with it myself. You know, I just wanted to, sort of, get back to work and get back to normal. You know, I am just surprised about how long it has taken.
I: Did you try and do the exercises in the blue book?
R: I did my exercises and I did what they told me when I went to see the Physio. And I told her all the exercises I was doing and she said that was great. Maria(W)

Although, confronting behaviour was evident in a small number or participants who were recovering slowly. Zach's confronting behaviour was surprising due to his concerns over the meaning of the pain he was experiencing (see below).

"I just decided to – well I have no cervical bone fracture and I would start exercising myself." Zach(S)

Participants' beliefs about the meaning of pain are thought to be a driver for avoidance/confrontation behaviours. Those who were recovering slowly were more likely to equate the pain with harm or injury to tissues. Beliefs about pain may exhibit themselves as catastrophic thinking. Evidence of catastrophic thinking was only seen in two participants and both were both recovering slowly.

"..because I thought maybe I had a tumour, I am going to be paralysed" Zach(S)

"I think it was just because when you are in a lot of pain you are scared. You don't want to do too much because you think you must cause more injury and end up with an injury for life." Connie(S)

Interestingly, although Zach showed evidence of catastrophic thinking he was not overly avoidant of activity as demonstrated above. It may be in this case catastrophic thinking contributed to his slower recovery via a different mechanism than the fear avoidance cycle (such as increased anxiety).

Although not necessarily catastrophic thinking, some participants expressed beliefs about their pain that resulted in them avoiding neck movements or exercises. Generally these participants showed concern that pain equated to tissue damage and exercising could be harmful. Evidence of these beliefs was more likely to be seen in those recovering slowly.

"I was scared of doing more damage than getting it right because of how much it hurt when I move in certain positions." Celia(S)

Beliefs associated with fear avoidance were not necessarily the only reason for failing to carry out exercises. One participant related that he did not do the exercises as he could not see how they were help.

"Because of the pain I was in with my neck and everything I was feeling pretty low anyway. I just didn't bother. I just thought 'Oh I just can't see them helping'" Thomas(S)

8.4.1.3 Self-efficacy

Definition:
The participants' confidence in their ability to manage their condition

Higher levels of self-efficacy were observed in those recovering well. These participants displayed greater confidence in dealing with or managing symptoms. They also sought solutions which included accessing health care professionals but still acknowledged their role in the recovery process.

"I thought one session was quite adequate because I needed the exercises and its only me that can do them, so for me that worked fine."

Lisa (W) commenting on the advice session she had received

Participants who were recovering slowly did not have the same confidence of those recovering well.

"... just say 'Am I still doing it right?' and 'Is my posture right and is my neck right?' Yes, I think so – just reassurance"

Louise(S) explaining why more physiotherapy was needed

Emma constantly referred to her need for reassurance and support.

"you see, in the [whiplash]book it says 'Well you've got to start doing this and you've got to start doing this.' For me personally I think a third person should always be involved – me as a person. I mean I felt… I couldn't have done it on my own - simple." Emma(S)

Lack of confidence to carry out the exercises was seen in other participants who were recovering slowly.

"I thought it would be quite nice to go back just for a short session to say – I think I am standing the way you want me to but am I? Just so someone can say to you – yes you are doing it right." Margaret(S)

Connie reported a loss of confidence directly related to her whiplash injury. She explained this loss of confidence:

"I think cause I am an independent woman and I am not used to other people doing things for me and when I had the accident I felt like an invalid and I couldn't do a lot and I had to hire a gardener and I had to hire somebody to come and do my housework. I felt like everything was gone and all of a sudden, you know, I was relying on people to do things for me and I didn't want it to stay for long. Um and of course, you fall into the trap of getting on your feet and starting to do things and you realise that you that you are hurting yourself more." Connie(S)

8.4.1.4 Personal situation

Definition:
Any factors related to their personal situation
that influenced recovery

One consideration was raised by participants who were recovering slowly regarding their personal situation. Although this was only identified in a small number of participants it may represent a barrier to treatment compliance that physiotherapists should be aware of. This was the issue of priority. Some participants felt that they were unable to prioritise resources such as time or money towards their own recovery.

"I'm not a selfish person and I feel like that would take up my time and money and costs and I can't think that's… I can't spend that money on me really when it's quite expensive to have treatments like that and I'd rather give the money to my children and the family to do something together " Louise(S)

Celia explains why she had failed to access physiotherapy treatment she had been offered through her GP. This is despite her insistence it is what she need to recover.

"We had a big court case and I've had lots of things, I mean this court case has been like for the last three years so we had a big court case the week before and it was a real big build

up of three years going to court. Even my son attended so it was… I had to prioritise and we had to go to this court case and then [Name], my son had his yearly review and all the professionals were there so that had to be another priority so its… unfortunately sometimes I have to come at the bottom of the list. It's like I'm walking, I'm breathing and eating and all the rest of it, its bugging me but sometimes you just have to put it to one side and concentrate on other things" Celia (S)

8.4.1.5 What is needed now

Definition:
Participants' beliefs about what they still needed to help their recovery or complete their recovery

The majority of participants were asked what was needed to complete or further their recovery (all but Maria and Zach). Not surprisingly those that were recovering slowly suggested that more treatment from health professionals was needed. This may reflect the fact that their own efforts had failed to alleviate symptoms and they were searching for assistance from others. The types of treatment suggested included further physiotherapy or alternative therapies such as massage or chiropractic treatment. For example, following attendance for the advice session Celia repeatedly mentioned that physiotherapy was what was needed.

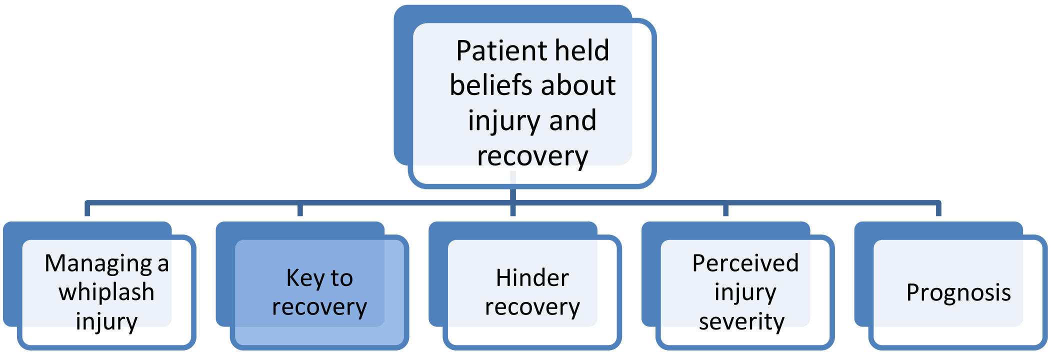
"I eventually went and had the consultation and she said that I probably actually need physiotherapy" Celia(S)

In contrast, those recovering well were most likely to suggest that continuation of exercises was the only thing that was needed. This may reflect that these participants had successfully managed their symptoms with exercises and were happy to continue to do so. Those recovering well were also more likely to suggest that time was needed to continue their recovery and for some participants the only thing that was needed.

"I'm not doing my exercises as much now to be honest with you because I don't feel it needs it. It's just there. It's like I've got my movement. I honestly don't think there's anything further……that can be done. It's just there now. It'll go away in its own time basically." Gary (W)

8.4.2 Key to recovery

Figure 33 Themes related to beliefs about injury and recovery – key to recovery



The second theme relating to beliefs about injury and recovery was "*key to recovery*" (Figure 33). This theme was generated from participant responses to a specific question. Participants were asked directly about the key to recovery and two main factors were identified.

All the participants suggested behavioural factors (i.e. behaviours they engaged in) were the key to recovery. Generally participants showed an awareness of current management approaches with the majority of participants suggesting that exercises and activity were important. When discussing the importance of exercise and activity a smaller proportion of participant emphasised the need to a paced approach to exercising or balancing them with rest.

R: Exercise – limiting the amount of exercise and don't worry too much about it, but get some good information so you can manage it and not overdoing it.
I: Yes and you think that that's the main thing?

R: Yes, because I used to be under the impression 'Oh no an injury. Don't do anything with it. Rest it', but you know…a limited amount of exercise does it good. George (W)

The second most frequent behaviour suggested was to consult a health professional with emphasis on getting the right advice or treatment. Participants acknowledged the expertise of health professionals. Several participants went on to emphasise the importance of actually following advice they were given. No difference was seen between those recovering well and those recovering slowly.

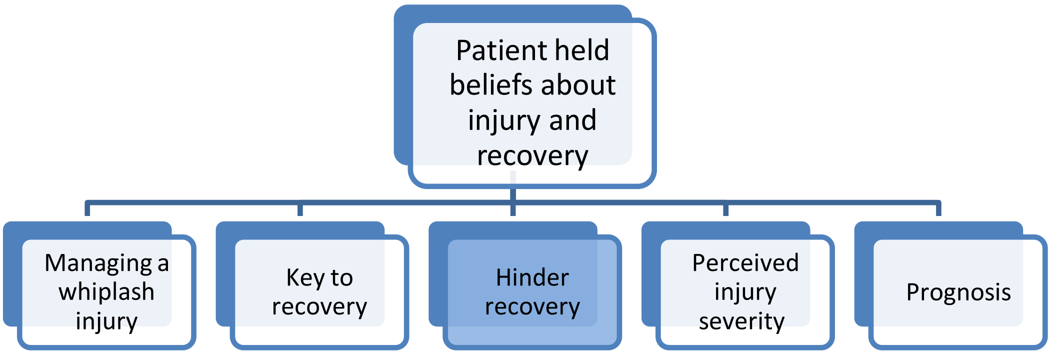
" Well I would just say from my point of view that it will get better with the right help and support and to stay positive about it and not to just sit about and do nothing, but to try and keep active and to take the advice of…you know, like a physio"
"That's the specialist [physio] and that's who needs to tell me what to do to help myself to get better – not that they can do it for me, but they can give me the advice to help themselves and I would say to people, stay positive, take the right advice and to follow it, so… Not just say 'yes' and walk out of the door and not do it… " Yvonne (W)

Cognitive factors (how participants thought about their injury) were also suggested as being important. However, the same consensus was not observed when considering cognitive factors. Cognitive factors were more likely to be acknowledged by those recovering well possibly indicating greater insight into their impact on pain and recovering. Eleven participants suggested that cognitive factors were important and the majority of these were recovering well. A positive attitude that you would recover was the most commonly suggested cognitive factor.

"You need perserverance. It is determination on your own part. You know not anybody elses. If you haven't got or you're not determined, you ain't have it in your head to get better quickly then you are not gunna" Maria (W)

8.4.3 Hinder recovery

Figure 34 Themes related to beliefs about injury and recovery – hinder recovery



The third theme relating to beliefs about injury and recovery was "*hinder recovery*" (Figure 34). This theme was also generated in response to a specific question. Most participants were asked what could hinder recovery (in general) following a whiplash injury (n=16) and, once again, behavioural and cognitive factors were suggested. No differences were observed between those recovering well and those recovering slowly.

The most commonly suggested behaviour that could hinder recovery was failure to be active or exercises. This, once again, indicated a general awareness that exercise and activity were an important aspect of recovery. Behaviours that may impede recovery were suggested by 9 participants and all suggested that being inactive could hinder recovery. Participants referred specifically to not exercising, resting or failing to follow advice.

"Taking no notice of what you were told cause obviously if they've given you an exercise and you're not going back and doing them you're not... you might not recover."

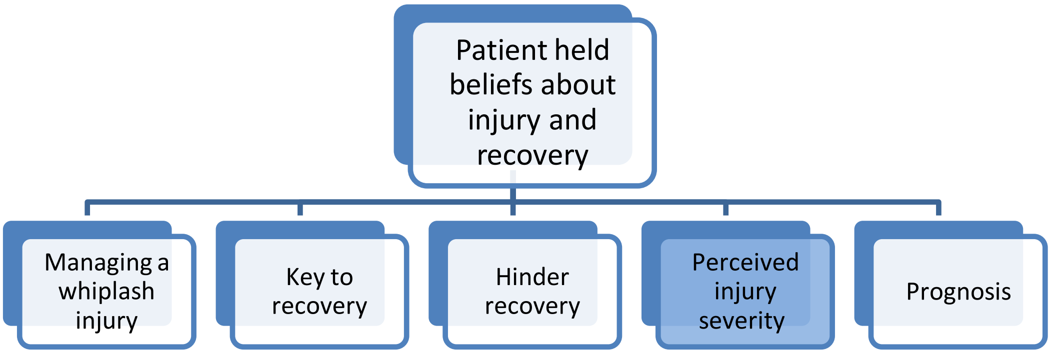
John (W)

Eight participants identified cognitive factors (how participants thought about their injury or recovery) that could hinder recover. The most commonly suggested cognitive factor was a negative attitude.

"People who look on things in a negative… with a negative outlook they're not going to get better. If you sit there and say 'oh god I'm going to be like this forever' you're never going to get better and you will be like it forever." Jane (W)

8.4.4 Perceived injury severity

Figure 35 Themes related to beliefs about injury and recovery – perceived injury severity



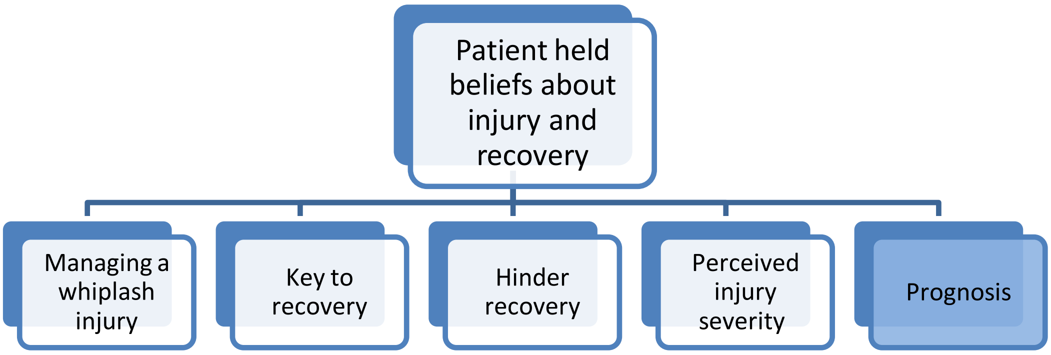
The fourth theme relating to beliefs about injury and recovery was "*perceived injury severity*" (Figure 35). Baseline injury severity as measured by the NDI was a predictive of outcome in the prospective cohort study. When comparing the baseline NDI scores those recovering slowly had slightly higher scores (mean=22.75, SD=10.5) than those recovering well (mean=20.25, SD=7.6. However, when the participants' perception of their injury severity is considered, it was apparent that those recovering well were more likely to suggest they had not perceived their injury as serious or severe.

Those participants recovering well were more likely to suggest they did not consider their injury as serious or severe compared to those recovering slowly.

"It was…because I play sports I know what a tightness or an injury sort of the thing is, rather than 'Have I broken my neck' sort of injury? So I wasn't overly panicked by the fact that I had pain in my neck and my head, so it was obviously a muscle sort of… So I didn't want to go in the ambulance, no but I did want to check that it wasn't… They'd said at the ambulance that it wasn't anything overly serious." Yvonne (W)

8.4.5 Prognosis

Figure 36 Themes related to beliefs about injury and recovery - prognosis



The final theme relating to beliefs about injury and recovery was "*prognosis*" (Figure 36). Participants who were recovering well tended to be more optimistic about outcome. This optimism was further reinforced by seeing improvements in their symptoms. Those recovering well were more likely to be optimistic from the start.

"It wasn't anything bad or anything I worried overly about anything to be honest with you."

Carol(W)

Initial concerns over symptoms were expressed by some participants who were recovering well. However, these concerns had subsided by the time they were interviewed. These participants were not necessarily symptom free but were optimistic they would continue to recover.

George had initially been worried about the impact of his injury but at interview was confident he would recover fully.

I: So where do you think you'll be a year from now?
R: I don't know – fully fit I hope.
I: Fully fit?
R: Yes.

I: And what's that based on?

R: Just how I am now really.

I: So because you've been making progress you expect you'll continue to make progress with that?

R: Yes. George (W)

This was not the case for those recovering slowly. Many participants recovering slowly expressed concern initially after injury and ongoing symptoms reinforced their worry or concern. All but one participant who was recovering slowly expressed ongoing concerns at interview.

I: Where do you think you'll be, in terms of your neck injury, in say, a year from now?

R: I am hoping it will be gone but I don't know. I don't know cause when I came back from holidays I felt really good, you know, not pain free but the pain was there I was aware of it but it wasn't as bad as it is now. Now, I am looking at the pain and I am experiencing a lot of pain at the moment and I don't know, as my physiotherapist said, it goes up and down and sometimes you can have a week or two good weeks and then you go down and then you go up. I don't know where I am going to be. I am hoping that I will be stress and pain free but I don't know. Connie(S)

The exception was Zach who had been very worried early on after his injury but at interview was optimistic about recovery.

"Well I am a great believer in a day at a time. So as a day passes by I feel that, well, eventually I will recover." Zach(S)

An important consideration was raised by participants when considering prognosis. Many participants suggested they thought it would be a short recovery time and were surprised about the ongoing nature of symptoms.

"I didn't know much and I never thought of…that it was going to take so long and it was going to be such a long process." Emma (S)

This mismatch between expectations and experience was a source of concern for some participants.

"I've found more about whiplash injuries via other sources available than I have from that initial A&E thing because it… I read about whiplash injuries even though on… not the NHS, the department of health I think it was. It will say it can last up to a year and plus and if I'd known that at A&E I wouldn't have felt so anxious after the first month or so thinking 'well why have I still got this, is it psychological, am I making it worse by doing… going back to A&E?' So if I'd know that it could be such a long process then I would have been less worried about it." Catherine (W)

Being able to establish realistic expectations appeared to benefit some participants. Carol and Caroline were reassured by the time frames offered them by the health professionals that they consulted.

Caroline emphasised how helpful it was to discuss her expected course of recovery.

"It is really because at least then you know that you perhaps not being unnecessarily pessimistic, that you know what to expect. I think it is helpful to discuss these things person to person as opposed to just being left to get on with it and not really know and wondering if you should go to the doctors, whether or not you should take the painkillers, that sort of thing really." Caroline(S)

It had been suggested to Carol that it would take a number of months to recover and this appeared to provide her with a basis for framing her expectations of recovery and alleviated her concerns about ongoing symptoms.

I: And are you worried about it?

R: No because everybody has been really sort of positive and this is a natural progression. The doctor … the physiotherapist sort of said… 'this is a natural progression and you're doing everything you should be doing so it should be ok' and the doctor at the insurance said 'this is quite normal, what you're going through is quite normal. Carol (W)

A wide range of time frames for recovery were suggested to participants by health professionals. Participants reported being given time frames of a few weeks to 18 months. Although, generally an optimistic outlook is important, unrealistically short time frames for recovery may not be helpful.

8.5 Belief formation

Another aim of this interview study was to gain an understanding of how participants formed beliefs about injury and recovery. There were a range of factors identified that had potentially influenced these beliefs and subsequent behaviour. These factors were separated into two themes: past experiences and current experiences.

8.5.1 Past experiences

Many participants' beliefs and behaviours were influenced by their past experiences. The impact of past experience varied from person to person. For many participants past experiences of injury and illness impacted positively on the way they managed or thought about their injury. This was more likely for those that were recovering well.

"If I can get over that [previous injury] and being in a wheelchair and stuck I can get over anything" Carol (W)

"I just get on. I mean with other things at the moment I'm the same. I have an in grown toenail at the moment it is 'Get on with it. Pull yourself together and get on with it.' That's something different, but she ends up… If I've got an infection, 'Get on with it. Take a couple of paracetamol and get on.' Now that's me." Gary (W)

Past experiences also contributed to participants' understanding of pain. Yvonne related how her experiences of managing netball injuries had given her understanding of the meaning of pain and she was not fearful of pain or re-injury.

"I've done sports and I know that sometimes you will get a little bit of pain but you don't stop the minute it hurts. You've just got to move on a little bit and try and test it out really" Yvonne (W)

Some participants reported that they utilised management strategies they had used for past problems.

"I was doing exercises before I saw you, which I was instructed to do five or six years ago when I had the last accident." George (W)

The positive impact of previous illness or injury was more likely to be observed in those recovering well. However, there were some examples of how past experiences had helped those recovering slowly to manage their symptoms. Two participants recovering slowly related how they used strategies for managing pain they had found helpful in managing previous injuries. Both participants had experienced long term pain problems with neck pain.

"..since the first accident I have always tried to have carrier bags of equal weight basically and if I am carrying a single object that is heavy I try to hold it up here near to my chest. Try to take the weight off so my arms aren't pulling down." Caroline(S)

Past experiences also had the potential to have a negative impact on how participants managed or thought about their injury. For some participants (n=2) previous experience of a whiplash injury appeared to add to their concerns over their symptoms.

George describes how concern over his symptoms prompted him to go to the ED.

"Because I've been in that situation before. Unfortunately I was a passenger in a car and we had somebody pull out on us and I just wanted to get it checked out basically."

George (W)

A previous whiplash injury also influenced expectations of recovery for some. For example, Steve thought in view of his previous injury he may not get back to 100% and there was a possibility of future problems although he was recovering well.

I: And what's going to get you that final two per cent?

R: I don't think I will get it back.

I: Why is that?

R: Because…it might be because I think I have to give leeway for anything to happen with it if that is going to have any future effect on me…you know…I don't know what ligaments may have been damaged.

I: Is that because you've had the problem before in your neck?

R: Yes, so I think that probably would have damaged something within me…you know…that my body's not telling me yet, so I am not encouraged about that, yes. Steve (W)

Past experienced could also contribute to unhelpful beliefs about pain. Louise described her experiences of LBP which may have contributed to fear avoidant behaviours with an underlying fear of re-injury being suggested here.

"I'm very careful with the way I move with my lower back because I've had a few trapped nerves as well over the years" Louise (S)

Other types of past experiences such as professional experience also had the potential to influence beliefs about pain. Zach's previous experience as a nurse had a strong influence on how his thinking and may have contributed to his catastrophic thinking demonstrated earlier.

”Maybe if I were a lay person probably I would be better. I don’t know if the understanding and as a professional you know, you think a lot of things and you sometimes wonder and psychologically you say, because I have a friend of mine who is paralysed now because of a vaccine he was given. He was given combined vaccines when he was ???????? and got paralysed because he reacted to polio so you look at him in a wheelchair and you think. This back. I might end up in a wheelchair. So psychologically you know your mind is not at rest.”

Zach (S)

However, this experience also influenced his behaviours as knew to do neck exercises and did not feel the need to consult the ED information he was given.

Past experiences had the potential to influence the treatment participants sought for their injury. A small number of participants related how past beneficial experiences of physiotherapy had prompted them to seek physiotherapy treatment through the trial. Although, generally participants found the physiotherapy interventions offered by the trial to be helpful, there was one example of how previous experiences of physiotherapy contributed to dissatisfaction with the trial treatment. Celia (recovering slowly), was unhappy with the advice session she had received as she felt that she needed “hands on” treatment. This was based on a very strong belief that physiotherapy was what she needed to recovery. This belief appeared to have developed following the rehabilitation she underwent following a serious injury which left her with ongoing pain. She reported little benefit from advice session she received.

I: You’ve obviously had quite positive experiences with physiotherapists in the past from the sounds of things?

R: Yes and especially the [local hospital]. They’ve been really good because they’d got me from being in full plaster up to my hips on both legs and two crutches, actually a Zimmer frame, to actually walking. They have been… I didn’t know what physiotherapy was until I went there and its not just the exercises it is the people themselves that take time and actually speak to you as person not as a number and that made a great difference.

Celia (S)

8.5.2 Current experiences

Within the theme of "current experiences" three sub-themes were identified: health professionals, family and friends and the symptoms experienced.

8.5.2.1 Health professionals

Health professionals appeared to exert considerable influence over the way that participants thought about or managed their injury. The majority of participants suggested they were influenced by the trial physiotherapists.

"and so it's only since I've been coming to see [physio] that I've started sort of doing the exercises." Thomas(S)

The influence of physiotherapist was generally to promote the return to activity and exercise. One exception was observed. One participant suggested that the physiotherapist reinforced her belief that a full course of physiotherapy treatment was what she needed to recover.

"...the lady [physio] said that… at [the hospital]... that I needed some physiotherapy just to get that stiffness." Celia(S) allocated to advice session

The GP was another source of advice and a proportion of participants suggested that the GP influenced how they thought about or managed their injury. Participants reported that GPs provided a variety of advice ranging from the encouragement of activity and exercises to advising time off work.

"...the GP said get movement back in my neck by holding on either side of your head and manipulating… not manipulating but gently move my head up and down, side to side so I could exercise the muscles." Catherine (W)

"She [GP] didn't recommend me going to work. Emma (S)

Participants were also influenced by the ED doctor. One difference observed between those recovering well and those recovering slowly was their response to the advice given in the ED. Only participants recovering well (n=5) reported that the ED doctor had been influential in encouraging them to stay active or exercise. These participants all attempted to be active or carry out exercises early on after injury following this advice.

"I thought I would get a collar and stuff but the woman doctor explained to me that they are trying not to use them because they want you to get on as best as you can with your normal life cause if it is still in the thing then it is not healing as well as it would be just going about your normal day to day duties sort of thing." Sam (W)

Another way that the ED consultation influenced participants was in the provision of reassurance that a serious injury had not been sustained (i.e. no fracture or dislocation). This was appreciated by participants in general.

I: Did you feel reassured that there wasn't anything serious going on after your visit?
R: Yes, I mean…you know…if the doctor tells me that it's nothing serious then I'll just take their word for it. At the end of the day, that's what their profession is and they're the experts, so I just followed the advice I was given. Yvonne (W)

The ED consultation also influenced healthcare access with a small number of participants consulting their GP on the advice of the ED doctor to consult their GP.

It was reported that health professionals in general were a source of information which influenced expectations of recovery as outlined in the prognosis section (Section 8.4.5).

"I saw my GP and he said to me that some people suffer, that whiplash, can take up to 18 months. Well, now I can see that he was right and I have spoken to some people that have had it before and it is over 2 years and I now know that the doctor was right." *Connie (S)*

8.5.2.2 Friends and family

Friends and family also appeared to influence participants in general. A small number of participants reported that friends and family encouraged them to exercise or be active.

"I've got a friend who's like an occupational therapist and I saw her 2 days afterwards and she was the one… because at first I didn't want to move my neck because it really hurt. She came round to see me and she said off the record… you know, she showed me the exercises and she said 'if you don't exercise you're going to have more problems in the long term'. She said 'they're most probably the exercises that the hospital would advise me in any case' so she showed me what I was meant to be doing." Celia (S)

However, others reported that friends and family encouraged inactivity or avoidance of activity.

"He'll say 'Don't lift that. It's no good for your neck and your back' or the children…you know… 'Don't climb over mummy' as I usually do and I usually give them piggy backs and… So yes, he's just been more aware of it." Louise(S)

Friend and family were also a source of concern for a small number of participants.

"...because all of the horror stories I'd heard [from friends] had lead me to believe that I'd never be normal again." Jane (W) relating how friends caused her to worry

8.5.2.3 The symptoms experienced

Another major influence on beliefs and behaviours were the symptoms experienced by participants. The pain experienced by participants had the capacity to shape their beliefs. Some participants described how their experiences changed their perceptions about whiplash injuries in general.

"To be honest all I thought I knew about whiplash injuries is its something people make up after they'd been in a car crash to claim money off people. I thought 'oh god yes they're sat there going 'oh, ouch I've got whiplash'' and I thought 'its not going to hurt anyone'. I was sadly completely wrong and I've never experienced anything so… you know, like you have little pains that last for a short… or big… you know, the pain level is high but only lasts a short amount of time. This was like a really quite high pain level that just lasted and wouldn't go away. I mean like now it is like two and a half months and I still… I'm still… you can still tell its there." Jane (W)

The ongoing nature and/or severity of symptoms experienced also changed expectations of recovery for some participants. This participant had expected to recover in a week or two.

I: By this stage had you changed your thinking about how long it might take you to recover?
R: Yes because it had been a little while by that point and I still was obviously in some discomfort with it. I mean I'd been… I can't remember how long it was afterwards. It must be about a month. Lisa(W)

For a small number of participants the pain experienced was described as the trigger for avoidant behaviour and catastrophic thinking.

"Once like I said, I turned quick to see a friend and it like, they were taking the mickey out of me behind me and one is on one side and the other one is the other side and they digged me in the ribs so I turned and quickly and my neck cricked again and I got the burning. Oh, no, I ain't doing that again so I don't want to put anything in the way of the healing process." Sam (W)

"I had this terrible pain and I thought I was going to be paralysed really because to bend – I could not – it was like someone is stabbing your spine you know." Zach(S)

In those participants recovering well a reduction in symptoms influenced how they managed their injury. Experiencing symptom improvement provided positive feedback about the management strategies utilised, increased their confidence in their ability to return to activities and alleviated concern. In those recovering slowly, the ongoing presence of pain, further reinforced avoidant behaviours or concerns over recovery.

"To be fair, after the first few hours after I took the pain killers I weren't too bad sort of thing so I thought, oh well, if it is going to be a long term, like more sort of fatal, then if obviously would have lasted a lot longer. Because the pain killers were helping I thought, well it ain't a long term thing." William (W)

8.6 Summary

This chapter has presented the results of the qualitative study. A summary of key findings is as follows:

The impact of a whiplash injury is psychological as well as physical.

Reassurance was an extremely important aspect of management in the ED as well as during subsequent physiotherapy treatment.

The importance of helping participants to form realistic expectations was emphasised.

There was consensus that exercises were the key to recovery which indicated a general awareness of current management strategies.

Features seen in those participants recovering well:

- More likely to acknowledge the impact of cognitive factors on recovery.
- Had greater confidence in their ability to manage their symptoms and more likely to have started exercises on their own.

- More likely to suggest they had <u>not</u> perceived their injury as serious or severe.
- Improvement in symptoms resulted in greater confidence and provided reassurance.
- Were more optimistic about their recovery.

Features seen in those participants recovering slowly:

- Although the majority of participants found the trial treatments helpful, those recovering slowly placed greater emphasis on the helpfulness of reassurance.
- Had less confidence in their ability to manage their own symptoms and placed greater emphasis on seeking more treatment from other professionals.
- Fear avoidance beliefs and behaviours were common early on in those recovering well and slowly but were a persistent feature of those recovering slowly.
- Were more likely to associate pain with doing harm or damage.

Beliefs and behaviours were influenced by past and current experiences:

- Previous injury or illness influenced how participants thought about and managed their injury.
- The actual experience of having a whiplash injury shaped beliefs and behaviours.
- Health professionals were extremely influential
- The symptoms experienced also influenced beliefs and behaviours and may contribute to the formation of unhelpful pain related beliefs such as fear avoidance beliefs.

9.0 Discussion - qualitative study

This chapter will discuss:

1. Considerations for patient management based on the findings of the qualitative study.
2. Methodological issues related to the qualitative study.

9.1 Considerations for patient management

9.1.1 Understanding the impact of a whiplash injury

The types of physical symptoms experienced by participants following their whiplash injury were similar to those generally described in the literature (7p102). The impact of symptoms on activities was wide-ranging although generally improvement was seen from onset to the time of interview. However, some participants experienced ongoing symptoms that continued to impact on their lives despite receiving physiotherapy treatment. This indicates that for a proportion of patients the present management of whiplash injuries could be improved upon. A better understanding of the psychological impact of injury may be of benefit.

The majority of participants reported being affected psychologically by their injury in the immediate post injury period. Health professionals working in the ED who deal with patients immediately following such injuries should be aware of this. The provision of reassurance early on appears to be an important aspect of ED management and the impact of this should not be overlooked. Participants experienced worry or concerns over ongoing symptoms. Reassurance was also a very important aspect of the physiotherapy treatments provided to participants.

The psychological impact of a whiplash injury has been reported in a previous qualitative study. Russell and Nicol (291) explored the experiences of whiplash patients and the GPs they consulted. This study described how patients were clearly distressed following their injury but this was not necessarily recognised by the GP they consulted. However, there was also evidence that patients benefited greatly when reassurance and support was provided (291).

9.1.2 Self-efficacy as a model for facilitating self-management and recovery

Many of the themes related to beliefs about injury and recovery provided insight into the participants' ability to self manage their condition. Physiotherapists have an important role in encouraging and equipping patients so that they have the confidence to self-manage their injury and facilitate their own recovery. There was consensus that exercises and maintaining activity were vital factors in managing a whiplash injury. This indicated a general awareness of current management strategies by all participants. However, participants recovering well had greater confidence in their own ability to manage their symptoms. The concept of self-efficacy (outlined in Chapter 2) provides a useful frame work to consider several of the features that separated those improving well from those improving slowly.

Participants who were recovering well were more likely to have exhibited confrontational beliefs and behaviours right from the start. It is possible that this is a result of the greater level of confidence they had to manage their own symptoms. Those recovering well appeared to have had greater benefit from their ED visit. Only participants recovering well reported that they commenced exercises on the advice of the ED doctor. Although this was not asked specifically it suggests that the ED consultation resulted in these participants having the confidence to commence exercising. Early commencement of exercises is thought to have a beneficial effect on outcome and participants were receptive to this advice in the ED. Health professionals who see participants early on after injury should be aware of their potential impact and provide appropriate reassurance and encouragement to ensure patients have the confidence to commence exercises. This could be as simple as making sure the patient can carry out the exercises they are given by taking the time to demonstrate them.

An interesting finding was that those recovering well were more likely to highlight the helpfulness of medication to control their symptoms early on. This suggests that effective pain control is an important aspect of injury management. The use of simple analgesics to control pain is a recommended part of treatment (279). Ensuring that patients have adequate pain control is one way to ensure they are able to stay active and carry out exercises which may contribute to greater self-efficacy and successful self-management.

In those participants recovering well a reduction in symptoms influenced how they managed their injury. Experiencing symptom improvement provided positive feedback about the management strategies utilised, increased their confidence in their ability to return to activities and alleviated concern. The process of seeing improvements may in itself lead to greater self-efficacy. As suggested by Bandura (64) and Turk (76) performance accomplishment is thought to be the greatest impact on establishing and strengthening self-efficacy. Those participants who are on a path to improvement will grow in confidence as a result of this experience. This idea is supported by the fact that those recovering well were most likely to suggest that continuation of exercises was the only thing needed to help them to fully recover. This reflected that these participants had successfully self-managed their symptoms with exercises and were happy to continue to do so. Participants recovering well were also more optimistic about their recovery. Experiencing improvement in symptoms not only improved confidence but also contributed to increased optimism. These findings highlight the importance of finding ways to improve the patient's confidence to deal with their symptoms and encourage self-management.

Those recovering slowly appeared to have less confidence in their ability to manage their own symptoms. The importance of reassurance from health professionals was more apparent in their narratives. They placed greater emphasis on seeking further treatment from health professionals which may reflect the lack of success they had experienced in alleviating their symptoms themselves. Failure to see improvement will further reinforce a lack of confidence to deal with symptoms (76). For those recovering slowly, ongoing symptoms also reinforced their worry or concern. It is also suggested that self-efficacy determines how long an individual will persist with coping behaviours (64). Patients who are struggling to recover may require extra encouragement and reassurance to persist with self-management strategies such as exercises when they do not see immediate benefit.

9.1.3 Understanding pain

It was expected that avoidance beliefs and behaviours would be more prevalent in those recovering slowly. However, this was not the case. Avoidance of movement and activity early on after a whiplash injury was a common and understandable reaction to the pain observed in both participants recovering well and slowly. However, it is when avoidance beliefs and behaviours become ongoing they become problematic (130). Ongoing avoidance beliefs and behaviours were more common in those recovering slowly. Those recovering well were more likely to overcome their avoidance beliefs and behaviours.

An individual's understanding of the meaning of pain is thought to be a driver for avoidance/confrontation behaviours (101). The actual pain experienced has the potential to influence beliefs and behaviours. Those who were recovering slowly were more likely to equate the pain with harm or injury to tissues. In contrast, those recovering well were more likely to suggest they had not perceived their injury as serious or severe potentially making them less likely to be fearful of exercise or activity. These differences in perceptions of injury severity were despite there being very little difference in baseline NDI scores between the two groups. One useful strategy for facilitating patients to overcome avoidance beliefs and behaviours may be to identify any unhelpful beliefs about pain. Pain is a complex phenomena and improving the patient's understanding of the pain they are experiencing is thought to improve outcomes in pain conditions (299, 300p111). Unhelpful pain beliefs need to be addressed to remove the fear of exercise or activity. This is potentially an important strategy for improving the patient's ability to self-manage their condition. Unhelpful pain beliefs appear to be modifiable as examples of how beliefs and behaviours changed were observed in this study. Changes in these types of beliefs have also been reported in studies investigating LBP (301, 302).

Catastrophic thinking is essentially the misinterpretation of pain. Evidence of catastrophic thinking was observed in two participants and both were both recovering slowly. However, it is important to highlight that although catastrophic thinking may be a driver for avoidance behaviours this is not always the case. Catastrophic thinking was not always linked to avoidance behaviours as demonstrated by one participant (Zach). It is possible that catastrophising may work via other mechanisms to influence outcome (e.g. increased anxiety) so still needs to be addressed. Similarly, beliefs associated with fear avoidance were not necessarily the only reason for failing to carry out exercises. One participant (Thomas) related that he did not do the exercises as he could not see how they would help. It should not be presumed that all participants who are non-compliant with exercises/treatment are fear avoidant and reasons for non compliance should be explored. Another consideration was raised by participants recovering slowly. This was the issue of priority. Some participants felt that they were unable to prioritise resources such as time or money towards their own recovery. This may be an important barrier to treatment compliance that physiotherapists should be aware of when dealing with patients who appear to be non-compliant with treatment.

When considering the complexity of pain, it was also noted that participants recovering well were more likely to acknowledge the impact of cognitive factors on recovery than those recovering slowly. This may possibly indicate a greater insight into link between cognitive factors and pain that are thought to exist (300p80). Gaining insight into the patient's understanding of the way their cognitions and pain interact may be another way to improve the patient's understanding of pain and facilitate recovery.

9.1.4 Optimistic but realistic expectations

Health professionals have an important role to play in helping patient's form realistic expectations of recovery. Although, generally an optimistic outlook is important, unrealistically short time frames for predicted recovery were not helpful to participants. Once again, reassurance that symptoms will improve is important. This needs to be balanced with an understanding that that improvements may occur over a number of weeks or months depending on the individual presentation. Physiotherapists could easily discuss with the patient their expectations of recovery during the initial physiotherapy assessment and then provide appropriate education and advice based on these expectations.

9.1.5 Understanding belief formation

Understanding how patients form beliefs about injury and recovery is important. Health professionals exerted considerable influence over the way that participants thought about or managed their injury. The beliefs held by health professionals have been shown to influence the information they provide to patients (303). Health practitioners who express beliefs that avoidance of work and activity may help recovery from back pain are more likely to advise patients to take time off work (304). Health professionals must ensure they are conveying the appropriate messages to patients based on the latest knowledge regarding pain and injury (305).

Another major influence on beliefs and behaviours were the symptoms experienced by participants. The pain experienced by participants had the capacity to shape their beliefs. Some authors have suggested that preconceived cultural expectations of whiplash injuries are important factors in outcome in WAD (306). However, this was not evident in this study. Many participants had no idea what to expect and others reported that preconceived ideas were altered in response to the symptoms experienced.

It was also apparent that past experiences are extremely influential. Those recovering well suggested that the way they had dealt with past injury or illness impacted positively on how they managed this injury. The impact of past behaviours has been demonstrated in relation to exercise behaviour where past exercise behaviour has been shown to moderate current exercise behaviour (307). Azjen (308) proposes that past experiences influence beliefs about behaviour which will determine behaviour. Understanding how patients have dealt with injury and illness in the past may help to identify potentially unhelpful beliefs and behaviours or potential barriers to recovery.

9.2 Methodological considerations

It is an acknowledged limitation of qualitative research that small sample sizes (compared to quantitative studies) results in limited ability to generalise findings to wider populations. However, the sampling method used aimed for maximum representation of the participants included in the larger prospective cohort study. On examination of baseline characteristics those included in the interview study appeared to broadly reflect those included in the prospective cohort study in the majority of factors. Also, generalisability is not necessarily an aim of IPA. One key feature of IPA is to identify issues or raise questions that may not be identified through quantitative methods. This study has achieved this. Important issues have been raised including the need to understand both the physical and psychological impact of whiplash injuries on patients, the need for facilitating realistic patient expectations of outcome, the role of fear avoidance in maintaining disability rather than predicting outcome, the need to address beliefs about pain and the overwhelming importance of reassurance.

One limitation of the study is that the interviewer was also responsible for assessing and randomising participants into Step 2 of MINT. This may have resulted in participants being reluctant to provide any criticism of the trial treatments. In addition, there was a significant time lag between injury and interview which may have affected the participants' ability to recall their symptoms, their thoughts/concerns in the immediate post injury period or the progress they had made. However, many participants did provide detailed accounts of their experiences from early on after their injury to the time of interview.

It was demonstrated that beliefs and behaviours change over time in response to symptoms and interaction with health professionals (i.e. some participants overcame fear avoidance beliefs and behaviours). Therefore, the timing of interview had the potential to influence findings. There was a difference in the timing of interview between the two treatment arms. Advice participants were interviewed earlier (mean=84 days post injury) on in their recovery compared to those who were allocated to the physiotherapy package (mean=120 days post injury). Those who interviewed later on after their injury had more time to be exposed to influences that had the potential to change beliefs and behaviours than those interviewed earlier on after their injury. However, participants who received the advice session and the physiotherapy package were fairly equally distributed between those recovering well and those recovering slowly which should limit the impact of this on the findings.

One of the aims of this study was to make comparisons with the results of the prospective cohort study. This will have influenced the identification of themes within the narratives so that comparisons could be made (this is discussed in Chapter 10). This could have resulted in the omission of themes not related to the constructs investigated in the cohort study. However, as demonstrated in the results, issues were identified that were not investigated in the cohort study such as influences on belief formation.

9.3 Summary

Based on this qualitative study the following recommendations can be made regarding patient management following an acute whiplash injury:

- Providing adequate reassurance is essential. Clinicians need to be aware of the potential psychological impact of sustaining a whiplash injury and attempt to alleviate concerns where possible.
- Treatment strategies should include ways to improve the patient's confidence to self-manage their condition such as ensuring they have the confidence to begin exercises early on after injury.
- Fear avoidance beliefs and behaviours are common early on after an injury but need to be addressed if they become persistent. There was evidence that these beliefs are modifiable.
- Beliefs about pain need to be assessed and addressed if they appear to be unhelpful to recovery. This may include highlighting the link between cognitive factors and pain.
- There is a need to help patients form realistic expectations of recovery.
- Health professionals exert considerable influence over patients and should be aware of this as they provide advice on returning to activity and exercise.
- The symptoms experienced by participants influenced beliefs and behaviours and may contribute to the formation of unhelpful pain related beliefs.
- Beliefs and behaviours were also influenced by past experiences. Understanding how patients have managed previous injury or illness may also help to facilitate their recovery or identify barriers to recovery.

10.0 Final discussion and conclusions

This thesis aimed to investigate the potential influence of patient held beliefs about injury and recovery on the development of late whiplash syndrome in participants taking part in MINT. As well as doing this it has also provided important information regarding the clinical presentation and course of recovery of whiplash injuries. Previous research findings have been confirmed regarding the importance of baseline disability as a prognostic factor for outcome. Greater insight into the psychological impact of whiplash injuries has been revealed.

The final chapter will to draw together the findings of the two studies presented in this thesis and discuss suggestions for future research.

10.1 Comparisons between the prospective cohort study and the qualitative study

10.1.1 Methods of classifying recovery status

The methods of classifying recovery status in the prospective cohort and qualitative studies were compared (Table 105). This examination revealed some agreement between the two systems used but also some discrepancies. There may be several reasons for the observed discrepancies. Firstly, the two classification systems measured slightly different concepts. One was based on disability (prospective cohort study) and the other largely on participant perception of their recovery (qualitative study). As demonstrated here, these two may not always be in agreement. For example, Carol, who had a previous neck problem, compared her current symptoms to her usual symptoms and rated herself as 85% improved.

However, as Carol experienced neck symptoms and related disability pre-injury this was reflected in her classification in the prospective cohort study where she was classified as having LWS. In contrast, Margaret was experiencing relatively mild symptoms and little disability due to her neck symptoms but rated herself as only 5% improved. This resulted in Margaret being classified as slow recovery in this qualitative study but recovered in the prospective cohort study.

Another difference between the two classification symptoms is that the participant's perceived recovery was potentially a much broader rating of recovery. It potentially incorporated perceptions of all types of symptoms experiences due to their whiplash injury and not just neck pain. Recovery meant different things to different participants and this is an area that would have benefited from further exploration. In contrast, disability related to neck pain is the predominant feature of the NDI used to classify participants in the prospective cohort study. The NDI will fail to capture disability related to other symptoms. For example, Zach was also suffering from significant back pain which would not have been captured by the NDI.

The issues raised here are similar to some of those already discussed in the prospective cohort study where the findings related to different outcomes were considered (recovery status or NDI score compared with participant perceived improvement). Recall error was highlighted as potential problem for participant perceived improvement. This was also potentially a problem for the participant rating of improvement used in the qualitative study. However, the qualitative study also took into consideration the whole narrative of each participant so was not just based on this rating which may have lessened the impact of recall error.

A problem that has been highlighted in the whiplash literature is the use of different outcomes and how this may impact on findings (19). The prospective cohort study, in particular, demonstrated how different outcomes can impact on findings. There is a need to gain better understanding into how patients perceive recovery and what this actually means in regard to disability and function. This is especially important when attempting to evaluate the effectiveness of treatments as changes in disability may not necessarily equate with the patient's perceptions of their improvement. Treatments deemed effective based on disability ratings may not actually be perceived as effective by patients (and vice versa).

10.1.2 Findings

The prospective cohort study found that participants with psychological morbidity at baseline (elevated GHQ-12 scores and IES) were more likely to have a poor outcome. The psychological impact of injury was also evident in the qualitative study although it was not possible to draw conclusions regarding the impact on outcome. No difference was seen between those recovering well and those recovering slowly but the interviews were not designed to formally evaluate the presence of post traumatic stress or other psychological problems such as anxiety or depression.

Despite some differences between the classification systems, there were common findings between the two different studies. The two studies were largely in agreement that a more optimistic outlook and higher levels of self-efficacy were beneficial to recovery. Perceiving that you were not seriously or severely injured was also a feature of those recovering well.

This also complements the findings of the prospective study where greater baseline disability was associated with poor outcome. It was suggested earlier in this thesis that ensuring adequate pain relief early on after injury may play in important role in minimising perceived disability by allowing patients to remain active and exercise. This is further supported by the qualitative study where those recovering well attributed, in part, their recovery to the use of effective medication early on after injury.

The two studies were also in agreement that presence of fear avoidance at baseline is not a risk factor for poor outcome following a whiplash injury. Both studies demonstrated that fear avoidance beliefs were common amongst participants following a whiplash injury. However, the qualitative study shed some light on the mechanism through which fear avoidance beliefs and behaviours contribute to ongoing disability. Participant narratives provided examples of the consequences of ongoing fear avoidance beliefs and behaviours and their contribution to maintaining disability. Participants also provided evidence that beliefs about the meaning of pain were also important factors when considering ongoing disability.

A history of chronic widespread pain was also identified as a risk factor in the prospective cohort study. The qualitative study demonstrated how past experiences of injury and illness had the potential to influence beliefs and behaviours about managing their whiplash injury. This may provide one explanation for why a history of chronic widespread pain results in poor outcome. Patients with a history of chronic pain may have developed unhelpful beliefs and behaviours which has the potential to influence how they manage any new injuries.

10.2 Summary of findings

Table 108 contains a summary of the main findings of this thesis based on both the prospective cohort study and qualitative study.

Table 108 Summary of findings

Summary of findings
• The impact of a whiplash injury is both physical and psychological. Greater psychological distress was observed in participants with greater number of symptoms at baseline. • Many patients do recover following a whiplash injury but a significant proportion experience ongoing disability and whose symptoms are resistant to perceived improvement. This suggests that for a proportion of patients current management strategies are not effective. • When evaluating outcome it is important to acknowledge that outcomes based on disability do not necessarily equate with patient perceptions of improvement. • Participants who reported higher levels of injury severity at baseline are at risk of LWS or greater disability at follow up. • Participants who were psychologically distressed are also at risk of LWS or greater disability at follow up. • Patient held beliefs do have the ability to influence outcome. Participant expectations of recovery influenced the development of LWS and ongoing disability. Less optimistic predicted recovery times were associated with poor outcome. • The importance of forming realistic expectations of recovery was emphasised in the qualitative study. • Similarly, those with lower expectations that treatment would benefit them were also at risk of poor outcome. • Participant's ability to cope (self-efficacy) influenced short term outcome. • High use of passive coping strategies has the potential to moderate the influence of expectations of outcome and self-efficacy on outcome. • Baseline fear avoidance and catastrophising were not associated with outcome even though they are often considered important risk factors for ongoing disability. • However, from the qualitative study, these factors as well as patients' beliefs about the meaning of pain, may contribute to maintaining disability. Reassurance was highlighted as an important management strategy. • Pre-existing factors associated with the development of LWS or ongoing disability included older age and a history of chronic widespread pain. • Greater risk of poor outcome was observed with increasing number of risk factors present at baseline.

10.3 Comparisons with the current evidence base

A systematic literature review was conducted as part of this thesis. The research presented in this thesis has further added to the available evidence base. The findings of this thesis add further support to baseline injury severity being an important factor in outcome following an acute whiplash injury. The systematic literature review concluded that psychological distress was not a risk factor for LWS but this thesis provided evidence that patients with higher levels of psychological distress are at risk of poor outcome. The role of age was previously inconclusive in the development of LWS but this study suggests that older patients are at risk of LWS. The systematic literature review concluded that an elevated post traumatic stress reaction was associated with LWS. This research also found that an elevated post traumatic stress reaction was associated with LWS although the impact was not as long term as previously suggested. Similarly, participants' ability to cope with their neck problem (self-efficacy) was found to influence short term outcome but not LWS as suggested by the systematic literature review. Belief factors such as fear avoidance and catastrophising were previously inconclusive but this thesis provides robust evidence that baseline fear avoidance and catastrophising are not associated with the development of LWS. The systematic literature review concluded that the use of passive coping strategies was not associated with LWS. This thesis confirmed these findings but also suggested that the use of passive coping may moderate the effects of other belief factors such as ability to cope and expectations of outcome. Expectations of outcome were not included in the original systematic literature review but the updated review suggested that expectations were predictive of LWS. This thesis further confirmed that participants' expectations of recovery measured by predicted time to recovery is an important determinant of outcome. Expectations of treatment benefit have previously been shown to influence outcome in chronic neck pain populations (317), however, this has not been studied before in an acute whiplash population. This thesis is the first research to suggest that expectations of treatment benefit is associated with the development of LWS.

10.4 Future research

Suggestions for future research are summarised in Table 109.

Table 109 Future research

Summary of suggested future research into the management of acute whiplash injuries
1. Test the efficacy of new treatment strategies such an ensuring early adequate pain relief, managing psychological distress, utilising a cognitive behavioural approach including pain education and using the number of risk factors to guide treatment choices. 2. Identify the optimal timing of interventions for the management of acute whiplash injuries. 3. Develop valid and reliable measures of outcome for acute whiplash injuries that takes into consideration both disability and the patients' perceptions of recovery.

10.4.1 New treatment strategies

New treatment strategies need to be investigated to improve the outcomes of patients who currently fail to respond to current management strategies. The findings of this thesis suggest several strategies that could be potentially useful in managing an acute whiplash injury. Future research could focus on evaluating the clinical and cost effectiveness of the following treatment strategies:

10.4.1.1 Adequate pain relief

It is clear that participant perceptions of injury severity influences outcome whether measured by a validated measure such as the NDI or explored qualitatively. It was suggested earlier in this thesis that ensuring adequate pain relief early on after injury may play in important role in minimising perceived disability by allowing patients to remain active and exercise. Physiotherapists are able to provide advice about the appropriate use of pain relief provided to patients. It may also be necessary to liaise with medical staff such as ED staff or GPs to ensure that medication is reviewed and modified if pain is not being controlled.

10.4.1.2 Manage psychological distress

The psychological impact of a whiplash injury was evident throughout this thesis and psychological distress was identified as a risk factor for poor outcome. The value of reassurance was emphasised by participants in the qualitative study. Providing reassurance appears to be a key part of patient management at all stages of recovery especially for patients with multiple symptoms and higher levels of disability. Alongside this reassurance, information and advice should be provided that gives patients the confidence to self-manage their own condition and potentially reduce the psychological distress they experience. The development of patient information materials that includes topics such as expectations of recovery, beliefs about pain and coping strategies to deal with pain may be a useful resource to provide patients early on after injury. Such information could also be delivered within a cognitive behavioural framework and this is discussed in the following section.

More severe psychological problems such as the suspected development of PTSD should be referred on for appropriate specialist management. Physiotherapists should be aware of the signs and symptoms of PTSD.

10.4.1.3 Utilise a cognitive behavioural approach including exercises and pain education

A cognitive behavioural approach is one potential treatment approach that has not been tested in patients following acute whiplash injures. However, elements of current practice such as the use of exercises should be continued. In MINT exercises were provided for participants who received both the physiotherapy package and the advice session. In the qualitative study, a large proportion of participants in the both arms of the trial identified exercises as the key to recovery following a whiplash injury and many attributed their recovery in some way to exercises. Exercises were part of the CB approach that was shown to be effective for LBP (285) and could also be included within a CB framework for patients with early WAD. Both the physiotherapy package and the advice session utilised neck and shoulder range of movement exercises. The physiotherapy package also included simple proprioceptive and spinal and scapular motor control exercises but no added benefit was observed from the addition of these more specific exercises. Although, deficits in proprioceptive and motor control have been demonstrated in WAD they have yet to be proven to be effective in improving clinical outcomes (309, 310).

A CB approach takes elements from the CB model. The CB model proposes that the way in which an individual thinks about their problem or condition will result in emotions which will influence how they behave (25). So in regards to pain, if an individual believes that pain means further tissue damage they will be fearful or anxious about movements that provoke pain and avoid these movements. Cognitive behavioural approaches attempt to influence behaviour indirectly by changing underlying beliefs that drive behaviours (284). Belief factors that were identified as important could be addressed using such an approach. Unhelpful beliefs about pain and injury or perceived barriers to recovery should be assessed for each patient. In particular, the importance of expectations of recovery was observed in both the prospective cohort study and qualitative study. These expectations are potentially modifiable, although, in the qualitative study it was demonstrated that an optimistic outlook was generally important, they also need to realistic. Physiotherapists need to consider each patients individual presentation and advice accordingly. Improving patient beliefs about their confidence to cope with or manage their injury (self-efficacy) should be another aim of patient management. The questions used to assess these beliefs could be used to prompt discussion and maybe a useful to identifying barriers to recovery.

The qualitative study demonstrated that beliefs about pain are potential barriers to recovery. These types of beliefs also need to be addressed if evident. On the basis of this, it is also recommended that pain education should be included as part of this CB approach. It has been proposed in chronic WAD a poor understanding of pain can lead to maladaptive attitudes, cognitions and behaviours (311). Nijs et al (311) propose that targeting inappropriate pain beliefs is an essential element of the initial management of chronic WAD. However, it may also prove an important factor in improving the early management of WAD. Pain education has been demonstrated to effectively change beliefs about pain resulting in reduced fear of movement and catastrophising and increased pain self-efficacy (299, 312, 313). Pain education has also been shown to improve clinical outcomes (314, 315). In fact, in a recent pilot study, pain education alone was demonstrated to be more effective than pain education combined with an exercise class in reducing LBP symptoms (312).

10.4.1.4 Use the number of risk factors present to guide treatment choices

These recommendations are not advocating intensive physiotherapy treatment for all patients in the early phase of recovery post whiplash. In fact, the most recent guidelines for the management of early WAD suggest that the best course for patients seeking treatment in the acute phase of recovery is to start with minimal intervention (316). MINT showed that a single advice session was just as effective as a package of physiotherapy care supporting these recommendations and around 60% of patients did make a good recovery. The economic analysis carried out in MINT concluded that it was not cost effective for the NHS to provide a package of physiotherapy for patients following a recent whiplash injury.

Further research needs to be done to establish whether screening and tailoring treatment to the number of risk factors present is an effective way to manage a recent whiplash injury. On initial presentation at physiotherapy, patients could be assessed for the presence of risk factors and given appropriate reassurance, advice on exercise and pain relief.

For participants with minimal risk factors present at baseline then a single advice session would be the starting point for intervention. This advice session could utilise the recommendations above. Follow up would only be required if the patient failed to progress. For participants with greater numbers of risk factors in addition to the advice session this could be followed by a subsequent review and follow up as required.
It is also possible that initial advice could be provided in a group. A CB approach is often delivered in a group situation (285). Pain education programmes have also been delivered in this way (312, 315) and shown to be almost as effective as individual sessions and more cost-effective (315). The way that a CB approach would be delivered requires further

consideration including a group versus individual approach, establishing the optimal number of sessions and content of such a programme.

10.4.2 Timing of interventions

Another consideration is the timing of intervention. The results presented in this thesis showed that the most improvement occurred between baseline and 4 months follow up. These were in line with other published findings. It is unclear if this represents the most opportune time for any intervention to be effective or that this is a period of natural improvement and more intensive treatments should be offered after this period. From a cost perspective the later would be the better option. However, this needs further investigation.

10.4.3 Measuring outcome in WAD

This thesis has raised several considerations when evaluating outcome in WAD, in particular, the differences between outcomes based on rating of disability and participant perceived improvement. The problem of recall error was raised in this thesis so this could involve developing ways to accurately measure perceptions of improvement. Further qualitative research would also provide a way to gain a greater understanding of patient perceptions of recovery and disability.

10.5 Conclusions

Beliefs about injury and recovery were shown to influence the development of LWS in patients following an acute whiplash injury. Expectations about outcome and the participant’s confidence to cope with their injury (self-efficacy) were important factors. These factors need to be considered along with the degree of disability and psychological distress experienced by patients. From the qualitative study, it would appear that the patients' understanding of pain is also important.

Current management strategies have proved ineffective for many patients with whiplash injury as around 40% of patients developed LWS. New approaches to patient management have been suggested which require evaluation of effectiveness.

11.0 Reference List

1. Spitzer WO, Skovron ML, Salmi LR, Cassidy JD, Duranceau J, Suissa S, et al. Scientific monograph of the Quebec Task Force on Whiplash-Associated Disorders: redefining "whiplash" and its management. Spine. 1995 Apr 15;20(8) Suppl(8):1S-73S.
2. Galasko C, Murray P, Stephenson W. Incident of whiplash-associated-disorders. BCMJ. 2002;44(5):237-40.
3. Barnsley L, Lord S, Bogduk N. Whiplash injury. Pain. 1994 Sep;58(3):283-307.
4. Miles K, Maimaris C, Finlay D, Barnes M. The incidence and prognostic significance of radiological abnormalities in soft tissue injuries to the cervical spine. Skeletal Radiol. 1988;17(7):493-6.
5. Quinlan K, Annest J, Myers B, Ryan G, Hill H. Neck strains and sprains among motor vehicle occupants-United States, 2000. Accid Anal Prev. 2004 Jan;36(1):21-7.
6. Versteegen G, Kingma J, Meijler W, ten Duis, H. Neck sprain after motor vehicle accidents in drivers and passengers. Eur Spine J. 2000;9(6):547-52.
7. Jull G, Sterling M, Falla D, Treleaven J, O'Leary S. Whiplash, Headache, and Neck Pain. Edinburgh: Churchill Livingstone; 2008.
8. Provinciali L, Baroni M, Illuminati L, Ceravolo MG. Multimodal treatment to prevent the late whiplash syndrome. Scand J Rehabil Med. 1996 May;28(2):105-11.
9. Moog M, Quintner J, Hall T, Zusman M. The late whiplash syndrome: a psychophysical study. Eur J Pain. 2002;6(4):283-94.
10. Haldorsen T, Waterloo K, Dahl A, Mellgren S, Davidsen P, Molin P. Symptoms and cognitive dysfunction in patients with the late whiplash syndrome. Appl Neuropsychol. 2003;10(3):170-5.
11. Balla J. The late whiplash syndrome: a study of an illness in Australia and Singapore. Cult Med Psychiatry. 1982 Jun;6(2):191-210.
12. Pennie B, Agambar L. Patterns of injury and recovery in whiplash. Injury. 1991 Jan;22(1):57-9.
13. Karlsborg M, Smed A, Jespersen H, Stephensen S, Cortsen M, Jennum P, et al. A prospective study of 39 patients with whiplash injury. Acta Neurologica Scandinavica. 1997 Feb;95(2):65-72.
14. Galasko SB, Gunzburg R, Szpalski M. The cost of whiplash-associated disorders. In: Whiplash Injuries: current concepts in prevention diagnosis, and treatment of the cervical whiplash syndrome. Philadelphia: Lippincott-Raven; 1998.
15. Lamb S, Williams M, Withers E, Perry J, Gates S, Williamson E, et al. A national survey of clinical practice for the management of whiplash-associated disorders in UK emergency departments. Emerg Med J. 2009 Sep;26(9):644-7.
16. Holm L, Carroll L, Cassidy J, Hogg-Johnson S, Côté P, Guzman J, et al. The burden and determinants of neck pain in whiplash-associated disorders after traffic collisions: results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. Spine. 2008 Feb;33(4 Suppl):S52-9.
17. Moore A, Jackson A, Jordan J, Hammersley S, Hill J, Mercer C, et al. Clinical guidelines for the physiotherapy management of whiplash associated disorder. London: Chartered Society of Physiotherapy; 2005.
18. Verhagen AP, Scholten-Peeters GG, de Bie RA, Bierma-Zeinstra SM. Conservative treatments for whiplash. Cochrane Database of Systematic Reviews. 2007 (2):CD003338.
19. Scholten-Peeters GG, Verhagen AP, Bekkering GE, van der Windt DA, Barnsley L, Oostendorp RA, et al. Prognostic factors of whiplash-associated disorders: a systematic review of prospective cohort studies. Pain. 2003 Jul;104(1-2):303-22.

20. Cote P, Cassidy JD, Carroll L, Frank JW, Bombardier C. A systematic review of the prognosis of acute whiplash and a new conceptual framework to synthesize the literature. Spine. 2001 Oct 1;26(19):E445-58.
21. Williams M, Williamson E, Gates S, Lamb S, Cooke M. A systematic literature review of physical prognostic factors for the development of Late Whiplash Syndrome. Spine. 2007 Dec;32(25):E764-80.
22. Pincus T, Burton AK, Vogel S, Field AP. A systematic review of psychological factors as predictors of chronicity/disability in prospective cohorts of low back pain. Spine. 2002 Mar 1;27(5):E109-20.
23. Linton S, Turk D, Gatchel R. A cognitive behavioural approach to the prevention of chronic back pain. In: Psychological approaches to pain management. New York: The Guilford Press; 2002. p. 317--33.
24. Pearsall J. The New Oxford Dictionary of English. New York: Oxford University Press; 1998.
25. White C. Cognitive behaviour therapy for chronic medical problems. Chichester: John Wiley and Sons; 2001.
26. Zusman M. Structure-oriented beliefs and disability due to back pain. Aust J Physiother. 1998;44(1):13-20.
27. Leventhal H, Diefenbach M, Leventhal E. Illness cognition: using common sense to understand treatment adherence and affect cognition interactions. Cognitive Therapy and Research. 1992;16(2):143-63.
28. Ogden E. Health psychology: a textbook. England: Open University Press; 2004.
29. Diefenbach M, Leventhal H. The common-sense model of illness representations:theoreticl and practical considerations. Journal of Social Distress and the Homeless. 1996;5(1):11-38.
30. Egger M, Smith G, Altman D, editors. Systematic reviews in health care: meta-analysis in context. 2nd ed. London2001.
31. Hill A. The environment and disease: association or causation? Proc R Soc Med. 1965 1965 May;58:295-300.
32. Altman D. Practical statistics for medical research. London: Chapman & Hall/CRC; 1991.
33. Rollman GB, Abdel-Shaheed J, Gillespie JM, Jones KS. Does past pain influence current pain: biological and psychosocial models of sex differences. European Journal of Pain. 2004 Oct;8(5):427-33.
34. Adams MA, Dolan P. Spine biomechanics. Journal of Biomechanics. 2005 Oct;38(10): 1972-83.
35. Coderre TJ, Katz J, Vaccarino AL, Melzack R. Contribution of central neuroplasticity to pathological pain: review of clinical and experimental evidence. Pain. 1993 Mar;52(3): 259-85.
36. Egger M, Ebrahim S, Davey Smith G. Where now for meta-analysis? Int J Epidemiol. 2002 Feb;31(1):1-5.
37. Kasch H, Bach FW, Jensen TS. Handicap after acute whiplash injury: a 1-year prospective study of risk factors. Neurology. 2001 Jun 26;56(12):1637-43.
38. Gatchel R, Deckel A, Weinberg N, Smith J. The utility of the Millon Behavioral Health Inventory in the study of chronic headaches. Headache. 1985 Jan;25(1):49-54.
39. Smed A. Cognitive function and distress after common whiplash injury. Acta Neurologica Scandinavica. 1997 Feb;95(2):73-80.
40. Atherton K, Wiles NJ, Lecky FE, Hawes SJ, Silman AJ, Macfarlane GJ, et al. Predictors of persistent neck pain after whiplash injury. Emergency Medicine Journal. 2006 Mar;23(3):195-201.

41. Sterling M, Jull G, Kenardy J. Physical and psychological factors maintain long-term predictive capacity post-whiplash injury. Pain. 2006 May;122(1-2):102-8.
42. Miettinen T, Leino E, Airaksinen O, Lindgren KA. The possibility to use simple validated questionnaires to predict long-term health problems after whiplash injury. Spine. 2004 Feb 1;29(3):E47-51.
43. Gargan M, Bannister G, Main C, Hollis S. The behavioural response to whiplash injury. The Journal of Bone and Joint Surgery British volume. 1997 Jul;79(4):523-6.
44. Nederhand MJ, Ijzerman MJ, Hermens HJ, Turk DC, Zilvold G. Predictive value of fear avoidance in developing chronic neck pain disability: consequences for clinical decision making. Archives of Physical Medicine and Rehabilitation. 2004 Mar;85(3):496-501.
45. Olsson I, Bunketorp O, Carlsson SG, Styf J. Prediction of outcome in whiplash-associated disorders using West Haven-Yale Multidimensional Pain Inventory. The Clinical Journal of Pain. 2002 Jul-Aug;18(4):238-44.
46. Kyhlback M, Thierfelder T, Soderlund A. Prognostic factors in whiplash-associated disorders. International Journal of Rehabilitation Research. 2002 Sep;25(3):181-7.
47.Hendriks EJ, Scholten-Peeters GG, van der Windt DA, Neeleman-van der Steen CW, Oostendorp RA, Verhagen AP. Prognostic factors for poor recovery in acute whiplash patients. Pain. 2005 Apr;114(3):408-16.
48.Pettersson K, Brandstrom S, Toolanen G, Hildingsson C, Nylander PO. Temperament and character: prognostic factors in whiplash patients? European Spine Journal . 2004 Aug;13(5):408-14.
49. Soderlund A, Olerud C, Lindberg P. Acute whiplash-associated disorders (WAD): the effects of early mobilization and prognostic factors in long-term symptomatology. Clinical rehabilitation. 2000 Oct;14(5):457-67.
50. Sterling M, Jull G, Vicenzino B, Kenardy J, Darnell R. Physical and psychological factors predict outcome following whiplash injury. Pain. 2005 Mar;114(1-2):141-8.
51. Borchgrevink GE, Stiles TC, Borchgrevink PC, Lereim I. Personality profile among symptomatic and recovered patients with neck sprain injury, measured by MCMI-I acutely and 6 months after car accidents. Journal of Psychosomatic Research. 1997 Apr;42(4): 357-67.
52. Mayou R, Bryant B. Outcome of 'whiplash' neck injury. Injury. 1996 Nov;27(9):617-23.
53. Mayou R, Bryant B. Psychiatry of whiplash neck injury. Br J Psychiatry. 2002 May;180:441-8.
54. Radanov BP, di Stefano G, Schnidrig A, Ballinari P. Role of psychosocial stress in recovery from common whiplash. Lancet. 1991 Sep 21;338(8769):712-5.
55. Radanov BP, Di Stefano G, Schnidrig A, Sturzenegger M, Augustiny KF. Cognitive functioning after common whiplash. A controlled follow-up study. Archives of Neurology. 1993 Jan;50(1):87-91.
56. Radanov BP, Sturzenegger M, Di Stefano G, Schnidrig A, Aljinovic M. Factors influencing recovery from headache after common whiplash. BMJ (Clinical Research Ed). 1993 Sep 11;307(6905):652-5.
57. Radanov BP, Di Stefano G, Schnidrig A, Sturzenegger M. Common whiplash: psychosomatic or somatopsychic? Journal of Neurology, Neurosurgery, and Psychiatry. 1994 Apr;57(4):486-90.
58. Radanov BP, Sturzenegger M, De Stefano G, Schnidrig A. Relationship between early somatic, radiological, cognitive and psychosocial findings and outcome during a one-year follow-up in 117 patients suffering from common whiplash. British Journal of Rheumatology. 1994 May;33(5):442-8.

59. Di Stefano G, Radanov BP. Course of attention and memory after common whiplash: a two-years prospective study with age, education and gender pair-matched patients. Acta Neurologica Scandinavica. 1995 May;91(5):346-52.
60. Radanov BP, Sturzenegger M, Di Stefano G. Long-term outcome after whiplash injury. A 2-year follow-up considering features of injury mechanism and somatic, radiologic, and psychosocial findings. Analytical Reviews of General Medicine, Neurology, Psychiatry, Dermatology, and Pediatrics. 1995 Sep;74(5):281-97.
61. Kasch H, Stengaard-Pedersen K, Arendt-Nielsen L, Staehelin Jensen T. Headache, neck pain, and neck mobility after acute whiplash injury: a prospective study. Spine. 2001 Jun 1;26(11):1246-51.
62. Kivioja J, Jensen I, Lindgren U. Early coping strategies do not influence the prognosis after whiplash injuries. Injury. 2005 Aug;36(8):935-40.
63. Crombez G, Vlaeyen JW, Heuts PH, Lysens R. Pain-related fear is more disabling than pain itself: evidence on the role of pain-related fear in chronic back pain disability. Pain. 1999 Mar;80(1-2):329-39.
64. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. Psychological Review. 1977 Mar;84(2):191-215.
65. Soderlund A, Lindberg P. Coping as a mediating factor between self-efficacy and disability in whiplash associated disorders (WAD). Journal of Whiplash & Related Disorders. 2002;1(2):25-37.
66. Altmaier EM, Russell DW, Feng Kao C, Lehmann TR, Weinstein JN. Role of self-efficacy in rehabilitation outcome amongst chronic low back pain patients. Journal of Counseling Psychology. 1993;40(3):335-9.
67. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Washington DC: APA; 2000.
68. Joseph S. Psychometric evaluation of Horowitz's Impact of Event Scale: a review. Journal of Traumatic Stress. 2000 Jan;13(1):101-13.
69. Linton SJ. A review of psychological risk factors in back and neck pain. Spine. 2000 May 1;25(9):1148-56.
70. Crook J, Milner R, Schultz IZ, Stringer B. Determinants of occupational disability following a low back injury: a critical review of the literature. Journal of Occupational Rehabilitation. 2002 Dec;12(4):277-95.
71. Simon G, Gater R, Kisely S, Piccinelli M. Somatic symptoms of distress: an international primary care study. Psychosom Med. 1996 1996 Sep-Oct;58(5):481-8.
72. Kori SH, Miller RP, Todd DD. Kinesiophobia: a new view of chronic pain behaviour. Pain Management. 1990;3:35-43.
73. Sullivan MJ, Thorn B, Haythornthwaite JA, Keefe F, Martin M, Bradley LA, et al. Theoretical perspectives on the relation between catastrophizing and pain. The Clinical Journal of Pain. 2001 Mar;17(1):52-64.
74. Sullivan MJL, Bishop SR, Pivik J. The Pain Catastrophizing Scale: Development and validation. Psychological Assessment. 1995;7(4):524-32.
75. Horowitz M, Wilner N, Alvarez W. Impact of Event Scale: a measure of subjective stress. Psychosomatic Medicine. 1979 May;41(3):209-18.
76. Turk DC. A diathesis-stress model of chronic pain and disability following traumatic injury. Pain Research and Management. 2002 Spring;7(1):9-19.
77. Di Stefano G, Radanov BP. Neuropsychological and psychosocial findings in follow-up of cervical vertebrae dislocations: a prospective clinical study. Zeitschrift fur Unfallchirurgie und Versicherungsmedizin. 1993;86(2):97-108.

78. Radanov BP, Sturzenegger M, Di Stefano G, Schnidrig A, Mumenthaler M. Results of a 1-year follow-up study of whiplash injury. Schweizerische medizinische Wochenschrift. 1993 Aug 21;123(33):1545-52.
79. Radanov P, Sturzenegger M, Di Stefano G. Prediction of recovery from dislocation of the cervical vertebrae (whiplash injury of the cervical vertebrae) with initial assessment of psychosocial variables. Der Orthopade. 1994 Aug;23(4):282-6.
80. Foletti GB, Regli F. Indirect cervical trauma: long-term adverse prognostic factors. Schweizerische Rundschau fur Medizin Praxis. 1987 Nov 17;76(47):1304-9.
81.Kageyama N, Tanaka M, Ikeda K, Nakajima S, Someda K. Traumatic cervical syndromes--diagnosis, therapy and prognosis. Brain and Nerve. 1969 Aug;21(8):893-901.
82. Huber A, Beran H, Trenkler J, Hager A, Witzmann A, Fischer J. Whiplash trauma of the cervical spine from the neurosurgical, traumatologic and psychologic viewpoint. Neurochirurgia. 1993 Mar;36(2):51-5.
83. Pujol A, Puig L, Mansilla J, Idiaquez I. Relevant factors in medico-legal prognosis of whiplash injury. Medicina Clinica. 2003 Jul 12;121(6):209-15.
84. Pincus T, Williams A. Models and measurements of depression in chronic pain. Journal of Psychosomatic Research. 1999;47(3):211-9.
85. Szklo M, Nieto FJ. Epidemilogy: Beyond the Basics. Gaithersburg, Maryland, USA: Apsen Publication; 2000.
86. Field A. Discovering statistics using SPSS. 3rd ed. London: SAGE Publications; 2009.
87. Sterling M, Kenardy J. The relationship between sensory and sympathetic nervous system changes and posttraumatic stress reaction following whiplash injury--a prospective study. Journal of Psychosomatic Research. 2006 Apr;60(4):387-93.
88. Kivioja J, Jensen I, Lindgren U. Neither the WAD-classification nor the Quebec Task Force follow-up regimen seems to be important for the outcome after a whiplash injury. A prospective study on 186 consecutive patients. Eur Spine J. 2008 Jul;17(7):930-5.
89. Berglund A, Bodin L, Jensen I, Wiklund A, Alfredsson L. The influence of prognostic factors on neck pain intensity, disability, anxiety and depression over a 2-year period in subjects with acute whiplash injury. Pain. 2006 Dec 5;125(3):244-56.
90. Holm LW, Carroll LJ, Cassidy JD, Skillgate E, Ahlbom A. Expectations for recovery important in the prognosis of whiplash injuries. PLoS Med. 2008 May 13;5(5):e105.
91. Buitenhuis J, de Jong PJ, Jaspers JP, Groothoff JW. Relationship between posttraumatic stress disorder symptoms and the course of whiplash complaints. J Psychosom Res. 2006 Nov;61(5):681-9.
92. Buitenhuis J, de Jong P, Jaspers J, Groothoff J. Catastrophizing and causal beliefs in whiplash. Spine. 2008 Oct;33(22):2427-33; discussion 34.
93. Buitenhuis J, de Jong PJ, Jaspers JP, Groothoff JW. Work disability after whiplash: a prospective cohort study. Spine. 2009 Feb 1;34(3):262-7.
94. Carstensen TB, Frostholm L, Oernboel E, Kongsted A, Kasch H, Jensen TS, et al. Post-trauma ratings of pre-collision pain and psychological distress predict poor outcome following acute whiplash trauma: a 12-month follow-up study. Pain. 2008 Oct 15;139(2):248-59.
95. Kongsted A, Bendix T, Qerama E, Kasch H, Bach FW, Korsholm L, et al. Acute stress response and recovery after whiplash injuries. A one-year prospective study. Eur J Pain. 2008 May;12(4):455-63.
96. Holland P. Statistics and causal inference. Journal of the American Statistical Association. 1986;81:945-60.
97. Moore D. Statistics: concepts and controversies. 5th ed. New York: W.H. Freeman and Company; 2000.

98. Nicol-Smith L. Causality, menopause, and depression: a critical review of the literature. BMJ. 1996 Nov;313(7067):1229-32.
99. Gatchel R, Peng Y, Peters M, Fuchs P, Turk D. The biopsychosocial approach to chronic pain: scientific advances and future directions. Psychol Bull. 2007 Jul;133(4):581-624.
100. Keefe F, Rumble M, Scipio C, Giordano L, Perri L. Psychological aspects of persistent pain: current state of the science. J Pain. 2004 May;5(4):195-211.
101. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. Pain. 2000 Apr;85(3):317-32.
102. Turk DC, Rudy TE. Cognitive factors and persistent pain: a glimpse into pandora's box. Cognitive Therapy and Research. 1992;16(2):99-122.
103. Lazarus R, Folkman S. Stress, appraisal, and coping. New York: Springer Publishing Company; 1984.
104. Folkman S, Moskowitz JT. Coping: pitfalls and promise. Annual Review of Psychology. 2004;55:745-74.
105. De Ridder D. What is wrong with coping assessment? A review of the conceptual and methodological issues. Psychology and Health. 1997;12:417-31.
106. Moos RH, Holahan CJ. Dispositional and contextual perspectives on coping: Toward an integrative framework. Journal of Clinical Psychology. 2003;59(12):1387-403.
107. Brown GK, Nicassio PM. Development of a questionnaire for the assessment of active and passive coping strategies in chronic pain patients. Pain. 1987 Oct;31(1):53-64.
108. Keefe FJ, Caldwell DS, Queen KT, Gil KM, Martinez S, Crisson JE, et al. Pain coping strategies in osteoarthritis patients. Journal of Consulting and Clinical Psychology. 1987 Apr;55(2):208-12.
109. Carroll LJ, Cassidy JD, Cote P. The role of pain coping strategies in prognosis after whiplash injury: Passive coping predicts slowed recovery. Pain. 2006 Sep;124(1-2):18-26.
110. Snow-Turek AL, Norris MP, Tan G. Active and passive coping strategies in chronic pain patients. Pain. 1996 Mar;64(3):455-62.
111. Carroll L, Mercado AC, Cassidy JD, Cjte P. A population-based study of factors associated with combinations of active and passive coping with neck and low back pain. Journal of Rehabilitation Medicine. 2002 Mar;34(2):67-72.
112. Blyth FM, March LM, Nicholas MK, Cousins MJ. Self-management of chronic pain: a population-based study. Pain. 2005 Feb;113(3):285-92.
113. Turner JA, Jensen MP, Romano JM. Do beliefs, coping, and catastrophizing independently predict functioning in patients with chronic pain? Pain. 2000;85(1-2):115-25.
114. Mercado AC, Carroll LJ, Cassidy JD, Cote P. Passive coping is a risk factor for disabling neck or low back pain. Pain. 2005 Sep;117(1-2):51-7.
115. Jones GT, Johnson RE, Wiles NJ, Chaddock C, Potter RG, Roberts C, et al. Predicting persistent disabling low back pain in general practice: a prospective cohort study. The British Journal of General Practice. 2006 May;56(526):334-41.
116. Klenerman L, Slade PD, Stanley IM, Pennie B, Reilly JP, Atchison LE, et al. The prediction of chronicity in patients with an acute attack of low back pain in a general practice setting. Spine. 1995 Feb 15;20(4):478-84.
117. Smeets R, Maher C, Nicholas M, Refshauge K, Herbert R. Do psychological characteristics predict response to exercise and advice for subacute low back pain? Arthritis Rheum. 2009 Sep;61(9):1202-9.
118. Pool J, Ostelo R, Knol D, Bouter L, de Vet H. Are psychological factors prognostic indicators of outcome in patients with sub-acute neck pain? Man Ther. 2009 Aug.
119. Turner JA, Aaron LA. Pain-related catastrophizing: what is it? The Clinical Journal of Pain. 2001 Mar;17(1):65-71.

120. Dar R, Leventhal H. Schematic processes in pain perception. Cognitive Therapy and Research. 1993;17(4):341-57.
121. Woby SR, Watson PJ, Roach NK, Urmston M. Adjustment to chronic low back pain - the relative influence of fear-avoidance beliefs, catastrophizing and appraisals of control. Behaviour Research and Therapy. 2004;42:761-74.
122. Pincus T, Morley S. Cognitive-processing bias in chronic pain: a review and integration. Psychological Bulletin. 2001 Sep;127(5):599-617.
123. Sullivan MJ, Martel MO, Tripp D, Savard A, Crombez G. The relation between catastrophizing and the communication of pain experience. Pain. 2006 Jun;122(3):282-8.
124. Buenaver L, Edwards R, Haythornthwaite J. Pain-related catastrophizing and perceived social responses: Inter-relationships in the context of chronic pain. Pain. 2007 2007 Feb;127(3):234-42.
125. Turner JA, Franklin G, FultonKehoe D, Sheppard L, Wickizer TM, Wu R, et al. Worker recovery expectations and fear-avoidance predict work disability in a population-based workers' compensation back pain sample. Spine. 2006 Mar 15;31(6):682-9.
126. Neubauer E, Junge A, Pirron P, Seemann H, Schiltenwolf M. HKF-R 10 - Screening for predicting chronicity in acute low back pain (LBP): A prospective clinical trial. European Journal of Pain. 2006 Aug;10(6):559-66.
127. van der Windt D, Kuijpers T, Jellema P, van der Heijden G, Bouter L. Do psychological factors predict outcome in both low-back pain and shoulder pain? Ann Rheum Dis. 2007 2007 Mar;66(3):313-9.
128. Picavet HS, Vlaeyen JW, Schouten JS. Pain catastrophizing and kinesiophobia: predictors of chronic low back pain. American Journal of Epidemiology. 2002 Dec 1;156(11):1028-34.
129. Lethem J, Slade PD, Troup JD, Bentley G. Outline of a Fear-Avoidance Model of exaggerated pain perception--I. Behaviour Research and Therapy. 1983;21(4):401-8.
130. Pincus T, Vogel S, Burton AK, Santos R, Field AP. Fear avoidance and prognosis in back pain: A systematic review and synthesis of current evidence. Arthritis and Rheumatism. 2006 Nov 28;54(12):3999-4010.
131. Vlaeyen JW, Kole-Snijders AM, Boeren RG, van Eek H. Fear of movement/(re)injury in chronic low back pain and its relation to behavioral performance. Pain. 1995 Sep;62(3): 363-72.
132. Vlaeyen J, de Jong J, Sieben JM, Crombez G, Turk D, Gatchel R. Graded exposure in vivo for pain-related fear. In: Psychological approaches to pain management: a practitioner's handbook. New York: The Guilford Press; 2002.
133. Vlaeyen JWS, Crombez G. Fear of movement/(re)injury, avoidance and pain disability in chronic low back pain patients. Manual Therapy. 1999;4(4):187-95.
134. Asmundson G, Norton P, Vlaeyen J, Asmundson G, Vlaeyen J, Crombez G. Fear-avoidance models of chronic pain: an overview. In: Understanding and treating fear of pain. Oxford: Oxford University Press; 2004.
135. Chartered Society of Physiotherapy. Clinical Guidelines for the Management of Acute Soft Tissue Injuries. London: CSP; 1998.
136. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain. 1993 Feb;52(2):157-68.
137. Sieben JM, Vlaeyen JWS, Tuerlinckx S, Portegijs PJM. Pain-related fear in acute low back pain: The first two weeks of a new episode. European Journal of Pain. 2002 May;6(3):229-37.
138. Sieben JM, Portegijs PJM, Vlaeyen JWS, Knottnerus JA. Pain-related fear at the start of a new low back pain episode. European Journal of Pain. 2005;9(6):635.

139. Kovacs FM, Muriel A, Abriaira V, Medina JM, Castillo Sanchez MD, Olabe J, et al. The influence of fear avoidance beliefs on disability and quality of life is sparse in Spanish low back pain patients. Spine. 2005 Nov 15;30(22):E676-82.
140. Burton AK, Tillotson KM, Main CJ, Hollis S. Psychosocial predictors of outcome in acute and subchronic low back trouble. Spine. 1995 Mar 15;20(6):722-8.
141. Werneke M, Hart DL. Centralization phenomenon as a prognostic factor for chronic low back pain and disability. Spine. 2001 Apr 1;26(7):758-64; discussion 65.
142. Poiraudeau S, Rannou F, Baron G, Le Henanff A, Coudeyre E, Rozenberg S, et al. Fear-avoidance beliefs about back pain in patients with subacute low back pain. Pain. 2006 Oct;124(3):305-11.
143. Kovacs F, Muriel A, Castillo Sánchez M, Medina J, Royuela A. Fear avoidance beliefs influence duration of sick leave in Spanish low back pain patients. Spine. 2007 2007 Jul;32(16):1761-6.
144. Fritz JM, George SZ. Identifying psychosocial variables in patients with acute work-related low back pain: the importance of fear-avoidance beliefs. Physical Therapy. 2002 Oct;82(10):973-83.
145. Fritz JM, George SZ, Delitto A. The role of fear-avoidance beliefs in acute low back pain: relationships with current and future disability and work status. Pain. 2001 Oct;94(1):7-15.
146. Soucy I, Truchon M, Cote D. Work-related factors contributing to chronic disability in low back pain. Work. 2006;26(3):313-26.
147. Storheim K, Ivar Brox J, Holm I, Bo K. Predictors of return to work in patients sick listed for sub-acute low back pain: a 12-month follow-up study. Journal of Rehabilitation Medicine. 2005 Nov;37(6):365-71.
148. George SZ, Bialosky JE, Donald DA. The centralization phenomenon and fear-avoidance beliefs as prognostic factors for acute low back pain: a preliminary investigation involving patients classified for specific exercise. The Journal of Orthopaedic and Sports Physical Therapy. 2005 Sep;35(9):580-8.
149. Swinkels-Meewisse I, Roelofs J, Schouten E, Verbeek A, Oostendorp R, Vlaeyen J. Fear of movement/(re)injury predicting chronic disabling low back pain: a prospective inception cohort study. Spine. 2006 Mar;31(6):658-64.
150. Boersma K, Linton SJ. Expectancy, fear and pain in the prediction of chronic pain and disability: a prospective analysis. European Journal of Pain. 2006 Aug;10(6):551-7.
151. Burton AK, McClune TD, Clarke RD, Main CJ. Long-term follow-up of patients with low back pain attending for manipulative care: outcomes and predictors. Manual Therapy. 2004;9(1):30-5.
152. Grotle M, Vollestad NK, Brox JI. Clinical course and impact of fear-avoidance beliefs in low back pain: prospective cohort study of acute and chronic low back pain: II. Spine. 2006 Apr 20;31(9):1038-46.
153. Allegrante J, Marks R. Self-efficacy in management of osteoarthritis. Rheum Dis Clin North Am. 2003 2003 Nov;29(4):747-68.
154. Nicholson R, Houle T, Rhudy J, Norton P. Psychological risk factors in headache. Headache. 2007 Mar;47(3):413-26.
155. Brister H, Turner JA, Aaron LA, Mancl L. Self-efficacy is associated with pain, functioning, and coping in patients with chronic temporomandibular disorder pain. Journal of Orofacial Pain. 2006 Spring;20(2):115-24.
156. French DJ, Holroyd KA, Pinell C, Malinoski PT, O'Donnell F, Hill KR. Perceived self-efficacy and headache-related disability. Headache. 2000 Sep;40(8):647-56.

157. Bunketorp L, Lindh M, Carlsson J, StenerVictorin E. The perception of pain and pain-related cognitions in subacute whiplash-associated disorders: its influence on prolonged disability. Disability and Rehabilitation. 2006 Mar 15;28(5):271-9.
158. Söderlund A, Lindberg P. Cognitive behavioural components in physiotherapy management of chronic whiplash associated disorders (WAD)--a randomised group study. G Ital Med Lav Ergon. 2007 Jan-Mar;29(1 Suppl A):A5-11.
159. Kyhlbäck M, Thierfelder T, Söderlund A. Prognostic factors in whiplash-associated disorders. International Journal of Rehabilitation Research. 2002 Sep;25(3):181-7.
160. Söderlund A, Olerud C, Lindberg P. Acute whiplash-associated disorders (WAD): the effects of early mobilization and prognostic factors in long-term symptomatology. Clinical Rehabilitation. 2000 Oct;14(5):457-67.
161.Zubieta J, Stohler C. Neurobiological mechanisms of placebo responses. Ann N Y Acad Sci. 2009 Mar;1156:198-210.
162. Wiech K, Ploner M, Tracey I. Neurocognitive aspects of pain perception. Trends Cogn Sci. 2008 Aug;12(8):306-13.
163. Stewart-Williams S. The placebo puzzle: putting together the pieces. Health Psychol. 2004 Mar;23(2):198-206.
164. Goffaux P, Redmond W, Rainville P, Marchand S. Descending analgesia--when the spine echoes what the brain expects. Pain. 2007 Jul;130(1-2):137-43.
165. Brown CA, Seymour B, Boyle Y, El-Deredy W, Jones AK. Modulation of pain ratings by expectation and uncertainty: Behavioral characteristics and anticipatory neural correlates. Pain. 2007 Jul 3.
166. Janzen J, Silvius J, Jacobs S, Slaughter S, Dalziel W, Drummond N. What is a health expectation? Developing a pragmatic conceptual model from psychological theory. Health Expect. 2006 Mar;9(1):37-48.
167. Mondloch MV, Cole DC, Frank JW. Does how you do depend on how you think you'll do? A systematic review of the evidence for a relation between patients' recovery expectations and health outcomes. Canadian Medical Association journal. 2001 Jul 24;165(2):174-9.
168.Sandström J, Esbjörnsson E. Return to work after rehabilitation. The significance of the patient's own prediction. Scand J Rehabil Med. 1986;18(1):29-33.
169.Iles R, Davidson M, Taylor N, O'Halloran P. Systematic review of the ability of recovery expectations to predict outcomes in non-chronic non-specific low back pain. J Occup Rehabil. 2009 Mar;19(1):25-40.
170.Fadyl J, McPherson K. Return to work after injury: a review of evidence regarding expectations and injury perceptions, and their influence on outcome. J Occup Rehabil. 2008 Dec;18(4):362-74.
171.Karjalainen K, Malmivaara A, Mutanen P, Pohjolainen T, Roine R, Hurri H. Outcome determinants of subacute low back pain. Spine. 2003 Dec 1;28(23):2634-40.
172.Enthoven P, Skargren E, Carstensen J, Oberg B. Predictive factors for 1-year and 5-year outcome for disability in a working population of patients with low back pain treated in primary care. Pain. 2006 May;122(1-2):137-44.
173.Underwood MR, Morton V, Farrin A, on behalf of the UKBtt. Do baseline characteristics predict response to treatment for low back pain? Secondary analysis of the UK BEAM dataset [ISRCTN32683578]. Rheumatology. 2007 Aug;46(8):1297-302.
174.Kjellman G, Skargren E, Oberg B. Prognostic factors for perceived pain and function at one-year follow-up in primary care patients with neck pain. Disability and Rehabilitation. 2002 May 10;24(7):364-70.
175. Hills R, Kitchen S. Toward a theory of patient satisfaction with physiotherapy: exploring the concept of satisfaction. Physiother Theory Pract. 2007 Sep-Oct;23(5):243-54.

176. King M, Nazareth I, Lampe F, Bower P, Chandler M, Morou M, et al. Impact of participant and physician intervention preferences on randomized trials: a systematic review. JAMA. 2005 Mar;293(9):1089-99.
177.Torgerson D, Moffett J. Patient preference and validity of randomized controlled trials. JAMA. 2005 Jul;294(1):41-2; author reply 2.
178. Kendrick D, Fielding K, Bentley E, Miller P, Kerslake R, Pringle M. The role of radiography in primary care patients with low back pain of at least 6 weeks duration: a randomised (unblinded) controlled trial. Health Technol Assess. 2001;5(30):1-69.
179. de C Williams A, Nicholas M, Richardson P, Pither C, Fernandes J. Generalizing from a controlled trial: the effects of patient preference versus randomization on the outcome of inpatient versus outpatient chronic pain management. Pain. 1999 Oct;83(1):57-65.
180. Preference Collaborative Review Group. Patients' preferences within randomised trials: systematic review and patient level meta-analysis. BMJ. 2008;337.
181. Stewart M, Maher C, Refshauge K, Herbert R, Nicholas M. Patient and clinician treatment preferences do not moderate the effect of exercise treatment in chronic whiplash-associated disorders. Eur J Pain. 2008 Oct;12(7):879-85.
182. Pincus T. Multinational Musculoskeletal Inception Cohort Statement. Personal communication; 2005.
183. Carroll L, Holm L, Hogg-Johnson S, Côté P, Cassidy J, Haldeman S, et al. Course and prognostic factors for neck pain in whiplash-associated disorders (WAD): results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. Spine. 2008 Feb;33(4 Suppl):S83-92.
184. Kamper S, Rebbeck T, Maher C, McAuley J, Sterling M. Course and prognostic factors of whiplash: a systematic review and meta-analysis. Pain. 2008 Sep;138(3):617-29.
185. Walton D, Pretty J, MacDermid J, Teasell R. Risk factors for persistent problems following whiplash injury: results of a systematic review and meta-analysis. J Orthop Sports Phys Ther. 2009 May;39(5):334-50.
186. McCracken LM, Asmundson G, Vlaeyen JW, Crombez G. A behavioural analysis of pain-related fear responses. In: Understanding and treating fear of pain. Oxford: Oxford University Press; 2004. p. 50-69.
187. Lett HS, Blumenthal JA, Babyak MA, Strauman TJ, Robins C, Sherwood A. Social support and coronary heart disease: Epidemiologic evidence and implications for treatment. Psychosomatic Medicine. 2005 Nov-Dec;67(6):869-78.
188. Evers AWM, Kraaimaat FW, Geene R, Jacobs JWG, Bijlsma JWJ. Pain coping and social support as predictors of long-term functional disability and pain in early rheumatoid arthritis. Behaviour Research and Therapy. 2003 Nov;41(11):1295-310. Eseer Sene.
189. Leskela U, Rytsala H, Komulainen E, Melartin T, Sokero P, LestelaMielonen P, et al. The influence of adversity and perceived social support on the outcome of major depressive disorder in subjects with different levels of depressive symptoms. Psychological Medicine. 2006 Jun;36(6):779-88.
190. Cobb S. Presidential Address-1976. Social support as a moderator of life stress. Psychosomatic Medicine. 1976 Sep-Oct;38(5):300-14.
191. Uchino BN. Social support and health: a review of physiological processes potentially underlying links to disease outcomes. Journal of Behavioral Medicine. 2006 Aug;29(4): 377-87.
192. Steenstra I, Verbeek J, Heymans M, Bongers P. Prognostic factors for duration of sick leave in patients sick listed with acute low back pain: a systematic review of the literature. Occup Environ Med. 2005 Dec;62(12):851-60.
193. Mallen C, Peat G, Thomas E, Dunn K, Croft P. Prognostic factors for musculoskeletal pain in primary care: a systematic review. Br J Gen Pract. 2007 Aug;57(541):655-61.

194. Brewer B. Adherence to Sport Injury Rehabilitation Programs. Journal of Applied Sport Psychology. 1998;10:70-82.
195. Mannion A, Helbling D, Pulkovski N, Sprott H. Spinal segmental stabilisation exercises for chronic low back pain: programme adherence and its influence on clinical outcome. Eur Spine J. 2009 Dec;18(12):1881-91.
196. Brewer B, Cornelius A, Van Raalte J, Brickner J, Sklar J, Corsetti J, et al. Rehabilitation adherence and anterior crutiate ligament reconstruction outcom. Psychology, Health and Medicine. 2004;9:163-75.
197. Kolt G, McEvoy J. Adherence to rehabilitation in patients with low back pain. Man Ther. 2003 May;8(2):110-6.
198. Lyngcoln A, Taylor N, Pizzari T, Baskus K. The relationship between adherence to hand therapy and short-term outcome after distal radius fracture. J Hand Ther.18(1):2-8.
199. Von Korff M, Moore J. Stepped care for back pain: activating approaches for primary care. Ann Intern Med. 2001 2001 May;134(9 Pt 2):911-7.
200. Lamb S, Gates S, Underwood M, Cooke M, Ashby D, Szczepura A, et al. Managing Injuries of the Neck Trial (MINT): design of a randomised controlled trial of treatments for whiplash associated disorders. BMC Musculoskelet Disord. 2007;8:7.
201. McClune T, Burton AK, Waddell G. Evaluation of an evidence based patient educational booklet for management of whiplash associated disorders. Emergency Medicine Journal. 2003 Nov;20(6):514-7.
202. Waddell G, Burton K, McClune T. The Whiplash Book. London: TSO (The Stationary Office); 2002.
203. Williamson E, Williams M, Hansen Z, Joseph S, Lamb S. Development and delivery of a physiotherapy intervention for the early management of whiplash injuries: the Managing Injuries of Neck Trial (MINT) Intervention. Physiotherapy. 2009 Mar;95(1):15-23.
204. Bowling A. Measuring disease: a review of disease-specific quality of life measurement scales. Second ed. Buckingham: Open University Press; 2001.
205. Streiner D, Norman G. Health measurement scales: a practical guide to their developement and use. Third ed. Oxford: Oxford University Press; 2003.
206. McDowell I. Measuring health: a guide to rating scales and questionnaires. Oxford: Oxford University Press; 2006.
207. Bland J, Altman D. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986 Feb;1(8476):307-10.
208. Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. Journal of Manipulative and Physiological Therapeutics. 1991 Sep;14(7):409-15.
209. MacDermid J, Walton D, Avery S, Blanchard A, Etruw E, McAlpine C, et al. Measurement properties of the neck disability index: a systematic review. J Orthop Sports Phys Ther. 2009 May;39(5):400-17.
210. Nieto R, Miró J, Huguet A. Disability in subacute whiplash patients: usefulness of the neck disability index. Spine. 2008 Aug;33(18):E630-5.
211. Von Korff M, Ormel J, Keefe F, Dworkin S. Grading the severity of chronic pain. Pain. 1992 Aug;50(2):133-49.
212. Underwood MR, Barnett AG, Vickers MR. Evaluation of two time-specific back pain outcome measures. Spine. 1999 Jun 1;24(11):1104-12.
213. Smith B, Penny K, Purves A, Munro C, Wilson B, Grimshaw J, et al. The Chronic Pain Grade questionnaire: validation and reliability in postal research. Pain. 1997 Jun;71(2): 141-7.
214. BenDebba MHJ, Ducker TBEJM. Cervical spine outcomes questionnaire. Spine. 2002;27(19):2116-24.

215. Thompson L, Boudreau R, Hannon M, Newman A, Chu C, Jansen M, et al. The knee pain map: reliability of a method to identify knee pain location and pattern. Arthritis Rheum. 2009 Jun;61(6):725-31.
216. Weiner D, Peterson B, Keefe F. Evaluating persistent pain in long term care residents: what role for pain maps? Pain. 1998 May;76(1-2):249-57.
217. Escalante A, Lichtenstein M, Lawrence V, Roberson M, Hazuda H. Where does it hurt? Stability of recordings of pain location using the McGill Pain Map. J Rheumatol. 1996 Oct;23(10):1788-93.
218. Olsson I, Bunketorp O, Carlsson S, Styf J. Prediction of outcome in whiplash-associated disorders using West Haven-Yale Multidimensional Pain Inventory. Clin J Pain. 2002 Jul-Aug;18(4):238-44.
219. Sterner Y, Gerdle B. Acute and chronic whiplash disorders--a review. Journal of rehabilitation medicine : official journal of the UEMS European Board of Physical and Rehabilitation Medicine. 2004 Sep;36(5):193-209.
220. Miettinen T, Lindgren KA, Airaksinen O, Leino E. Whiplash injuries in Finland: a prospective 1-year follow-up study. Clinical & Experimental Rheumatology. 2002;20(3): 399-402.
221. Sterling M. A proposed new classification system for whiplash associated disorders--implications for assessment and management. Manual Therapy. 2004 May;9(2):60-70.
222. Williams M, McCarthy C, Chorti A, Cook M, Gates S. A systematic review of reliability and validity studies of methods for measuring active. Journal of Manipulative and Physiological. 2010 Feb; 33(2):138-55.
223. Vernon H. The Neck Disability Index: state-of-the-art, 1991-2008. J Manipulative Physiol Ther. 2008 Sep;31(7):491-502.
224. George SZ, Fritz JM, Erhard RE. A comparison of fear-avoidance beliefs in patients with lumbar spine pain and cervical spine pain. Spine. 2001 Oct 1;26(19):2139-45.
225. Cleland J, Fritz J, Childs J. Psychometric properties of the Fear-Avoidance Beliefs Questionnaire and Tampa Scale of Kinesiophobia in patients with neck pain. Am J Phys Med Rehabil. 2008 Feb;87(2):109-17.
226. Miró J, Nieto R, Huguet A. The Catalan version of the Pain Catastrophizing Scale: a useful instrument to assess catastrophic thinking in whiplash patients. J Pain. 2008 May;9(5):397-406.
227. Preston C, Colman A. Optimal number of response categories in rating scales: reliability, validity, discriminating power, and respondent preferences. Acta Psychol (Amst). 2000 Mar;104(1):1-15.
228. Klaber Moffett JA, Jackson DA, Richmond S, Hahn S, Coulton S, Farrin A, et al. Randomised trial of a brief physiotherapy intervention compared with usual physiotherapy for neck pain patients: outcomes and patients' preference. BMJ (Clinical Research Ed). 2005 Jan 8;330(7482):75.
229. Devilly G, Borkovec T. Psychometric properties of the credibility/expectancy questionnaire. Journal of Behaviour Therapy and Experimental Psychology. 2000;31:73-86.
230. Borkovec T, Nau S. Credibility of analogue therapy rationales. Journal of Behaviour Therapy and Experimental Psychology. 1972;3:257-60.
231. Rosenstiel A, Keefe F. The use of coping strategies in chronic low back pain patients: relationship to patient characteristics and current adjustment. Pain. 1983 Sep;17(1):33-44.
232. Jensen MP, Keefe FJ, Lefebvre JC, Romano JM, Turner JA. One- and two-item measures of pain beliefs and coping strategies. Pain. 2003 Aug;104(3):453-69.
233. Main C, Waddell G. A comparison of cognitive measures in low back pain: statistical structure and clinical validity at initial assessment. Pain. 1991 Sep;46(3):287-98.

234. Kovacs FM, Muriel A, Medina JM, Abraira V, Sanchez MD, Jauregui JO, et al. Psychometric characteristics of the Spanish version of the FAB questionnaire. Spine. 2006 Jan 1;31(1):104-10.
235. Pfingsten M, Kroner-Herwig B, Leibing E, Kronshage U, Hildebrandt J. Validation of the German version of the Fear-Avoidance Beliefs Questionnaire (FABQ). European journal of pain. 2000;4(3):259-66.
236. Chaory K, Fayad F, Rannou F, Lefevre-Colau MM, Fermanian J, Revel M, et al. Validation of the French version of the fear avoidance belief questionnaire. Spine. 2004 Apr 15;29(8):908-13.
237. Meyer K, Sprott H, Mannion A. Cross-cultural adaptation, reliability, and validity of the German version of the Pain Catastrophizing Scale. J Psychosom Res. 2008 May;64(5): 469-78.
238. Yap J, Lau J, Chen P, Gin T, Wong T, Chan I, et al. Validation of the Chinese Pain Catastrophizing Scale (HK-PCS) in patients with chronic pain. Pain Med. 2008 Mar;9(2): 186-95.
239. Osman A, Barrios F, Gutierrez P, Kopper B, Merrifield T, Grittmann L. The Pain Catastrophizing Scale: further psychometric evaluation with adult samples. J Behav Med. 2000 Aug;23(4):351-65.
240. Osman A, Barrios F, Kopper B, Hauptmann W, Jones J, O'Neill E. Factor structure, reliability, and validity of the Pain Catastrophizing Scale. J Behav Med. 1997 Dec;20(6): 589-605.
241. Sundin E, Horowitz M. Horowitz's Impact of Event Scale evaluation of 20 years of use. Psychosom Med. 2003;65(5):870-6.
242. Turner S, Lee D. Measures in Post Traumatic Stress Disorder: A Practitioner's Guide. Windsor: The NFER-NELSON Publishing Company Ltd.; 1998.
243. Australian Centre for Post Traumatic Mental Health. Australian guidelines for the treatment of adults with acute stress disorder and posttraumatic stress disorder: practitioner guide: National Health and Medical Research Council; 2007.
244. Goldberg D, Williams P. A User's Guide to the General health Questionnaire. Windsor: NFER; 1988.
245. Sánchez-López MP, Dresch V. The 12-Item General Health Questionnaire (GHQ-12): reliability, external validity and factor structure in the Spanish population. Psicothema. 2008 Nov;20(4):839-43.
246. Donath S. The validity of the 12-item General Health Questionnaire in Australia: a comparison between three scoring methods. Aust N Z J Psychiatry. 2001 Apr;35(2):231-5.
247. Goldberg DP, Gater R, Sartorius N, Ustun TB, Piccinelli M, Gureje O, et al. The validity of two versions of the GHQ in the WHO study of mental illness in general health care. Psychological Medicine. 1997 Jan;27(1):191-7.
248. Picardi A, Abeni D, Pasquini P. Assessing psychological distress in patients with skin diseases: reliability, validity and factor structure of the GHQ-12. J Eur Acad Dermatol Venereol. 2001 Sep;15(5):410-7.
249. Laranjeira C. General health questionnaire--12 items: adaptation study to the Portuguese population. Epidemiol Psichiatr Soc.17(2):148-51.
250. Ip W, Martin C. Psychometric properties of the 12-item General Health Questionnaire (GHQ-12) in Chinese women during pregnancy and in the postnatal period. Psychol Health Med. 2006 Feb;11(1):60-9.
251. Montazeri A, Harirchi A, Shariati M, Garmaroudi G, Ebadi M, Fateh A. The 12-item General Health Questionnaire (GHQ-12): translation and validation study of the Iranian version. Health Qual Life Outcomes. 2003;1:66.

252. Quek K, Low W, Razack A, Loh C. Reliability and validity of the General Health Questionnaire (GHQ-12) among urological patients: a Malaysian study. Psychiatry Clin Neurosci. 2001 Oct;55(5):509-13.
253. Schmitz N, Kruse J, Tress W. Psychometric properties of the General Health Questionnaire (GHQ-12) in a German primary care sample. Acta Psychiatr Scand. 1999 Dec;100(6):462-8.
254. Piccinelli M, Bisoffi G, Bon M, Cunico L, Tansella M. Validity and test-retest reliability of the Italian version of the 12-item General Health Questionnaire in general practice: a comparison between three scoring methods. Compr Psychiatry. 1993;34(3):198-205.
255. MacFarlane GJ, Croft PR, Schollum J, Silman AJ. Widespread pain: is an improved classification possible? The Journal of Rheumatology. 1996 Sep;23(9):1628-32.
256. Hunt I, Silman A, Benjamin S, McBeth J, Macfarlane G. The prevalence and associated features of chronic widespread pain in the community using the 'Manchester' definition of chronic widespread pain. Rheumatology. 1999 Mar;38(3):275-9.
257. Zimet GD, Dahlem NW, Zimet SG, Farley GK. The Multidimensional Scale of Perceived Social Support. Journal of personality assessment. 1988 Spr;52(1):30-41.
258. Kazarian S, McCabe S. Dimensions of social support in the MSPSS: factorial structure, reliability and theoretical implications. Journal of Community Psychology. 1991;19(2): 150-60.
259. Clara I, Cox B, Enns M, Murray L, Torgrudc L. Confirmatory factor analysis of the multidimensional scale of perceived social support in clinically distressed and student samples. J Pers Assess. 2003 Dec;81(3):265-70.
260. Eker D, Arkar H. Perceived social support: psychometric properties of the MSPSS in normal and pathological groups in a developing country. Soc Psychiatry Psychiatr Epidemiol. 1995 May;30(3):121-6.
261. Canty-Mitchell J, Zimet G. Psychometric properties of the Multidimensional Scale of Perceived Social Support in urban adolescents. Am J Community Psychol. 2000 Jun;28(3):391-400.
262. Stanley M, Beck J, Zebb B. Psychometric properties of the MSPSS in older adults. Aging and Mental Health. 1998;2(3):186-93.
263. Zimet G, Powell S, Farley G, Werkman S, Berkoff K. Psychometric characteristics of the Multidimensional Scale of Perceived Social Support. J Pers Assess. 1990;55(3-4):610-7.
264. Ware JJ, Kosinski M, Keller S. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996 Mar;34(3):220-33.
265. Ware J, Kosinski M, Keller S. SF-12: how to score the SF-12 physical and mental health summary scales. Lincoln: QualityMetric Incorporated. 1998.
266. Burton AK, Waddell G, Tillotson KM, Summerton N. Information and advice to patients with back pain can have a positive effect. A randomized controlled trial of a novel educational booklet in primary care. Spine. 1999 Dec 1;24(23):2484-91.
267. Sullivan M. The Pain Catastrophizing Scale: User Manual. Montreal: University Centre for Research on Pain and Disability, University of Montreal; 2004.
268. Hosmer D, Lemeshow S. Applied Logistic Regresson. 2nd ed: John Wiley and Sons, Inc; 2000.
269. Hicks M. Research methods for clinical therapists: applied project design and analysis. Third ed. Edinburgh: Churchill Livingston; 1999.
270. Spitalnic S. Risk assessment II: odds ratio. Hospital Physician. 2006;42(1):23-6.
271. Altman D, Bland J. Quartiles, quintiles, centiles, and other quantiles. BMJ. 1994 Oct;309(6960):996.

272. Bhandari M, Lochner H, Tornetta Pr. Effect of continuous versus dichotomous outcome variables on study power when sample sizes of orthopaedic randomized trials are small. Arch Orthop Trauma Surg. 2002 Mar;122(2):96-8.
273. Kraemer H, Wilson G, Fairburn C, Agras W. Mediators and moderators of treatment effects in randomized clinical trials. Arch Gen Psychiatry. 2002 Oct;59(10):877-83.
274. Baron RM, Kenny DA. The moderator-mediator variable distinction in social psychological research: conceptual, strategic, and statistical considerations. Journal of Personality and Social Psychology. 1986 Dec;51(6):1173-82.
275. Ackelman B, U. L. Validity and reliability of a modified version of the neck disability index. J Rehabil Med. 2002;34:284-7.
276. Mayou R, Bryant B. Outcome of 'whiplash' neck injury. Injury. 1996 Nov;27(9):617-23.
277. Gargan MF, Bannister GC. The rate of recovery following whiplash injury. Eur Spine J. 1994;3(3):162-4.
278. Gargan M, Bannister G, Main C, Hollis S. The behavioural response to whiplash injury. J Bone Joint Surg Br. 1997 Jul;79(4):523-6.
279. Motor Accident Authority NSW Australia. Guidelines for the Management of Acute Whiplash-Associated Disorders for HealthProfessionals. 2nd ed. 2007.
280. Wallis BJ, Lord SM, Bogduk N. Resolution of psychological distress of whiplash patients following treatment by radiofrequency neurotomy: a randomised, double-blind, placebo-controlled trial. Pain. 1997 Oct;73(1):15-22.
281. Sterling M. Physical and psychological aspects of whiplash: important considerations for primary care assessment, part 2--case studies. Man Ther. 2009 Feb;14(1):e8-12.
282. Carroll LJ, Holm LW, Ferrari R, Ozegovic D, Cassidy JD. Recovery in whiplash-associated disorders: do you get what you expect? J Rheumatol. 2009 May;36(5):1063-70.
283. Ozegovic D, Carroll LJ, David Cassidy J. Does expecting mean achieving? The association between expecting to return to work and recovery in whiplash associated disorders: a population-based prospective cohort study. Eur Spine J. 2009 Jun;18(6):893-9.
284. Hansen Z, Daykin A, Lamb S. A cognitive-behavioural programme for the management of low back pain in primary care: a description and justification of the intervention used in the Back Skills Training Trial (BeST; ISRCTN 54717854). Physiotherapy. 2010 Jun;96(2):87-94.
285. Lamb S, Hansen Z, Lall R, Castelnuovo E, Withers E, Nichols V, et al. Group cognitive behavioural treatment for low-back pain in primary care: a randomised controlled trial and cost-effectiveness analysis. Lancet. 2010 Mar;375(9718):916-23.
286. Kasch H, Qerama E, Bach FW, Jensen TS. Reduced cold pressor pain tolerance in non-recovered whiplash patients: a 1-year prospective study. European Journal of Pain. 2005 Oct;9(5):561-9.
287. Biggerstaff D, Thompson A. Interpretative Phenomenological Analysis (IPA): a qualitative methodology of choice for healthcare research. Qualitative research in psychology. 2008;5:172-83.
288. Malterud K. The art and science of clinical knowledge: evidence beyond measures and numbers. Lancet. 2001 Aug;358(9279):397-400.
289. Lewin S, Glenton C, Oxman A. Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study. BMJ. 2009;339:b3496.
290. Giacomini M, Cook D. Users' guides to the medical literature: XXIII. Qualitative research in health care A. Are the results of the study valid? Evidence-Based Medicine Working Group. JAMA. 2000 Jul;284(3):357-62.
291. Russell G, Nicol P. 'I've broken my neck or something!' The general practice experience of whiplash. Fam Pract. 2009 Apr;26(2):115-20.

292. Arksey H, Knight P. Interviewing for social scientists. London: SAGE Publications Ltd; 1999.
293. QSR: NVIVO qualitative data analysis software. Version 7. QSR International Pty Ltd; 2006.
294. Smith J, Flowers P, Larkin M. Interpretative Phoneomological Analysis: theory, method and research. London: SAGE Publications; 2009.
295. Smith J, Osborn M. Interpretative phenomenological analysis. Smith J, editor. London: SAGE Publications; 2003.
296. Osborn M, Smith J. The personal experience of chronic benign low back pain: An interpretive phenomenological analysis. British Journal of Health Psychology. 1998;3:65-83.
297. Malterud K. Qualitative research: standards, challenges, and guidelines. Lancet. 2001 Aug;358(9280):483-8.
298. Miles M, Huberman A. Qualitative data analysis. Second ed. Thousand Oaks: SAGE Publications Ltd; 1994.
299. Moseley GL, Nicholas MK, Hodges PW. A randomized controlled trial of intensive neurophysiology education in chronic low back pain. The Clinical journal of pain. 2004 Sep-Oct;20(5):324-30.
300. Butler D, Moseley L. Explain Pain. First edition ed. Adelaide: NOI Australasia Pty Ltd; 2003.
301. Woby SR, Watson PJ, Roach NK, Urmston M. Are changes in fear-avoidance beliefs, catastrophizing, and appraisals of control, predictive of changes in chronic low back pain and disability? European Journal of Pain. 2004 Jun;8(3):201-10.
302. Buchbinder R, Jolley D, Wyatt M. 2001 Volvo Award Winner in Clinical Studies: Effects of a media campaign on back pain beliefs and its potential influence on management of low back pain in general practice. Spine. 2001 Dec;26(23):2535-42.
303. Houben R, Ostelo R, Vlaeyen J, Wolters P, Peters M, Stomp-van den Berg S. Health care providers' orientations towards common low back pain predict perceived harmfulness of physical activities and recommendations regarding return to normal activity. Eur J Pain. 2005 Apr;9(2):173-83.
304. Bishop A, Foster N, Thomas E, Hay E. How does the self-reported clinical management of patients with low back pain relate to the attitudes and beliefs of health care practitioners? A survey of UK general practitioners and physiotherapists. Pain. 2008 Mar;135(1-2):187-95.
305. Moseley L. Reconceptualising pain according to modern science. Physical Therapy Reviews. 2007;12:169-78.
306. Ferrari R, Obelieniene D, Russell A, Darlington P, Gervais R, Green P. Laypersons' expectation of the sequelae of whiplash injury. A cross-cultural comparative study between Canada and Lithuania. Medical Science Monitor. 2002 Nov;8(11):CR728-34.
307.Norman P, Mark C, Bell R. The theory of planned behaviour and exercise: evidence for the moderating role of past behaviour. British Journal of Health Psychology. 2000;5:249-61.
308. Ajzen I. Nature and operation of attitudes. Annu Rev Psychol. 2001;52:27-58.
309. Jull G, Kristjansson E, Dall'Alba P. Impairment in the cervical flexors: a comparison of whiplash and insidious onset neck pain patients. Manual Therapy. 2004 May;9(2):89-94.
310. Jull G, Sterling M, Kenardy J, Beller E. Does the presence of sensory hypersensitivity influence outcomes of physical rehabilitation for chronic whiplash?--A preliminary RCT. Pain. 2007 2007 May;129(1-2):28-34.
311. Nijs J, Van Oosterwijck J, De Hertogh W. Rehabilitation of chronic whiplash: treatment of cervical dysfunctions or chronic pain syndrome? Clin Rheumatol. 2009 Mar;28(3):243-51.

312. Ryan C, Gray H, Newton M, Granat M. Pain biology education and exercise classes compared to pain biology education alone for individuals with chronic low back pain: a pilot randomised controlled trial. Man Ther. 2010 Aug;15(4):382-7.
313. Moseley G. Evidence for a direct relationship between cognitive and physical change during an education intervention in people with chronic low back pain. Eur J Pain. 2004 Feb;8(1):39-45.
314. Moseley L. Combined physiotherapy and education is efficacious for chronic low back pain. Aust J Physiother. 2002;48(4):297-302.
315. Moseley L. Combining forces - combining cognition targeted motor control training with group or individual pain physiology education: a successful treatment for chonic low back pain. Journal of Manual and Manipulative Therapy. 2003;11:88-94.
316. Hurwitz E, Carragee E, van der Velde G, Carroll L, Nordin M, Guzman J, et al. Treatment of neck pain: noninvasive interventions: results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. Spine. 2008 Feb;33(4 Suppl):S123-52.
317. Hill J, Lewis M, Sim J, Dziedzic K. Preictors of Poor Outcome in Patients with Neck Pain Treated by Physical Therapy. Clin J Pain. 2007; 23:683-690.
318. Peduzzi P, Concato J, Kemper I, Holford T, Feinstein, A. A Simulation study of the number of events per variable in logistic regression analysis. J Clin Epidemiol 1996; 49(12):1373-1379.
319. Nau R. Stepwise and all possible regressions [online]. 2005. Available at: http://www.duke.edu/~rnau/regstep.htm [accessed 2/7/2011].
320. Analystsoft. Statplus help system: regression [online].2007. Available at: http://www.analystsoft.com/en/products/statplus/content/help/src/analysis_regression_multiple_binary_forward_stepwise_backward_regression_model.html [accessed 2/7/2011].
321. British Pain Society. Frequently asked questions [online]. 2006. Available at: http://www.britishpainsociety.org/media_faq.htm [accessed 7/7/2011].
322. Sterling M, Hendrikz J, Kenardy, J. Similar factors predict disability and posttraumatic stress disorder trajectories after whiplash injury. Pain 2011; 152:1272-1278.

Appendix 1: MINT protocol paper

BMC Musculoskeletal Disorders

Managing Injuries of the Neck Trial (MINT): design of a randomised controlled trial of treatments for whiplash associated disorders

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Abstract

Background: A substantial proportion of patients with whiplash injuries develop chronic symptoms. However, the best treatment of acute injuries to prevent long-term problems is uncertain. A stepped care treatment pathway has been proposed, in which patients are given advice and education at their initial visit to the emergency department (ED), followed by review at three weeks and physiotherapy for those with persisting symptoms. MINT is a two-stage randomised controlled trial to evaluate two components of such a pathway: 1. use of The Whiplash Book versus usual advice when patients first attend the emergency department; 2. referral to physiotherapy versus reinforcement of advice for patients with continuing symptoms at three weeks.

Methods: Evaluation of the Whiplash Book versus usual advice uses a cluster randomised design in emergency departments of eight NHS Trusts. Eligible patients are identified by clinicians in participating emergency departments and are sent a study questionnaire within a week of their ED attendance. Three thousand participants will be included. Patients with persisting symptoms three weeks after their ED attendance are eligible to join an individually randomised study of physiotherapy versus reinforcement of the advice given in ED. Six hundred participants will be randomised. Follow-up is at 4, 8 and 12 months after their ED attendance. Primary outcome is the Neck Disability Index (NDI), and secondary outcomes include quality of life and time to return to work and normal activities. An economic evaluation is being carried out.

Conclusion: This paper describes the protocol and operational aspects of a complex intervention trial based in NHS emergency and physiotherapy departments, evaluating two components of a stepped-care approach to the treatment of whiplash injuries. The trial uses two randomisations, with the first stage being cluster randomised and the second individually randomised.

Background

Whiplash injuries are a major health and economic problem around the world. In the UK, their annual cost to the economy is about £2,553 million (1990 prices), representing about 18% of the total costs of all road traffic collisions and 0.4% of the Gross Domestic Product[1]. The costs are caused by absence from work due to injury and considerable health service costs. Most patients recover quickly but a substantial proportion, estimated by different studies at between 19% and 60%[2,3], may develop chronic symptoms. These patients generate the majority of costs, and prevention of chronic symptoms is therefore a priority in treatment of whiplash injuries.

Definitions of whiplash and associated conditions vary between published studies. The Quebec Task Force (QTF) definitions are internationally recognised and are used in this study[4]. Whiplash is the mechanism of injury (acceleration-deceleration injuries usually in the frontal plane), whiplash injuries are the soft tissue injuries that result and Whiplash Associated Disorder (WAD) describes the pattern of symptoms that arise (Table 1). A further term, late whiplash syndrome, is used to describe the chronic complications of whiplash.

Despite whiplash being a common injury, there are few good quality randomised trials upon which to base recommendations for practice[5]. In the mid 1990s the QTF undertook an extensive review and expert consensus exercise[4], and found that there was insufficient evidence supporting the treatments currently used. They concluded that promoting activity in the early stages was probably the most effective strategy, soft collars were not helpful, and physiotherapy, a very common treatment, required rigorous evaluation. The QTF proposed a clinical pathway in which patients are given advice and education at the initial contact, and then reviewed at three weeks. Patients with persisting symptoms would then be provided with more intensive treatment.

A stepped care clinical pathway as proposed by the QTF is the model evaluated in this trial. The advice and education component to be evaluated is The Whiplash Book[6]. This has been developed largely based on the results of a systematic review[7], which suggested that psychological risk factors are the strongest predictors of poor outcome in whiplash patients, and argued that advice to resume normal activity, using a cognitive-behavioural approach, should be the treatment of choice for early management. However, other systematic reviews have suggested that physical and psychological factors may carry equivalent amounts of risk for poor outcome[8]. Furthermore, most of the literature cited to support the early activity and key health promotion messages was from the field of low back pain and other chronic conditions. It is questionable whether these results are transferable to acute whiplash injuries, as the conditions differ markedly in their causes and psychological consequences. For example, phobic travel anxiety and other psychological manifestations of shock are common after whiplash[9], but rarely occur with low back pain.

The second component of the stepped care approach evaluated in MINT is physiotherapy for patients whose symptoms have not resolved by three weeks. Physiotherapy treatments that are commonly used for whiplash patients include hot and cold therapy, electrotherapies, mobilisation, manipulation, exercises of many different kinds, and traction. There is good quality trial evidence to support the effectiveness of mobilisation and exercise in the management of chronic neck pain[10-12], but it is uncertain whether these treatments are effective for whiplash patients. The Cochrane review of conservative treatments for whiplash[4] concluded that there was some evidence that active treatments are superior to passive, though the existing trials were not of high quality. Another review concluded that there was moderate quality evidence that exercises and mobilisations commonly used by physiotherapists were effective[13], but this was based on just three small trials, which reported short-term outcomes only, did not perform intention to treat analyses, and did not have blinding of outcome assessment. For evaluation in MINT we have designed a package of physiotherapy treatments that, according to current evidence, are those most likely to be effective in prevention of late whiplash syndrome and to be acceptable to practitioners.

Table 1: Case definitions of Whiplash Associated Disorders

Term	Definition
WAD Grade 0	No neck complaints or signs
WAD Grade I	Complaint of pain, stiffness or tenderness, but no physical signs
WAD Grade II	Complaint of pain, stiffness or tenderness, and musculo-skeletal signs
WAD Grade III	Complaint of pain, stiffness or tenderness and neurological signs Could also have musculo-skeletal signs.
WAD Grade IV	Fracture or dislocation
Late whiplash syndrome	Presence of pain, restriction of motion or other symptoms at six months or more after the injury, sufficient to hinder return to normal activities such as driving, usual occupation and leisure.

Current practice

A national survey of practice in the UK indicated that the most common treatment for whiplash in emergency departments (ED) is advice, but the content and quality of the advice varies [unpublished data]. Over 90% of departments suggest using analgesics and gradually increasing movement of the neck. Some departments use soft collars as well, suggesting that they should be removed and the neck exercised on a regular basis.

Methods

MINT is a multi-centre randomised controlled trial to estimate the clinical effectiveness of a stepped care approach to whiplash injuries on clinical outcomes over 12 months, the effectiveness in pre-specified sub-groups of patients (those with severe physical symptoms, prior neck problems, psychological or physical risk factors for poor outcome, and those seeking compensation), and the costs and cost-effectiveness of each strategy.

The trial will use two separate randomisations: the first stage is a cluster randomised trial in which NHS Trusts are randomised to use the Whiplash Book or give their usual advice, for all patients presenting with whiplash injuries. The second stage is individual randomisation to physiotherapy or the control intervention of a single advice session reinforcing the advice given in ED, for patients still experiencing whiplash symptoms at three weeks. The two parts of the trial have a common system of follow-up at four, eight and 12 months.

The trial is being run in 12 NHS Acute Trusts in the UK: Heart of England NHS Foundation Trust (Heartlands and Solihull Hospitals), North Bristol NHS Trust (Frenchay Hospital), Oxford Radcliffe Hospitals NHS Trust (John Radcliffe Hospital), University Hospitals Coventry and Warwickshire NHS Trust (Walsgrave Hospital and Hospital of St Cross, Rugby), Gloucestershire Hospitals NHS Trust (Cheltenham and Royal Gloucester Hospitals), South Warwickshire General Hospitals NHS Trust (Warwick Hospital), Worcestershire Acute Hospitals NHS Trust (Alexandra Hospital, Redditch), University Hospitals Birmingham NHS Trust (Selly Oak Hospital), Kettering General Hospital NHS Trust (Kettering General Hospital), Buckinghamshire Hospitals NHS Trust (Stoke Mandeville Hospital, Countess of Chester Hospital NHS Foundation Trust (Countess of Chester Hospital), and Gwent Healthcare NHS Trust (Royal Gwent Hospital, Newport). Some Trusts comprise several hospitals and have more than one Emergency Department.

Ethics Committee approval

MINT was approved by the Trent Multicentre Research Ethics Committee and by the Local Research Ethics Committee and the Research and Development Committee of each participating centre.

Stage 1: Cluster randomised trial of the whiplash book versus usual advice

Inclusion and exclusion criteria

All people who attend ED with a whiplash injury of less than six weeks duration will be included in the trial, except those with any of the following exclusion criteria:

1. Age less than 18 years.

2. Fractures or dislocations of the spine or other bones.

3. Head injuries with more than a transient loss of consciousness or with a Glasgow Coma Score of 12 or less at any stage of their assessment in hospital.

4. Admission to in-patient services.

5. Severe psychiatric illness.

Identifying participants and consent

Because the first part of the trial is cluster randomised, individual consent for participation is not sought. This is an accepted procedure for cluster randomised trials where individuals do not have a choice of whether to receive the trial intervention[14]. All eligible patients at each participating hospital are included unless they indicate that they do not wish to participate in data collection. Clinicians in ED are responsible for identifying eligible participants. Details of whiplash patients are recorded on the trial proforma, a short form developed specifically for MINT that replaces the normal methods of clinical data collection in participating centres. It is intended to avoid duplication of recording of information for clinical and research purposes, and hence allows collection of a routine core clinical data set, including injury severity, pain intensity and WAD grade diagnosis. It contains tick boxes to ensure that clinicians have provided potential participants with the trial information sheet and have discussed the study with them, and also records if the patient would prefer not to receive the study questionnaires. The proforma is self-copying; one copy is filed in the medical notes as a treatment record and the second copy is passed to the research team to notify them that a patient has been asked to participate. Completed proformas are collected in a secure place in the ED and forwarded to the MINT research team twice a week. Patients are informed about the possibility that they may be eligible for stage 2 of the study but detailed information about this is not given at this stage, as the majority of patients who participate in stage 1 will not have persistent symptoms at 3 weeks and hence will not be eligible for stage 2. Patients are also asked for their contact details (address, phone number, mobile phone and email), to assist with sending out and following up questionnaires.

Randomisation

The unit of randomisation is the NHS Trust. Participating Trusts were randomised before the start of recruitment by the project statisticians, to usual advice or the Whiplash Book. Trusts were pair matched on size (number of ED attendances per year), star rating, and ethnic composition of the surrounding area. We randomised by Trust rather than by ED to avoid contamination when staff of one Trust worked in more than one ED. Randomisation used a table of random numbers, starting at a random place to ensure that the allocations were not known before ran- domisation. The allocation depended on whether the next digit was even or odd. One of each pair was randomised to the Whiplash Book, and the other member was allo- cated to usual advice.

Delivery of interventions

Training of ED staff in the trial procedures is given before the start of recruitment, and there is frequent contact between the centres and the trial team to identify and resolve any problems. Eligible patients are given a letter of introduction about the study, signed by their local ED consultant, and the study is discussed with them. If they are willing to participate, they are told that they will receive a questionnaire in a few days time. They are asked to return this and to contact the MINT study team if they continue to have problems after two weeks. The introduc- tion letter does not mention randomisation of hospitals to The Whiplash Book or usual advice, but simply states that the hospital is taking part in a study of advice given to patients with whiplash injuries. ED clinicians provide a copy of either the ED's usual advice leaflet or the Whip- lash Book, and verbal guidance on management of whip- lash injuries. We have obtained copies of the usual advice leaflets from all of the EDs participating in MINT, so that the content of the advice in the control arm can be docu- mented.

Baseline data collection

All whiplash patients that are eligible for MINT and have not asked to be excluded are sent a copy of the MINT base- line questionnaire within a week of their ED attendance. This includes demographic information and baseline administration of some of the outcome measures. If the questionnaire is not returned within a week, participants are sent a reminder by SMS text message, email or post.

Stage 2: Individually randomised trial of physiotherapy versus reinforcement of advice given in ED

Identifying participants and consent

Participants in Stage 1 are asked to contact the study office if they continue to have symptoms two weeks after their attendance at ED. An appointment is then made for the patient with a research physiotherapist based at their local hospital. At this appointment, their eligibility for Stage 2 of the trial is assessed. If eligible, trial participation is dis- cussed and the patient is asked to sign a study consent form prior to randomisation. Information about Stage 2 of MINT is sent to patients several days before their research clinic appointment, ensuring that they have suf- ficient time to consider participation.

Inclusion and exclusion criteria

Participants in Stage 1 of MINT are eligible for the second part of the trial if they:

- Report symptoms in the 24 hours before attendance at the physiotherapy research clinic approximately three weeks after attendance at ED

- Are WAD grade I-III at this time

- Do not have any contra-indications to physiotherapy treatment. These include central cord compression or upper motor neuron lesion, complete nerve root com- pression or lower motor neuron lesion, suspected vascular injury or haemorrhagic event.

Randomisation

Randomisation to physiotherapy or reinforcement of advice is via a central telephone randomisation service, based at the Cancer Research Clinical Trials Unit, Univer- sity of Birmingham. Randomisation is stratified by centre, to avoid imbalance between centres giving different advice in ED, and members of the same household are assigned to the same intervention, to reduce the chance of contamination. This will be taken into account in the trial analysis. If eligible patients decline participation, their reasons for doing so are recorded.

Interventions

All interventions are delivered by physiotherapists who are independent of the recruitment and randomisation procedures, and have attended a 1.5 day training session by the trial team. The same therapists deliver both the physiotherapy and control interventions, and each treat- ment session is recorded in a treatment log. A sample of sessions of both interventions is observed for quality con- trol purposes. All treatments should be completed within four months of the patient's first attendance at ED.

(a) Physiotherapy

Participants who are randomised to the physiotherapy package have up to six sessions of therapy, over an eight week period. The components of the intervention are described in a training and reference manual. The choice of physiotherapy treatments has been made using two principles; first, there is evidence that the treatments are effective for chronic neck dysfunction and are likely to be effective for whiplash injuries, based on expert opinion or limited trial evidence, and second, the treatments target established and potentially modifiable risk factors for developing late whiplash syndrome, including reduced cervical range of motion, high pain intensity, and adverse psychological reactions to the injury.

Three treatments are included in the physiotherapy package:

(1) Mobilisation (gentle manipulation) of the cervical and upper thoracic spine according to Maitland[15].

(2) Exercises for the cervical spine, thoracic spine and shoulder to improve range of movement and muscle control.

(3) A cognitive behavioural approach to treatment delivery, which has been effective in physiotherapy for other painful conditions[16].

Manipulation (Maitland Grade IV) of the cervical spine is excluded from this treatment package. Both whiplash injury and cervical manipulation have the potential to cause damage to the vertebral artery that may result in a cerebrovascular event. In common with some, but not all, authorities we consider that recent trauma is a contraindication to cervical manipulation.

(b) Reinforcement of advice

Participants randomised to reinforcement of advice receive a single 40-minute session of advice from a physiotherapist. At this session, the physiotherapist re-states the advice that the patient was given at the time of their ED attendance (either the Whiplash Book or the hospital's usual advice), discusses any queries that the patient may have, and may check the exercises that the patient was given in ED. The physiotherapist can only give advice regarding progression of exercises or activities specified in the Whiplash Book or usual advice. They cannot prescribe new exercises or use any "hands on" treatment. No review appointments are offered to these patients. They are advised to see their GP if they have ongoing problems.

Other treatments

Participants may seek other forms of treatment during the follow up period from their GP or other health professionals. If the trial interventions are effective, this should be evident in a reduction in additional treatments. Such treatments, including changes in the amount or types of analgesia used, use of physical treatments (osteopathy, chiropractic or physiotherapy), alternative therapies, or referral to secondary care services will be recorded as a treatment outcome.

Outcome measures and data collection

Follow-up data collection is by postal questionnaire. The outcome measures are detailed in Table 2. The primary outcome is return to normal function after the whiplash injury, measured using the Neck Disability Index (NDI). The NDI is a self-completed questionnaire that has been used successfully in a postal format in trials of neck treatments[10,17]. It assesses pain-related activity restrictions in 10 areas including personal care, lifting, sleeping, driving, concentration, reading and work. The SF-12 and EQ-5D are included to assess generic health-related quality of life, and to enable a single utility score for economic evaluation to be derived from the EQ-5D. Participants also rate whether they have improved, remained the same, or worsened, and their satisfaction with treatment. Resource use is assessed by a short questionnaire which asks about additional NHS or private hospital treatment for the whiplash injury, any GP consultations, manipulation, massage or other treatment. Participants are asked to distinguish between prescriptionand out-of-pocket expenses

`Table 2: Outcome measures

Domain	Measures*	Time points
Function	Neck Disability Index	4, 8, 12 months
	Time to return to work and normal activities (including driving)	4, 8, 12 months
Health-related quality of life	SF12	0, 4, 8, 12 months
Satisfaction	5 point Likert scale	4, 8, 12 months
Economics	Resource use questionnaire	0, 4, 8, 12 months
	EQ-5D (health utility)	0, 4, 8, 12 months

Participants are asked at 12 month follow-up whether they have pursued and settled a compensation claim related to their whiplash injury. It is not asked at 4 or 8 month follow-up to avoid stimulation of claims among the trial population.

A research assistant who has not been involved in the recruitment or randomisation processes is responsible for mailing follow up questionnaires, and for entering responses onto the study database. Blinding of the study team will be maintained until final analysis of the data has been completed.

Statistical analysis

The analysis will be by intention to treat. All patients will be analysed in the groups to which they were randomised, regardless of the treatment that they actually received. The two main comparisons will be Whiplash Book versus usual advice, and physiotherapy package versus reinforcement of ED advice. The comparison of ED advice interventions will use appropriate methods to take account of the cluster randomisation[18]. Estimates of treatment effect with 95% confidence intervals, and the numbers needed to treat, will be reported. Additional exploratory analyses will investigate whether there is an interaction between the ED advice intervention and physiotherapy.

Four pre-specified subgroup analyses will be undertaken:

1. severe physical symptoms at trial entry (WAD Grade III versus WAD Grade I or II)

2. adverse psychological reactions at trial entry (yes/no)

3. pre-existing neck pain versus no pre-existing neck pain

4. compensation; claim being pursued versus not being pursued

Statistical tests of interaction will be used to perform subgroup analyses[19].

Economic analysis will use cost-minimisation, or cost-effectiveness and cost-utility analysis, depending on the clinical results. For cost-utility analysis, the EQ-5D will be used to generate utility scores, which will provide an estimate of the incremental cost of any benefit gained in terms of improved health status. Decision modelling will be used to investigate the costs and benefits of the different patient management routes, and uncertainty will be quantified by multi-way sensitivity analyses[20].

Sample size

For the primary outcome of NDI, there is consensus that a minimal clinically importance difference lies in the range of 3–5 percentage points, with a standard deviation of about 8%[8]. We therefore aim to be able to detect a difference between the groups of three percentage points (i.e. 0.375 standard deviations), both for the comparison of the Whiplash Book and usual advice, and for physiotherapy versus reinforcement of advice. For the individually randomised comparison (physiotherapy versus reinforcement of advice), 211 per group will be required, based on 90% power and 1% significance level. Assuming a worst case scenario of 30% loss to follow-up gives a total sample size of 300 per group (600 in total)[21]. The comparison of ED advice interventions is cluster randomised, so larger numbers are needed. Originally it was planned that eight centres would participate, recruiting 4,800 participants. This was revised with the inclusion of four additional centres, which allowed reduction of the overall sample size required to achieve the same power. Assuming an intra-cluster correlation co-efficient of 0.02, and an average of 120 patients per centre gives an inflation factor of 5.94[22], leading to a sample size of 713 in each group. Allowing for 30% loss to follow up, 1020 participants per group will be needed (2040 in total). To allow for a reduction in power caused by unequal sample sizes among clusters, the target sample size has been set to 3000 (an average of 250 per cluster). The assumptions underlying the sample size calculation will be monitored by the DMEC during recruitment and adjustments may be made during the course of the trial.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

SEL designed the study, secured funding and contributed to writing the paper.

SG contributed to protocol revisions and drafted the paper.

MRU contributed to design of the study and securing funding and revised the paper.

MWC contributed to design of the study and securing funding and revised the paper.

DA was responsible for statistical aspects of study development, contributed to securing funding and revised the paper.

AS was responsible for economic aspects of study development, contributed to securing funding and revised the paper.

MAW was responsible for the clinical trial co-ordination and design of the intervention.

EMW was responsible for assisting with the clinical trial co-ordination and design of the intervention.

EJW was responsible for the trial co-ordination, recruitment, data cleaning and management.

SM was responsible for statistical analyses of the study and development and maintenance of the study databases.

AG was responsible for economic analyses of the study. All authors read and approved the manuscript.

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References

1.Galasko SB: **The cost of whiplash-associated disorders.** In *Whiplash Injuries: current concepts in prevention diagnosis, and treatment of the cervical whiplash syndrome* Edited by: Gunzburg R, Szpalski M. Philadelphia: Lippincott-Raven; 1998:283-290.
2.Barnsley L, Lord S, Bogduk N: **Whiplash injury: clinical review.***Pain* 1994, **58:**283-307.
3.Stovner LJ: **The nosologic status of the whiplash syndrome: acritical review based on a methodological approach.** *Spine*1996, **21:**2735-2746.
4.Spitzer WO, Skovron ML, Salmi LR, Cassidy JD, Duranceau J, Suissa S, Zeiss E: **Scientific monograph of the Quebec Task Force on Whiplash-Associated Disorders: redefining "whiplash" and its management.** *Spine* 1995, **20(8 Suppl):**1S-73S.
5. Verhagen AP, Scholten-Peeters GGM, de Bie RA, Bierma-Zeinstra SMA: **Conservative treatments for whiplash.** *The Cochrane Database of Systematic Reviews* 2004.
6.TSO: **The Whiplash Book.** London: The Stationery Office Ltd;2002.
7.McClune T, Burton AK, Waddell G: **Whiplash asstion of trials in primary care.** *Clinical Trials* 2005, **2:**91-98. **ociated disorders: a review of the literature to guide patient information and advice.** *Emerg Med J* 2002, **19:**499-506.
8.Cote P, Cassidy JD, Carroll L, Frank JW, Bombardier C: **A systematic review of the prognosis of acute whiplash and a new conceptual framework to synthesize the literature.** *Spine* 2001,**26:**E445-458.
9.Mayou R, Bryant B: **Outcome of 'whiplash' neck injury.** *Injury* 1996, **27:**617-23.
10. Hoving JL, Koes BW, de Vet HC, van der Windt DA, Assendelft WJ, van Mameren H, Deville WL, Pool JJ, Scholten RJ, Bouter LM: **Manual therapy, physical therapy, or continued care by a general practitioner for patients with neck pain. A randomized, controlled trial.** *Ann Intern Med* **136:**713-22.
11. Evans R, Bronfort G, Nelson B, Goldsmith CH: **Two-year Follow up of a randomized clinical trial of spinal manipulation and two types of exercise for patients with chronic neck pain.***Spine* 2002, **27:**2383-2389.
12. Kjellman G, Oberg B: **A randomized clinical trial comparing general exercise, McKenzie treatment and a control group in patients with neck pain.** *J Rehabil Med* 2002, **34:**183-190.
13. Sarig-Bahat H: **Evidence for exercise therapy in mechanicalneck disorders.** *Man Ther* 2003, **8:**10-20.
Eldridge SM, Ashy D, Feder GS: **Informed patient consent to participation in cluster randomized trials: an empirical exploration of trials in primary care.** *Clinical Trials* 2005, **2:**91-98.
15. Maitland GD: *Peripheral Manipulation* 5th edition. Butterworth-Heinemann .
16. Klaber Moffett J, Torgerson D, Bell-Syer S, Jackson D, Llewlyn-Phillips , Farrin A, Barber J: **Randomised controlled trial of exercise for low back pain: clinical outcomes, costs, and preferences.** *BMJ* 1999, **319:**279-83.
17. Rosenfeld M, Gunnarsson R, Borenstein P: **Early intervention in whiplash-associated disorders: a comparison of two treatment protocols.** *Spine* 2000, **25:**1782-7.
18. Donner A, Klar N: *Design and analysis of cluster randomization trials in health research* London: Arnold; 2000.
19. Brookes ST, Whitley E, Peters TJ, Mulheran PA, Egger M, Davey Smith G: **Sub-group analyses in randomised controlled trial: quantifying the risks of false-positives and false-negatives.** *Health Technol Assess* **5(33):**.
20. Hunink MGM, Bult JR, deVries J, Weinstein MC: **Uncertainty in decision models analysing cost-effectiveness: the joint distribution of incremental costs and effectiveness evaluated with a nonparametric bootstrap method.** *Medical Decision Making*1998, **18:**337-346.
21. Pocock SJ: *Clinical trials: A Practical Approach* Chichester: Wiley; 1983.
22. Eldridge SM, Ashby D: *Statistical Concepts* London: Royal College of General Practitioners; 2000.

Appendix 2: Physiotherapy intervention paper

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Development and delivery of a physiotherapy intervention for the early management of whiplash injuries: The Managing Injuries of Neck Trial (MINT) Intervention

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Abstract

This paper describes the development and implementation of a physiotherapy intervention for a large multi-centred randomised controlled trial of the early management of whiplash injuries in an NHS setting. Participants were eligible if they were classified as having Whiplash Associated Disorder grade I – III and self-referred for treatment within 6 weeks of injury. The intervention development was informed through a variety of methods including the current evidence base, published guidelines, clinician opinion, a pilot study and expert opinion. The intervention was targeted at known, potentially modifiable risk factors for poor recovery, and utilised manual therapy, exercises and psychological strategies. The treatment was individually tailored, with a maximum of 6 treatments allowed within the trial protocol over an 8 week period. The intervention was delivered to 300 participants. The amount and types of treatments delivered are described.

Introduction

In 2003, the National Institute of Health Research, Health Technology Assessment programme commissioned a large-scale pragmatic randomised controlled trial to investigate the clinical and cost-effectiveness of a variety of interventions for the management of acute whiplash. This was in response to the well documented persistence of symptoms (referred to as whiplash associated disorders – see Table 1) in a substantial number of people who suffer a whiplash injury, and paucity of evidence to inform treatment choices (1).

Table 1 Whiplash Associated Disorders (1)

Whiplash Associated Disorders	The signs and symptoms experienced following a whiplash injury
WAD Grade 0	No neck complaints or signs
WAD Grade I	Complaint of pain, stiffness or tenderness, but no physical signs.
WAD Grade II	Complaint of pain, stiffness or tenderness, and musculo-skeletal signs (decreased range of motion, point tenderness etc).
WAD Grade III	Complaint of pain, stiffness or tenderness and neurological signs (decreased or absent deep tendon reflexes, weakness and senory deficits). Could also have musculo-skeletal signs.
WAD Grade IV	Fracture or dislocation

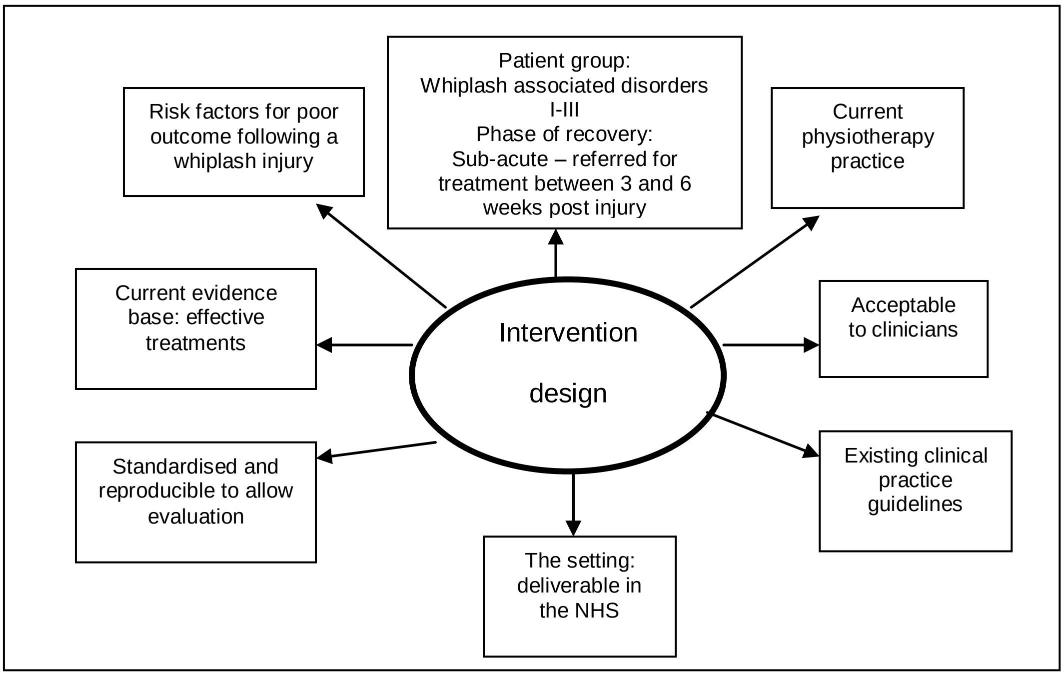
We have designed and completed recruitment to a trial (Managing Injuries of the Neck Trial HTA number 02/35/02) that tested a stepped care approach. Having recruited over 3,000 patients, it is the largest definitive trial of whiplash treatments undertaken to date. The design of the study is described elsewhere (2). Briefly, a stepped care approach is one which matches the intervention to the needs of the patient, providing more intensive treatments to those with more severe clinical presentation (3). Step one investigated educational interventions in a National Health Service (NHS) Emergency Department (ED) setting (n=3533). In step two, we investigated the effectiveness of additional physiotherapy for those with ongoing symptoms three to six weeks after their injury (n=599) by randomising patients to receive a physiotherapy intervention or a control intervention (an advice session). The aim was to prevent the development of late whiplash syndrome which is defined as the presence of pain, restriction of motion or other symptoms six months or more after a whiplash injury, sufficient to hinder return to normal activities such as driving, usual occupation and leisure (1). LWS is reported in between 16% (4) and 71% (5) of people experiencing a whiplash injury.

Physiotherapy is a complex intervention (6). A trial of any complex intervention should include a description of the intervention and its components (as well as the rationale for their inclusion) as an essential step of reporting (6). The purpose of this paper is to describe the rationale for the treatment selections used in the physiotherapy intervention tested, and to describe the treatments delivered.
Development of the physiotherapy intervention

We used a number of principles to develop the physiotherapy package:
[1] The need to design an intervention that was reflective of best practice in the UK-NHS and was consistent with high quality, evidence based clinical guidelines.
[2] To ensure the intervention was informed by the evidence base and discouraged the use of treatments for which there is evidence of no effect. Evidence considered comprised both randomised controlled trials, and observational studies of risk factors for poor recovery.
[3] To ensure the intervention could be delivered within the context of the UK-NHS in terms of staffing and time, and respected physiotherapist's autonomy in clinical decision making.
[4] To ensure the intervention was documented to a standard that promoted consistency in delivery, and would enable replication.

This was achieved by a triangulation of methods (shown in Figure 1) – including systematic reviews of the randomised controlled trials and observational studies, a review of clinical guidelines, expert peer review and piloting to test the feasibility and acceptability of the intervention.

Figure 1 Intervention design considerations



Current practice:
Physiotherapy is a common treatment for a whiplash injury but there is no published information that outlines the treatments most commonly used by physiotherapists or the amount and frequency of physiotherapy treatment provided in the UK. Spitzer et al (1) suggests the following treatments are used in

the treatment of whiplash injuries: manipulation, mobilisation, exercises, postural advice, relaxation, traction, heat, ice, massage, acupuncture and electrotherapy. These are the types of treatments available to Physiotherapists who practice in the UK and reflect the types of treatments upon which recommendations have been made in published clinical guidelines (7).

Evidence base:

Randomised controlled trials (RCTs)

Over 10 years ago, the Quebec Task Force identified the lack of good quality trial evidence to inform recommendations for physiotherapy practice in whiplash management (1). In 2007 the field had not moved much further forward - the Cochrane review of conservative treatments for whiplash (8) concluded that there was no clear evidence to recommend the best treatment for whiplash injuries. However, there was a trend that active interventions were more effective than passive interventions. Two studies supported the use of exercise to reduce pain intensity (Rosenfeld et al (9); Schnabel et al (10)) although there is no direct comparative evidence to inform the exact choice of exercise type. Studies have reported favourable outcomes for manual therapy (11, 12), but are methodologically weak, with only short term follow up and no patient-rated outcomes. Provinciali et al (13) describe an intervention of relaxation and postural training, psychological support, eye fixation exercises and manual treatment, which resulted in quicker return to work. The intervention was not described sufficiently to allow detailed scrutiny of the components.

Although weak, the evidence suggests that interventions that comprise exercise, manual therapy and psychological approaches are most likely to be successful. Similar observations have been made in chronic neck pain treatments (14) with the strongest evidence being for the combination of mobilisation and exercises. No evidence was found in randomised controlled trials evaluating the use of electrotherapy, acupuncture, massage, traction, heat and cold to support their inclusion in the intervention.

Observational studies

There is an extensive literature of observational studies related to whiplash and these were explored to assist in the identification of potentially modifiable risk factors for poor outcome (treatment targets). We carried out two systematic reviews investigating risk factors for the development of chronic whiplash symptoms. The first review focused on physical risk factors (15) and highlighted initial pain intensity and functional impairment as risk factors. Whilst the evidence was less extensive, range of movement (ROM) has been shown to be predictive of chronicity. People with persisting symptoms demonstrate at least a 25% reduction in ROM when compared to normal subjects (16). Deficits in cervical joint position sense (17) and muscle function (18, 19) has been also identified both acute and chronic subjects with whiplash associated disorders (WAD) suggesting that exercises that address these factors may be beneficial.

The second review focused on psychological risk factors (20) and identified low levels of self-efficacy and an elevated post traumatic stress response (measured on the Impact of Event Scale (21)) as risk factors for poor outcome. Fear avoidance, catastrophising, coping and distress management were also identified as potential treatment targets (evidence summarised in Williamson et al (20)).

Clinical guidelines and expert opinion

Our physiotherapy intervention was developed in 2005 and, at that time the only published guidelines available were those by Scholten-Peeters et al (22). These guidelines emphasised the importance of ROM exercises, muscle retraining, postural retraining and encouragement of an incremental increase in activities. There was also endorsement of the need to address the psychological risk factors. Since then, the Chartered Society of Physiotherapy (CSP) has also produced clinical guidelines for the management of WAD which include endorsement for manual therapy techniques (both articular and soft tissue techniques) (7). The intervention is consistent with these guidelines. The targeting of the psychological factors was also supported by a recently published Delphi survey (23).

The MINT intervention:

We adopted a risk factor modification approach. Having identified potential risk factors for poor recovery after the injury as well as potentially effective treatments, we utilised a framework common in physiotherapy – assessment of a range of risk factors (history, physical examination, psychological factors) to identify treatment targets and then matched treatments to the risk factor profile (detailed in Table 2). The intervention consisted of an assessment and up to six sessions of treatment over an eight week period, based on our knowledge of patterns of physiotherapy provision in the UK. If further treatment was deemed essential, this was permitted but was quantified as an additional resource use. Patients were to be offered an appointment within 14 days of referral if possible.

A standardised assessment form was used to record risk factors and treatment targets. This included several questions to elicit health beliefs and the short version of the survey of pain attitudes questionnaire (24). A treatment planner was devised to encourage consistency in clinical decision making by facilitating physiotherapists toward identifying risk factors/treatment targets. The treatment planner encouraged an integrated approach to the management of both physical and psychological factors utilising three main components; [1] manual therapy, [2] exercise and [3] psychological strategies and self-management advice.

Manual Therapy:
The Maitland approach (25) was used because it is the most widely practiced in the UK and is taught in all undergraduate courses. A small number of other related techniques (NAGS and SNAGS (26)) and soft tissue techniques were also included as they are frequently used by physiotherapists in the UK. Treatments were aimed at the cervical, upper thoracic and shoulder region. Treatment of the upper thoracic spine was included because 15-20% of people experience thoracic spine pain after whiplash (27). The following techniques were permitted:
Cervical spine mobilisations i.e. Maitland techniques Grade I – IV
Thoracic spine mobilisations i.e. Maitland techniques Grade I – IV
Thoracic spine manipulation i.e. Maitland techniques Grade V
Shoulder-complex mobilisations

Cervical spine grade V manipulations were not included. Although the risk of adverse event are relatively small, vertebral artery dissection is a potential complication of manipulation (28) and it has been recognised that pre-manipulative testing may fail to identify those at risk (29). There are reports of vertebral artery damage in patients with minor whiplash injuries making this patient group higher risk for an adverse reaction to manipulation (30-32). Whilst we recognise that the safety of manipulation is contested from both sides, we decided that the potential benefit did not outweigh the risk that maybe involved.

Exercise therapy:
The majority of exercises included in the intervention were general exercises for the cervical, thoracic and shoulder regions as aimed at the restoration of movement. Two exercises were also included to improve postural muscle control in standing (upper cervical flexion exercises and scapular setting) as well as a simple proprioception-enhancing exercise.

Exercises were prescribed according to participant's risk profile, and exercises were reviewed regularly and progressed to facilitate return to activities and work. A graded approach was encouraged to avoid flare ups and skills such as goal setting and pacing were taught to assist in this process (33, 34). Exercise sheets were provided to help standardise the exercises used.

Psychological strategies and self-management advice:
The third aspect of the physiotherapy intervention involved psychological strategies and self-management advice. Simple strategies for dealing with psychological factors were to be delivered along side the other elements of the intervention. Although this was not a cognitive behavioural (CB) intervention, a CB Therapist was consulted to develop these strategies which included the use of specific questioning techniques to identify treatment targets and included questioning about beliefs about pain, injury and recovery and coping strategies used. Specific approaches for the management of identified treatment targets included goal setting and pacing, education about pain and recovery, facilitation of effective coping strategies and reassurance. Physiotherapists also provided self-management advice covering aspects such as posture and positioning.

A clinical psychologist was consulted to develop guidelines for managing patients who may be suffering from a stress reaction. This included how to identify these patients and the action to be taken (i.e. where to refer patients). It was emphasised that it was important that their physiotherapy management continued where possible. Guidelines were also developed for advice on managing mild travel anxiety with an emphasis on when it was appropriate to refer these patients on for management.

More information (including the assessment form and treatment planner) is available at: www.warwick.ac.uk/go/whiplash

Pilot Study:
The next step was to conduct a pilot study to determine acceptability of the intervention to clinicians and feasibility in an NHS setting. The pilot ran from May to September 2005 and involved three senior outpatient physiotherapists. The physiotherapists attended a half day training session and each received a comprehensive manual describing the intervention. The physiotherapy intervention was then delivered to seven patients who fulfilled the criteria for the trial. The treating physiotherapists provided their feedback on the training and their experiences of the intervention. The main feedback from the physiotherapists was that they lacked confidence in the use of the psychological strategies. This was not unexpected as this was the element of the treatment package that was most unfamiliar to them. More time was allocated to this in subsequent training sessions. An NHS patient user group was also consulted.

Peer review:
Following the pilot study minor modifications were made to the intervention manual and this was then reviewed by two experienced researchers (C.M., M.S.) (one of whom was involved in research into WAD) and an experienced senior physiotherapist (H.W.). Minor changes were made in response to their feedback.

Physiotherapist training and support:
All physiotherapists received training in the package. Training was held over one or one and a half days depending on the number of physiotherapists attending. Training was provided by two senior physiotherapists working on MINT and a third physiotherapist who was also a qualified CB therapist and had extensive experience in providing training for physiotherapists in CB skills. Physiotherapists were provided with a training manual that contained a detailed account of the trial background, procedures, physiotherapy assessment, treatment planning and treatments. Training for the manual therapy and exercise components of the intervention focused on the types of treatments that were permissible in the intervention as these components were felt to reflect standard physiotherapy practice. More specific training was provided in certain aspects of the psychological intervention such as identifying post traumatic stress reactions or managing mild travel anxiety. However, the majority of the psychological component was based on a biopsychosocial model which the majority of physiotherapists were familiar with. Case studies were discussed to ensure the physiotherapists were familiar with the assessment form, treatment planner and integration of the 3 components of the intervention.

Throughout the trial regular contact was made with the physiotherapists to provide any support that was needed. Quality control visits were carried out by a health professional who was trained to assess that the key components of the intervention were delivered and to ensure the smooth implementation of the intervention. An update evening was held to reinforce the key aspects of the intervention. The treating physiotherapists completed a treatment log for each patient to record the treatments delivered and to monitor attendance rates.

Table 2 Summary of risk factor assessment and intervention

Risk factor	**Treatment aim**	**Method of assessment**	**Interventions to modify risk factors**
Physical Risk Factors			
1. Restricted range of movement	Restore range of movement	Subjective report from the patient. Objective measurement of active cervical, thoracic and shoulder range of movement. Assessment of passive joint movements including physiological and accessory movements.	Manual therapy ROM Exercises Paced return to functional activities Education re: Active involvement of the patient in their recovery Setting baseline and pacing
2. High pain intensity	Reduce pain	Subjective report by patient regarding sleep, ability to control pain, ability to function. Visual analogue scale	1. Education re: Pain mechanisms Activity modification and pacing Relaxation Symptom control e.g. use of heat/cold, medication Posture 2. Reassurance 3. Manual therapy
Psychological risk factors			
1. Self-efficacy	Increase self-efficacy through equipping the patient with effective coping skills.	Questioning about their ability to cope with the injury/pain or concerns about their condition. Survey of Pain Attitudes (SOPA)	Reassurance and encouragement Achievement of goals through realistic goal setting and effective pacing Educate/discuss ways of coping e.g. heat, cold, positioning, relaxation techniques, exercises, pacing
2. Beliefs about pain and injury	Modify/address unhelpful beliefs	Questioning of patient about their expectations of treatment, ways they cope, the meaning of pain, reasons for not returning to activities, concerns about their condition expectations for recovery. SOPA General observation e.g. looking for reluctance to move which may mean they are fear avoidant	Address unhelpful beliefs about pain/injury: education about pain mechanisms/meaning of pain, role of physiotherapy in their recovery, ways to control pain Address fear avoidance: education re: fear avoidance cycle, exercises, manual therapy Reassurance Teach pacing and goal setting
3. Anxiety and stress	Reduce psychological distress related to symptoms. Facilitate reduction of post-traumatic stress through referral to appropriate agencies	Questioning of patient .e.g sleep patterns, ability to drive. General observation for signs of anxiety e.g. patient is agitated or on edge	Distress related to symptoms: Education and advice re: symptom management Reassurance Relaxation Post-traumatic stress: Refer to G.P. or psychologist for appropriate management

Results

Participating physiotherapists:
The physiotherapy intervention was delivered from January 2006 to January 2008. 55 Physiotherapists from 12 NHS hospital trusts (16 physiotherapy departments) attended training. All of the physiotherapists were senior clinicians with the majority being a Senior II or Senior I (Whitley grading). Physiotherapists attending the training reported that they had been qualified for a range of 2 – 33 years (Median = 6.5 years, IQR=4.5 -18) with years of experience working in outpatients ranging from 1-28 (Median = 4.0, IQR=3.0-11.25).

Treatments delivered:
599 patients (WAD grade I n=84(14%), WAD grade II n=442 (74%), WAD grade III n=73 (12%)) took part in the second step of MINT with 300 patients randomly selected to receive the physiotherapy intervention (299 patients were randomised to receive a control intervention). Attendance rates and the number of treatment sessions for which patients attended are shown in Table 3. In Table 3 patients are classified into four categories. Patients were classified as partial completers if they attended for the assessment and at least one treatment session. Treatment was terminated when the patient failed to attend for subsequent treatment. Patients were classified as having completed treatment if the treatment was completed as intended and discharge was by mutual agreement between the physiotherapist and patient. The number of treatments delivered (excluding the assessment) ranged from 0 to 23 (Median = 3.0, IQR = 1.0-5.0) with 14 (4.7%) patients receiving greater than the recommended six treatment sessions. The time allocated to the assessment session was between 40 and 60 minutes with the majority of centres allocating 60 minutes (n= 8, 66%). Treatment sessions ranged from 20 to 30 minutes with the majority of centres allocating 30 minutes (n=9, 75%). The timing for delivery of the physiotherapy intervention is included in Table 4. 63% of patients attending for the physiotherapy intervention were seen within 14 days of referral. The majority of patients (91%) were seen within 28 days of referral. 62% of patients completed their treatment in the recommended eight weeks (56 days) and 87% of patients completed within 12 weeks (84 days).

Table 3 Physiotherapy attendance

Physiotherapy Package (n=300)	**Number of participants (%)**	**Number of treatments (excluding assessment)**
Failed to attend any appointments	34(11%)	N/A
Attended for assessment only*	26 (9%)	N/A
Partial completion of treatment	45 (15%)	Median =2, IQR= 1-3 Range=1-6
Completed treatment	201(67%)	Median = 4, IQR = 2-6 Range=0-23

* 6 participants only attended for initial assessment and then no further treatment was required so these participants are also included in the completed physiotherapy package category

Table 4 Timing of delivery of interventions

Days post injury when referred for treatment (n=300)	Median=31 (IQR=24 -39) Range=7–74
Physiotherapy waiting times - days from date of referral to first appointment* (n=286)*	Median=12, IQR=7-19, Range=0-129
Days post injury until first appointment (n=286)*	Median=45, IQR = 35-55 Range=15–177
Time from initial to final appointment (days) (n=246)**	Median=45, IQR=28-71 Range=0-428

* Missing data is from participants who were unable to be contacted or failed to respond to requests to contact the physiotherapy departments to make initial appointments.
** Includes data from partial completers or completers of treatments only.

Information about the content of the treatment sessions was available for 259 patients of the 266 patients who attended at least one appointment. Seven patients were assessed but did not receive any treatment during this session. Of the 259 patients, the majority of the patients received a combination of manual therapy, exercises and psychological strategies and self-management advice with the next most common combination of treatment being exercises and psychological strategies and self-management advice (See Table 5). Psychological strategies and self-management advice were used with the majority of patients (n=246, 95%). Those most frequently included were advice regarding posture and positioning (76%), reassurance (75%), pain education (56%), advice on return to work or activities (56%) and goal

Table 5 Types of treatments delivered in the physiotherapy package (n=259)

Type of treatment delivered		**Number of patients receiving the treatment (%)**
Combinations of treatments delivered	Manual therapy, exercises and psychological strategies	190 (73%)
	Exercises and psychological strategies	45 (18%)
	Manual therapy and psychological strategies	10 (4%)
	Manual therapy and exercises	9 (4%)
	Manual therapy only	2 (1%)
	Exercises only	2 (1%)
	Psychological strategies only	1 (0.5%)
Manual therapy techniques	Soft tissue techniques	123 (48%)
	Maitland cervical mobilisations	123 (48%)
	NAGS and SNAGS (cervical or thoracic)	86 (33%)
	Maitland thoracic mobilisations	71 (27%)
	Other manual therapy	42(16%)
	Shoulder mobilisations	15 (6%)
	Thoracic manipulation	5 (2%)
Exercises	Cervical ROM exercises	244(94%)
	Cervical or scapular stability exercises	118 (46%)
	Thoracic ROM exercises	106 (41%)
	Shoulder ROM exercises	88 (34%)
	Other exercises	69 (27%)
	Proprioception exercises	28 (11%)
Psychological strategies and self-management advice	Advice re: posture and positioning	194 (76%)
	Reassurance	194(75%)
	Pain education	144 (56%)
	Advice re: return to work or activities	145 (56%)
	Goal setting or pacing	119 (46%)
	Advice re: medication and symptomatic control	87 (34%)
	Relaxation	56 (22%)
	Advice re: travel anxiety	27 (10%)
	Referral to GP/Psychologist for stress reaction	10 (4%)

setting and pacing (46%). 10% of patients also received advice on travel anxiety with a small number of patients (4%) being referred on with a suspected stress reaction. Almost all patients received guidance on some form of exercises (n= 246, 95%) with the most common being cervical ROM exercises. Manual therapy was used to a lesser degree (n=211, 81%) with soft tissue techniques and Maitland cervical mobilisations being used most frequently. Two protocol violations were reported which involved the use of electrotherapy. Both of the patients received the treatment once.

Discussion

We have designed and tested a physiotherapy intervention for the early management of whiplash that has the potential to improve clinical outcomes. The strengths of the intervention are that it was informed by a variety of sources including the current evidence base, published guidelines and feedback from NHS clinicians. Using a risk factor approach has enabled us to provide an individually tailored programme for each patient that was based on the best evidence available in regard to known risk factors and treatment approaches. Physiotherapy practice is complex and published research often fails to sufficiently describe interventions making it difficult to translate findings into clinical practice. This has been avoided by presenting a detailed overview of the intervention.

The pragmatic approach taken resulted in the challenge of implementing the intervention within the constraints of busy NHS physiotherapy departments. Departments attempted to see patients within 14 days of referral but this was not always achieved due to the lack of appointments. Despite this the intervention has been successfully implemented alongside the challenges of waiting list pressures and staff shortages with the majority of patients successfully receiving the physiotherapy package as intended. All the physiotherapists participating in the trial received training. However, minimal training would be required to take this approach into clinical practice. The manual therapy and exercises were standard physiotherapy practice. Most of the psychological aspects were also familiar to the treating physiotherapists as they are in line with the biopsychosocial model of management that has been promoted for managing LBP for some time now. Some training may be required regarding the integration of psychological component with manual therapy and exercises, post traumatic stress and travel anxiety but this could easily be included in a department in-service training programme.

Some of the participating physiotherapists had expressed concern that the recommended six treatments would not be adequate. For the majority of patients it was sufficient as the average number of treatments for those completing treatment was around four treatments with only 14 patients requiring greater than six treatments. 67% of patients completed their treatment in the recommended eight weeks which may have been influenced by lack of availability of follow up appointments. However, it may indicate that these patients benefit from more prolonged contact with a physiotherapist than anticipated (but not necessarily more treatment).

The treatments delivered were dependent on the patient's risk factor profile. One shortcoming of this report was that the assessment forms were not collected for all patients to check that the treatments were matched to risk factors. The data about the treatments delivered was based on information supplied by the treating physiotherapists. This method has shortcomings as it relies on the treating physiotherapist to truthfully report their treatments and it may be argued that physiotherapists would only report those treatments carried out within the trial protocol. However, a proportion of patient assessments were assessed as part of the quality control process and no major problems were identified. From the information gathered the majority of patients received treatments from the three main components. One surprising finding was the frequent use of soft tissue techniques as part of manual therapy treatments. Unfortunately, information regarding the specific techniques used (e.g. trigger point releases, soft tissue massage, specific soft tissue mobilisations etc) was not collected but this suggests that physiotherapists feel these techniques are effective in managing WAD.

The potential for patients to experience a stress reaction following a whiplash injury is one factor that differentiates this population from those related to other painful conditions. The proportion of patients identified with a suspected stress reaction was similar to that reported by Mayou and Bryant (35) who reported 5% of their sample being classified as having post traumatic stress disorder. A small number of patients also received advice on travel anxiety which may represent a very mild form of stress reaction. Although these issues only affected a small proportion of patients their consideration is important.

Conclusion

This paper has presented the development and delivery of a physiotherapy intervention for the early management of whiplash injuries which is being evaluated as part of a multi-centre RCT. If this physiotherapy intervention is found to be effective in improving clinical outcomes when compared to an advice session then further dissemination of the physiotherapy intervention is recommended.

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Ethical approval

Ethical approval for this study was given by Trent Multi-Centre Research Ethics Committee (MREC 04/4/003).

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Conflicts of interest

No conflict of interest to declare.

References:

1. Spitzer W, Skovron M, Salmi L, Cassidy J, Duranceau J, Suissa S, et al. Scientific monograph of the Quebec Task Force on Whiplash-Associated Disorders: redefining "whiplash" and its management. Spine 1995;20:1S-73S.
2. Lamb S, Gates S, Underwood M, Cooke M, Ashby D, Szczepura A, et al. Managing Injuries of the Neck Trial (MINT): design of a randomised controlled trial of treatments for whiplash associated disorders. BMC Musculoskelet Disord 2007;8:7.
3. Von Korff M, Moore J. Stepped care for back pain: activating approaches for primary care. Ann Intern Med 2001;134:911-7.
4. Pennie B, Agambar L. Patterns of injury and recovery in whiplash. Injury 1991;22:57-9.
5. Karlsborg M, Smed A, Jespersen H, Stephensen S, Cortsen M, Jennum P, et al. A prospective study of 39 patients with whiplash injury. Acta Neurol Scand 1997;95:65-72.
6. MRC. A framework for development and evaluation of RCTS for complex interventions to improve health.2000.
7. Moore A, Jackson A, Jordan J, Hammersley S, Hill J, Mercer C, et al. Clinical guidelines for the physiotherapy management of whiplash associated disorder. London: Chartered Society of Physiotherapy; 2005.
8. Verhagen A, Scholten-Peeters G, van Wijngaarden S, de Bie R, Bierma-Zeinstra S. Conservative treatments for whiplash. Cochrane Database Syst Rev 2007(2):CD003338.

9. Rosenfeld M, Gunnarsson R, Borenstein P. Early intervention in whiplash-associated disorders: a comparison of two treatment protocols. Spine 2000;25:1782-7.
10. Schnabel M, Ferrari R, Vassiliou T, Kaluza G. Randomised, controlled outcome study of active mobilisation compared with collar therapy for whiplash injury. Emerg Med J
2004;21:306-10.
11. Mealy K, Brennan H, Fenelon G. Early mobilization of acute whiplash injuries. Br Med J (Clin Res Ed) 1986;292:656-7.
12. McKinney L, Dornan J, Ryan M. The role of physiotherapy in the management of acute neck sprains following road-traffic accidents. Arch Emerg Med 1989;6:27-33.
13. Provinciali L, Baroni M, Illuminati L, Ceravolo M. Multimodal treatment to prevent the late whiplash syndrome. Scand J Rehabil Med 1996;28:105-11.
14. Gross AR, Kay T, Hondras M, Goldsmith C, Haines T, Peloso P, et al. Manual therapy for mechanical neck disorders: a systematic review. Man Ther 2002;7:131-49.
15. Williams M, E. W, Gates S, Lamb SE, Cooke M. A systematic literature review of physical factors and the development of late whiplash syndrome. Spine 2007;32:E764-E80.
16. Dall'Alba P, Sterling M, Treleaven J, Edwards S, Jull G. Cervical range of motion discriminates between asymptomatic persons and those with whiplash. Spine 2001;26:2090-4.
17. Treleaven J, Jull G, Sterling M. Dizziness and unsteadiness following whiplash injury: characteristic features and relationship with cervical joint position error. J Rehabil Med 2003;35:36-43.
18. Sterling M, Jull G, Vicenzino B, Kenardy J, Darnell R. Development of motor system dysfunction following whiplash injury. Pain 2003;103:65-73.
19. Jull G, Kristjansson E, Dall'Alba P. Impairment in the cervical flexors: a comparison of whiplash and insidious onset neck pain patients. Man Ther 2004;9:89-94.
20. Williamson E, Williams M, Gates S, Lamb S. A systematic literature review of psychological factors and the development of late whiplash syndrome. Pain 2008;135:20-30.
21. Horowitz M, Wilner N, Alvarez W. Impact of Event Scale: a measure of subjective stress. Psychosom Med 1979;41:209-18.
22. Scholten-Peeters G, Bekkering G, Verhagen A, van Der Windt D, Lanser K, Hendriks E, et al. Clinical practice guideline for the physiotherapy of patients with whiplash-associated disorders. Spine 2002;27:412-22.
23. Miró J, Nieto R, Huguet A. Predictive factors of chronic pain and disability in whiplash: A Delphi poll. Eur J Pain 2008;12:30-47.
24. Jensen M, Keefe F, Lefebvre J, Romano J, Turner J. One- and two-item measures of pain beliefs and coping strategies. Pain 2003;104:453-69.
25. Maitland G, Hengeveld E, Banks L, English K. Maitland’s vertebral manipulation. 6th Edition ed. Oxford.: Butterworths Heinemann; 2001.
26. Mulligan B. Manual therapy: NAGS, SNAGS, MWMS etc. Wellington: Plane View Science Ltd; 1995.
27. Mayou R, Bryant B. Psychiatry of whiplash neck injury. Br J Psychiatry 2002;180:441-8.
28. Di Fabio R. Manipulation of the cervical spine: risks and benefits. Phys Ther 1999;79:50-65.
29. Refshauge K, Parry S, Shirley D, Larsen D, Rivett D, Boland R. Professional responsibility in relation to cervical spine manipulation. Aust J Physiother 2002;48:171-9; discussion 80-5.
30. Norris JW, Beletsky V, Nadareishvili ZG. Sudden neck movement and cervical artery dissection. The Canadian Stroke Consortium. CMAJ 2000;163:38-40.
31. De Decker K, Van Havenbergh T, D'Archambeau O, Jorens P. Basilar artery thrombosis in a trauma patient. Case report and review of the literature. Resuscitation 2003;59(1):147-54.
32. Friedman D, Flanders A, Thomas C, Millar W. Vertebral artery injury after acute cervical spine trauma: rate of occurrence as detected by MR angiography and assessment of clinical consequences. AJR Am J Roentgenol 1995;164:443-7; discussion 8-9.
33. Harding V. Minimising chronicity after whiplash injury. In: Gifford L, editor. Topical Issues in Pain Physiotherapy Pain Association Year Book. Cornwall: NOI Press; 1998. p. 105-14.
34. Moseley L, Butler, D. Explain Pain. Adelaide: NOI Australasia Pty Ltd; 2003.
35. Mayou R, Bryant B. Outcome of 'whiplash' neck injury. Injury 1996;27:617-23.

Appendix 3: Research clinic questionnaire

Section 1:

Please place a cross in one box only.

1. **Although you will be given one of the treatments by chance, if you could choose which treatment to have what would be your preference?**

One session of advice with a physiotherapist
I don't mind which treatment I receive
A course of physiotherapy

2. **How long do you think it will take for you to recover from your neck injury?**

In the next 2 weeks
2—8 weeks
2—6 months
6—12 months
More than a year
I am not sure I will recover

Section 3: This section helps us to understand how much your neck pain has affected your ability to manage everyday activities. We realise that you may feel that more than one statement may relate to you, but please place a cross in the box for the one choice which most closely describes your problem right now.

1. Pain Intensity

A. I have no pain at the moment …………………………………………………. ☐ 1

B. The pain is mild at the moment ……………………………………………….. ☐ 2

C. The pain comes and goes and is moderate……………………………………. ☐ 3

D. The pain is moderate and does not vary much ……………………………….. ☐ 4

E. The pain is severe but comes and goes……………………………………….. ☐ 5

F. The pain is severe and does not vary much …………………………………… ☐ 6

2. Personal Care (washing, dressing etc.)

A. I can look after myself without causing extra pain …………………………….. ☐ 1

B. I can look after myself normally but it causes extra pain ……………………... ☐ 2

C. It is painful to look after myself and I am slow and careful …………………… ☐ 3

D. I need some help, but manage most of my personal care…………………… ☐ 4

E. I need help every day in most aspects of self-care…………………………… ☐ 5

F. I do not get dressed, I wash with difficulty and stay in bed …………………… ☐ 6

3. Lifting

A. I can lift heavy weights without extra pain ……………………………………… ☐ 1

B. I can lift heavy weights, but it causes extra pain ……………………………….. ☐ 2

C. Pain prevents me from lifting heavy weights off the floor but I can if they are conveniently positioned, for example on a table ....………………… ☐ 3

D. Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned ……………...................……………….. ☐ 4

E. I can lift very light weights ……………………………………………………... ☐ 5

F. I cannot lift or carry anything at all ……………………………………………….. ☐ 6

4. Reading

A. I can read as much as I want to with no pain in my neck …………………….. ☐ 1

B. I can read as much as I want with slight pain in my neck …………………….. ☐ 2

C. I can read as much as I want with moderate pain in my neck ……………….. ☐ 3

D. I cannot read as much as I want because of moderate pain in my neck …… ☐ 4

E. I cannot read as much as I want because of severe pain in my neck ………. ☐ 5

F. I cannot read at all ………………………………………………………………… ☐ 6

5. Headache

A. I have no headaches at all ……………………………………………………….. ☐ 1

B. I have slight headaches which come infrequently …………………………….. ☐ 2

C. I have moderate headaches which come infrequently ……………………….. ☐ 3

D. I have moderate headaches which come frequently ………………………….. ☐ 4

E. I have severe headaches which come frequently ……………………………... ☐ 5

F. I have headaches almost all the time …………………………………………… ☐ 6

6. Concentration

A. I can concentrate fully when I want to with no difficulty ………………………. ☐ 1

B. I can concentrate fully when I want to with slight difficulty …………………… ☐ 2

C. I have a fair degree of difficulty in concentrating when I want to …………… ☐ 3

D. I have a lot of difficulty in concentrating when I want to ……………………… ☐ 4

E. I have a great deal of difficulty in concentrating when I want to ……………. ☐ 5

F. I cannot concentrate at all ……………………………………………………….. ☐ 6

7. Work

A. I can do as much work as I want to …………………………………………….. ☐ 1

B. I can only do my usual work, but no more ……………………………………... ☐ 2

C. I can do most of my usual work, but no more ………………………………… ☐ 3

D. I cannot do my usual work ……………………………………………………….. ☐ 4

E. I can hardly do any work at all …………………………………………………… ☐ 5

F. I cannot do any work at all ……………………………………………………….. ☐ 6

8. Driving

A. I can drive my car without neck pain …………………………………………….. ☐ 1

B. I can drive my car as long as I want with slight pain in my neck …………….. ☐ 2

C. I can drive my car as long as I want with moderate pain in my neck ……….. ☐ 3

D. I cannot drive my car as long as I want because of moderate pain in my neck ……………………………………………………………………………………………. ☐ 4

E. I can hardly drive my car at all because of severe pain in my neck ………… ☐ 5

F. I cannot drive my car at all ……………………………………………………….. ☐ 6

9. Sleeping

A. I have no trouble sleeping ………………………………………………………….. ☐ 1.

My sleep is slightly disturbed (less than 1 hour sleepless) …………………….. ☐ 2

C. My sleep is mildly disturbed (1—2 hours sleepless) ………………………….. ☐ 3

D. My sleep is moderately disturbed (2—3 hours sleepless) ……………………. ☐ 4

E. My sleep is greatly disturbed (3—5 hours sleepless) …………………………. ☐ 5

F. My sleep is completely disturbed (5—7 hours sleepless) …………………….. ☐ 6

10. Recreation

A. I am able to engage in all recreational activities with no pain in my neck at all ……………………………………………………………….. ☐ 1

B. I am able to engage in all recreational activities with some pain in my neck ………………………………………………………………………. ☐ 2

C. I am able to engage in most, but not all recreational activities because of pain in my neck ……………………………………………………………. ☐ 3

D. I am able to engage in a few of my usual recreational activities because of pain in my neck ……………………………………………………………. ☐ 4

E. I can hardly do any recreational activities because of pain in my neck …….. ☐ 5

F. I cannot do any recreational activities at all …………………………………… ☐ 6

Section 3: This section is about the severity of your neck problem:

For the next three questions please circle the number which represents the severity of your neck pain.

1. In the last week, how bad has your worst neck pain been on a scale of 0-10 where 0 is 'no pain' and 10 is 'as bad as a pain could be'?

2. In the last week, on average how bad has your neck pain been on a scale of 0-10 where 0 is 'no pain' and 10 is 'as bad as a pain could be'?

0 1 2 3 4 5 6 7 8 9 10

3. How would you rate your neck pain today on a scale of 0-10 where 0 is 'no pain' and 10 is 'as bad as a pain could be'?

0 1 2 3 4 5 6 7 8 9 10

Section 4: This section is about your neck movement:

For the next two questions please circle the number which represents your ability to move your neck.

1. How much are you able to turn your neck today on a scale of 1 to 5 where 1 is 'unable to turn' and 5 is 'able to turn normally'?

1 2 3 4 5

2. How much are you able to look up or down today on a scale of 1 to 5 where 1 is 'unable to look up or down' and 5 is 'able to look up or down normally'?

1 2 3 4 5

Section 5: This section is to determine what you believe about your neck pain. Here are some of the things which other patients have told us about their pain.

For each statement please circle the number from 0 to 6 to say how much physical activities such as bending lifting walking or driving affect or would affect your neck pain.

	Completely disagree			Unsure			Completely agree
1. Physical activity makes my pain worse	0	1	2	3	4	5	6
2. Physical activity might harm my neck	0	1	2	3	4	5	6
3. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6
4. I cannot do physical activities which (might) make my pain worse	0	1	2	3	4	5	6

For each statement please circle the number from 0 to 6 to say how much you agree with these statements.

	Completely disagree			Unsure			Completely agree
5. When you have injured your neck it is best to exercise your neck to help you to recover.	0	1	2	3	4	5	6
6. I feel I am able to cope with my neck problem even when it is painful.	0	1	2	3	4	5	6

Section 6 : We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

0= Not at all
1= To a slight degree
2= To a moderate degree
3= To a great degree
4= All the time

When I'm in pain ...

1. I worry all the time about whether the pain will end
2. I feel I can't go on
3. It's terrible and I think it's never going to get any better
4. It's awful and I feel that it overwhelms me
5. I feel I can't stand it anymore
6. I become afraid that the pain will get worse
7. I keep thinking of other painful events
8. I anxiously want the pain to go away
9. I can't seem to keep it out of my mind
10. I keep thinking about how much it hurts
11. I keep thinking about how badly I want the pain to stop
12. There's nothing I can do to reduce the intensity of the pain
13. I wonder whether something serious may happen

Section 7: Individuals who experience pain have developed a number of ways to cope, or deal with their pain. These include saying things to themselves when they experience pain, or engaging in different activities. Below is a list of things that people have reported doing when they feel pain. For each activity, please indicate, using the scale below, how much you engage in that activity when you feel pain, where 0 indicates you never do that when you are experiencing pain, a 3 indicates you sometimes do that when you are experiencing pain, and a 6 indicates you always do it when you are experiencing pain. Remember, you can use any along the scale.

0	1	2	3	4	5	6
Never do			Sometimes do that			Always do that

1. I think of things I enjoy doing
2. I just think of it as some other sensation, such as numbness
3. It is terrible and I feel it is never going to get any better
4. I don't pay any attention to it
5. I pray for the pain to stop
6. I tell myself I can't let the pain stand in the way of what I want to do
7. I do something active, like household chores or projects

Section 8: Below is a list of comments made by people after stressful life events. Please check each item indicating how frequently these comments were true for you in regard to your recent neck injury during the last 7 days. If they did not occur during that time, please mark the “not at all” column.

	Not at all	Rarely	Sometimes	Often
1. I thought about it when I didn't mean to.	0	1	2	3
2. I avoided letting myself get upset when I thought about it or was reminded of it	0	1	2	3
3. I tried to remove it from memory	0	1	2	3
4. I had trouble falling asleep or staying asleep, because of the pictures or thoughts about it that came into my head	0	1	2	3
5. I had waves of strong feelings about it	0	1	2	3
6. I had dreams about it	0	1	2	3
7. I stayed away from reminders of it	0	1	2	3
8. I felt as if it hadn’t happened or it wasn’t real	0	1	2	3
9. I tried not to talk about it	0	1	2	3
10. Pictures about it popped into my head	0	1	2	3
11. Other things kept making me think about it	0	1	2	3
12. I was aware that I still had a lot of feelings about it, but I didn’t try to deal with them	0	1	2	3
13. I tried not to think about it	0	1	2	3
14. Any reminder brought back feelings about it	0	1	2	3
15. My feelings about it were kind of numb	0	1	2	3

Section 9: We are interested in how you feel about the following statements. Read each statement carefully. Indicate how you feel about each statement.

1= Very strongly disagree
2= Strongly disagree
3= Mildly disagree
4= Neutral
5= Mildly agree
6= Strongly agree
7= Very strongly agree

1. There is a special person who is around when I am in need
2. There is a special person with whom I can share my joys and sorrows
3. My family really tries to help me
4. I get the emotional help and support I need from my family
5. I have a special person who is a real source of comfort to me
6. My friends really try to help me
7. I can count on my friends when things go wrong
8. I can talk about my problems with my family
9. I have friends with whom I can share my joys and sorrows
10. There is a special person in my life who cares about my feelings
11. My family is willing to help me make decisions
12. I can talk about my problems with my friends

Section 10: We should like to know if you have had any medical complaints, and how your health has been in general, *over the past few weeks*. Please answer ALL the questions simply by placing a cross in the box which you think most nearly applies to you. Remember that we want to know about present and recent complaints, not those you had in the past. It is important that you try to answer ALL the questions.

1. Have you recently been able to concentrate on whatever you're doing?

Better than usual ☐ 1

Same as usual ☐ 2

Less than usual ☐ 3

Much less than usual ☐ 4

2. Have you recently lost much sleep over worry?

Not at all ☐ 1

No more than usual ☐ 2

Rather more than usual ☐ 3

Much more than usual ☐ 4

3. Have you recently felt that you are playing a useful part in things?

More so than usual ☐ 1

Same as usual ☐ 2

Less useful than usual ☐ 3

Much less useful ☐ 4

4. Have you recently felt capable of making decisions about things?

More so than usual ☐ 1

Same as usual ☐ 2

Less so than usual ☐ 3

Much less capable ☐ 4

5. Have you recently felt constantly under strain?

Not at all ☐ 1

No more than usual ☐ 2

Rather more than usual ☐ 3

Much more than usual ☐ 4

6. Have you recently felt you couldn’t overcome your difficulties?

Not at all ☐ 1

No more than usual ☐ 2

Rather more than usual ☐ 3

Much more than usual ☐ 4

7. Have you recently been able to enjoy your normal day-to-day activities?

More so than usual ☐ 1

Same as usual ☐ 2

Less so than usual ☐ 3

Much less than usual ☐ 4

8. Have you recently been able to face up to your problems?

More so than usual ☐ 1

Same as usual ☐ 2

Less able than usual ☐ 3

Much less able ☐ 4

9. Have you recently been feeling unhappy and depressed?

Not at all ☐ 1

No more than usual ☐ 2

Rather more than usual ☐ 3

Much more than usual ☐ 4

10. Have you recently been losing confidence in yourself?

Not at all ☐ 1

No more than usual ☐ 2

Rather more than usual ☐ 3

Much more than usual ☐ 4

11. Have you recently been thinking of yourself as a worthless person?

Not at all ☐ 1

No more than usual ☐ 2

Rather more than usual ☐ 3

Much more than usual ☐ 4

12. Have you recently been feeling reasonably happy, all things considered?

More so than usual ☐ 1

About the same as usual ☐ 2

Less so than usual ☐ 3

Much less than usual ☐ 4

Section 11: This question is to be completed after you have been told what treatment you will be receiving:

Please rate on a scale of 0—10 how confident you are that this treatment will be successful in reducing the symptoms due to your recent injury where 0 is ‘no confidence at all’ and 10 is ‘complete confidence’?

0 1 2 3 4 5 6 7 8 9 10

Appendix 4: Research clinic assessment

To be completed by the Research Clinician:

Section 1:

1. **Please identify all areas where the patient is experiencing their symptoms since their neck injury:**

Skull	Neck	Right Shoulder	Right arm above elbow
Right arm below elbow		Right hand	Left shoulder
Left arm above elbow		Left arm below elbow	Left hand

2. **Please ask the patient the following questions (Yes/No):**

a. Do you have any difficulty swallowing?
b. Do you have headaches which you feel are related to your neck condition?
c. Do you have numbness, weakness, or tingling in your arms or hands?
d. Do you have difficulty grasping, picking up, or holding things in your hands?
e. Do you have numbness, clumsiness, or weakness in your legs?

3. **Widespread chronic pain (Manchester definitions):**

Did the patient experience the following? (Yes/No):

a) Pain in two sections of two contralateral limbs.
b) Pain in the axial skeleton.
c) This pain was present for at least 3 months prior to neck injury.
d) Did the patient fulfil the Manchester Definition of Chronic Widespread Pain prior to their injury. If Yes—Must have answered "Yes" to all 3 criteria listed above.

Section 2: Physical Examination

Cervical Range of Motion:	**Range of Motion (degrees)**	**Limitation Pain / Stiffness / Spasm**
Active Flexion		
Active Extension		
Active Right Rotation		
Active Left Rotation		
Active Right Lateral Flexion		
Active Left Lateral Flexion		
Passive Flexion		
Passive Extension		
Passive Right Rotation		
Passive Left Rotation		
Passive Right Lateral Flexion		
Passive Left Lateral Flexion		
Active Shoulder Range of Motion:		
Right Abduction		
Left Abduction		

Appendix 5: Ethical approval for the prospective cohort study.

Trent Multi-centre Research Ethics Committee

Chairma Dr Robert Bang
Administrator: Jill Marshall

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Your Ref:

28 April 2004

Professor Sarah Lamb
Professor of Rehabilitation
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Dear Professor Lamb

MREC/04/4/003 - *please quote this number* on *all correspondence*
Managing Injuries of the Neck (MINT)
Funder's ref no: 02/35/02

Thank you for your letter of 7 April 2004, responding to the Committee's request for further information on the above research and submitting revised documentation.

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

Confirmation of ethical opinion

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

Multi-site studies requiring site-specific assessment

You should now arrange for site-specific assessment to be carried out for all sites at which Principal Investigators are to be appointed to conduct the research locally. *(In future under the new REC system you will be able to apply for SSA earlier on in the process, once you have received notice* of *validation* of *your application).*

Part C of the application form (complete with all signatures) together with a copy of the Principal Investigator's CV, should be sent to the relevant Local Research Ethics Committee (LREC) for each site. No further documents need to be submitted. Site-specific assessment is confined to an assessment of the suitability of the local investigators, support staff, site and facilities.

The local assessor will be either the LREC itself or another assessor approved for the site by the relevant Office for Research Ethics Committees. Local assessors have 30 days in which to notify this Committee whether or not there is any objection on site-specific grounds. We will then confirm the favourable ethical opinion for each site in writing to you.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

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

- Application form dated 5.11.03
- Patient information sheet Version 2 dated 7.7.04
- Patient consent form Version 1 dated 5.11.03
- Health Questionnaire - SF36
- Hospital Anxiety and Depression Scale (HAD)
- EuroQol Quality of Life Questionnaire
- GP letter Version 1 dated 5.11.03
- Protocol Version 2 dated 6.4.04
- Confirmation of funding/peer review from NHCCT A dated 13 October 2003
- Article: Validity and Reliability of a modified version of the Neck Disability Index - J Rehab Med 2002; 34, 284-287
- Article: Cervical Spines Outcome Questionnaire: SPINE Vo127, No 19, pp 2116-2124
- Additional proposal to include randomised sub-study of incentives to promote the return of postal follow up questionnaires, embedded within the whiplash study - Prof Lamb's email of 5.1.04
- Method of initial recruitment to study
- Payments to researcher
- Provision of expenses for subjects
- Compensation arrangements for subjects
- Indemnity for investigators
- Chief Investigator's CV- Professor Sarah Lamb

Management approval - multi-site studies requiring site-specific assessment

If you are the Chief Investigator as well as the Principal Investigator for the lead site, you should obtain final management approval from your host organisation before commencing this research.

The study should not commence at any site until the local Principal Investigator has obtained final management approval from the relevant host organisation.

Notification of other bodies

We shall notify the research sponsor that the study has a favourable ethical opinion.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Yours sincerely

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Jill Marshal!
Trent MREC Administrator
on behalf of Dr Robert Bing, Chairman

Enclosures Standard approval conditions [SL-AC1]

Appendix 6: Qualitative study – ethical approval

Trent Multi-centre Research Ethics Committee
Chairman: Or Robert Bing
Administrator: Jill Marshall
Your Ref:

Derwent Shared Services
Laurie House
Colyear Street
Derby
DE1 1LJ

21 April 2006

Telephone: 01332 868905
Fax: 01332 868930
Email: Jill.Marshall@derwentsharedservices.nhs.uk

Professor Sarah Lamb
Professor of Rehabilitation
Room 104, Avon Building
Westwood Campus
Coventry
CV47AL

Dear Professor Lamb

Study title: Managing injuries of the Neck (MINT)

REC reference: *04/4/003*

Amendment number:
Amendment 2

Amendment date:
30th March 2006

The above amendment was reviewed at the meeting of the Trent MREC Substantial Amendment Sub Committee held on 19 April 2006.

Ethical comments:
Some concerns were raised that consideration should be given to the safety of the research physiotherapist when visiting patients in their own homes.

Ethical opinion:

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents:

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter		06 April 2006
Notice of Substantial Amendment (non-CTIMPs)	Amendment 2	30 March 2006
Participant Information Sheet	Additional leaflet - Patient Interviews, Version 1	20 March 2006
Interview SchedulesITopic Guides	Interview Schedules - Version 1	20 March 2006
Participant Consent Form	Patient Interviews - Version 1	20 March 2006
Participant Information Sheet	Leaflet -Version 7	12 September 2005

MREC/04/4/003

The Central Office for Research Ethics Committees is responsible for the operational management of Multi-centre Research Ethics Committees

WPH 0772

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Site-specific issues

It was noted as part of the review that the amendment has no implications for the suitability of local investigators, sites or facilities (where applicable). There is therefore no need to inform Local Research Ethics Committees of the amendment.

Management approval

All investigators and research collaborators in the NHS should notify the R&D Department for the relevant NHS care organisation of this amendment and check whether it affects local management approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Yours sincerely

Jill Marshal!
Trent MREC Manager

Copy to: Mrs Claudine Childs, NHS R&D Technology Assessment, 728 Bolderwood, University of Southampton, Southampton SO16 7PX

MREC/04/4/003