THE UNIVERSITY OF HULL

Conservative Management of Non-specific Neck Pain: Effectiveness of Treatment, Predictors of Treatment Outcome and Upper Limb Disability

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by

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Abstract

Neck pain is a prevalent musculoskeletal problem that consumes considerable NHS resources. The socioeconomic impact for individuals, industry and society is high. However research into the management of neck pain is sparse. Reviews of the evidence revealed relatively little high quality evidence relating to the development, progression and management of non-specific neck pain. There is emerging evidence for the use of dynamic strengthening, proprioceptive and postural exercises for neck pain, although it is not known whether group exercise based on this emerging evidence is effective compared to usual physiotherapy. There is little evidence for prognostic factors for the progression of neck pain or outcome of treatment. Consequently clinicians are unable to predict which patients are likely to develop recurrent, persistent or chronic problems and have difficulty directing patients towards the most effective treatment approaches. Finally, there is anecdotal understanding that neck problems may lead to the development of upper limb disability and that upper limb disability may influence treatment outcome for patients with neck pain. Currently the relationship between neck pain and upper limb disability remains unquantified. The information gained from these reviews was utilised in the design of a randomised controlled trial to compare group based Graded Exercise Treatment and Usual Physiotherapy (GET UP) for patients with non-specific neck pain.

The first aim of this thesis was to investigate the effectiveness of a graded neck and upper limb exercise programme (GET) compared with "usual physiotherapy" (UP). A randomised controlled trial of 151 patients showed that patients receiving UP and GET interventions had reduced neck pain and disability six months following intervention. Neck pain and disability scores in the UP group reduced by 7.7% at six month follow-up whilst those in the GET group reduced by 5.0%. For patients who completed treatment as per protocol, GET (8.8%) was as effective as UP (9.0%). The second aim was to investigate patient psychological, socio-demographic and physical variables which predicted treatment outcome. After adjusting for baseline neck pain and disability and treatment allocation, general linear modelling identified that, regardless of intervention, deprivation status significantly predicted treatment outcome at six months. In addition, baseline fear avoidance and treatment allocation interacted to predict six month outcome. Patients with high fear avoidance were predicted to have better outcome following GET. Those with low fear avoidance were predicted to have better

outcome in UP. The final aim was to investigate the relationship between neck pain and upper limb disability. Pair wise analysis revealed a strong positive correlation between neck pain and disability and upper limb disability. Linear regression indicated that the severity of upper limb disability was predicted by two main baseline variables: higher NPQ scores and lower pain self efficacy scores.

In conclusion GET and UP produced small but clinically meaningful reductions in neck pain and disability. Adherence to both forms of treatment, particularly GET, was a problem. For the subgroup group of patients who adhered to the treatment protocol, GET was as effective as UP, therefore the barriers to adhering with these treaments need to be better understood by clinicians and researchers alike. The GET programme appeared to be particularly beneficial for patients exhibiting high levels of fear avoidance beliefs. Therefore patients with neck pain should be assessed for the presence of fear avoidance beliefs and where appropriate directed towards active neck and upper limb rehabilitation. Patients from areas of social deprivation fared less well with physiotherapy than those from more affluent areas, regardless of intervention type. There is a need for more research into the influence of deprivation on treatment outcome. In particular there is a need to develop and evaluate innovative and targeted approaches which are suitable for such patients. Finally, clinicians should be aware that higher levels of neck pain and lower levels of pain self efficacy may provide an early indication of the presence of upper limb disability. Effective ways of managing neck related upper limb disability need further investigation since neither treatment was effective at reducing upper limb disability.

CHAPTER 1

INTRODUCTION, AIMS AND OUTLINE OF THE THESIS

1.1 INTRODUCTION & MOTIVATION FOR THIS THESIS

In this thesis the conservative management of neck pain is explored. Quantitative methods were used firstly, to assess the effectiveness of two physiotherapy interventions, namely: Graded Exercise Treatment (GET) and Usual Physiotherapy (UP); secondly, to investigate predictors of outcome following GET or UP interventions and thirdly, to explore the relationship between neck pain and upper limb disability.

The topics in this thesis were conceived out of the author's experience of working with patients with neck pain and developed following discussions with physiotherapy colleagues. There was a general view that some patients with neck pain also experienced associated upper limb disability, though we did not know how many. In addition we agreed that our clinical practise at that time meant that upper limb disability in these patients was not assessed or rehabilitated. We felt that we were at risk of merely alleviating neck pain symptoms rather than rehabilitating neck and upper limb function. We therefore became curious whether we could enhance treatment effectiveness for these patients. There was little evidence to answer our questions so the author developed a neck and upper limb exercise programme. It was piloted on a small group of neck pain patients who were about to be discharged from usual physiotherapy. Patients were asked to participate in between nine to 12 exercise classes over a six week period. The patients who participated in the exercise class achieved on average 50% reduction of their neck pain and disability. Naturally, this audit raised more questions than answers. For example:

1) Some patients achieved total abolition of their symptoms, whilst one did not improve at all. Why should this should be the case?
2) What is the relationship between neck pain and upper limb disability? Who develops upper limb disability and why?

The overall success of this class in a small group of patients and the desire to answer these questions has been the motivation for this present research. The neck and upper limb exercise class is presented in this thesis as Graded Exercise Treatment (GET).

1.2 INCIDENCE OF NECK PAIN

Neck pain is a common musculoskeletal problem that will affect a substantial proportion of people at some point in their lives (Croft et al., 2001). The lifetime prevalence of neck pain in different countries is high, with more than two thirds of individuals experiencing a problem with neck pain at some point in their lives (Makela et al., 1991; Cote et al., 1998). Approximately 34.4%-54% of the general population experience neck pain in a 12 month period (Bovim et al., 1994; Cote et al., 2000; Korhonen et al., 2003). The point prevalence ranges between 10-25% depending on the population and the definition of neck pain (Westerling and Jonsson, 1980; Hasvold and Johnsen, 1993; Cote et al., 1998; Hoving et al., 2002). Between 13.8% and 19.3% of the general population report symptoms which last for six months or more (Brattberg et al., 1989; Bovim et al., 1994). Approximately 10% of the general population report severe levels of neck pain intensity with a further 5 % reporting severely disabling neck pain (Cote et al., 1998).

Epidemiological information for the general UK population is sparse. Neck pain is one of the four most commonly reported musculoskeletal disorders in the UK (Urwin et al., 1998). Fourteen percent of a UK population complain of pain lasting for longer than a week in a one-month period, although this figure is higher in more socially deprived areas and lower in more affluent areas (Urwin et al., 1998; Lock et al., 1999). About one third of the population experience some form of neck pain in a one-month period (Hill et al., 2004), and around one fifth of previously pain free adults report a new episode of neck pain in a one-year period (Croft et al., 2001). These figures appear consistent with those for populations from other countries.

1.3 COURSE OF NECK PAIN

The literature regarding the course of neck pain is also sparse. Some authors suggest that the majority of patients can expect to recover from an episode of neck pain (Enthoven et al., 2004; Hoving et al., 2004). This may not be entirely accurate since several studies show that the majority of neck patients continue to have pain and disability after one year (Kjellman et al., 2002; Bot et al., 2005). There are indications that the course of neck pain in the general population is similar to low back pain (LBP), being highly variable, with a recurrent pattern of intermittent pain and disability over a period of years (Croft et al., 2001; Cote et al., 2004). The greatest improvements in pain and disability are likely to occur in the first one to three months after the onset of

an episode of neck/shoulder pain. Thereafter only small amounts of change are likely to occur (Öberg et al., 2003; Pernold et al., 2005). A study of UK adults with neck pain demonstrated that approximately 48% of people continued to report persistence of neck pain some 12 months later (Hill et al., 2004). This figure was higher (68%) in a similar Dutch population (Bot et al., 2005). In the longer term (30 months), problems with persistence of neck pain may be expected for as many as 88% of the population with neck pain (Öberg et al., 2003). For the majority of individuals the severity of pain and disability is not likely to increase markedly over a 5 year period (Pernold et al., 2005). However, it is not known how many people with neck pain go onto develop functionally limiting problems that warrant the attention of a health care professional. It has been reported that 0.6% of the general Saskatchewan population develop disabling neck pain each year and that a total of 5% of that population have significantly disabling neck pain (Cote et al., 1998; Cote et al., 2004). This figure is likely to be similar in the UK.

1.4 COSTS ASSOCIATED WITH NECK PAIN.

Few studies have investigated the cost implications of neck pain to society and none were found relating to UK populations. A Swedish study (Hansson and Hansson 2005) estimated that the annual total costs for back and neck problems corresponded to 1% of Gross National Product. In the Netherlands in 1996, the cost of neck pain was calculated at $686.2 million i.e. around 0.1% of Gross Domestic Product at that time (Borghouts et al., 1999). Of this figure, 23% was related to direct health care costs (e.g. hospital, ambulance and general practice care etc) and 77% to indirect costs (e.g. production loss, work absence etc). Of the direct health care costs, 84% (around $133 million) was due to paramedical cost, the majority of which were physiotherapy related. These costs are now 10 years out of date, in a country with a population one quarter the size of the UK. The overall cost implication of neck pain to the UK and the NHS is therefore likely to be considerable.

The cost of physiotherapy management of neck pain in the UK has not been established. In the UK, it has been estimated that 15.5%-22% of referrals to NHS physiotherapy outpatient departments were for neck pain (Hackett et al., 1987; May 2003). A Finnish study of 1123 general practice consultations for musculoskeletal pain identified that back pain and neck pain were the conditions most frequently referred for physiotherapy (Mantyselka et al., 2002). In a Dutch study of chronic, non-specific neck pain patients seeking general practitioner care, 51% were referred for physiotherapy treatment

(Borghouts et al., 1999). Once neck pain became chronic a large number (44%) of patients continued to seek help from their GP annually (Borghouts et al., 1999). Presumably, a proportion of these patients were given repeat referrals for physiotherapy.

In 1998 the annual cost of NHS and private sector physiotherapy for LBP was estimated at £250 million (Maniadakis and Gray 2000). The prevalence rate of neck pain (14%) was reported as being lower than LBP (23%), indicating that neck pain is possibly less physiotherapy intensive than LBP (Urwin et al., 1998). However, one study reported that the number of people with persistent neck pain is similar to the number experiencing persistent LBP (Brattberg et al., 1989). This indicates that similar physiotherapy resources may be expended in the management of neck and LBP. Additionally, it appears that all forms of musculoskeletal disability are on the increase (Maniadakis and Gray 2000). If this is the case then the cost implication of neck pain to physiotherapy departments is assumed to be considerable. In addition, back and neck pain, the consumption of health care resources tends to be highly skewed with about 6% of the sufferers accounting for more than 50% of the costs (Linton and Ryberg 2000).

1.5 FACTORS ASSOCIATED WITH THE DEVELOPMENT AND PROGRESSION OF NECK PAIN

The development and persistence of non-specific neck symptoms are probably related to multiple factors (Borghouts et al., 1998; Linton, 2000; Ariens et al., 2001). Several reviews have investigated the risk factors for the development of neck pain (Stock, 1991; Westgaard, 1999; Ariens et al., 2000; Ariens et al., 2001). Other reviews have investigated the prognostic factors for the progression of neck pain (Borghouts et al., 1998; Linton 2000). These reviews relied heavily on the results of cross-sectional and case-control studies. Their conclusions therefore need to be treated cautiously since case control designs may yield optimistic results related to bias in the selection of the control group, recall bias and inaccuracies of retrospective data. Cross-sectional studies cannot determine whether the exposure or outcome came first (Altman, 1991).

The identification of risk factors that predispose individuals to develop neck pain may contribute to strategies for primary prevention. Primary prevention is aimed at reducing the risk of initial onset of neck pain (Lahad et al., 1994). Occupational health departments may be interested in addressing any workplace factors that predispose their employees to neck injury. The identification of factors which predispose individuals to

developing persistent or recurrent neck problems may contribute to strategies for secondary prevention. Secondary prevention is directed towards reducing the risk of developing recurrent, persistent or chronic neck problems. Clinicians treating neck pain might address or reduce the impact of those factors that increase the risk of developing persistent neck pain (Hill et al., 2004). The identification of factors that predict outcome following intervention may enhance treatment effectiveness. Clinicians may be able to guide treatment of patients in a particular direction or avoid treatments that may be detrimental to certain individuals. However, there are few studies investigating factors that predict outcome following intervention for neck pain. This thesis is concerned with investigating variables that predict outcome of treatment.

1.6 NECK DYSFUNCTION AND UPPER LIMB DISABILITY

The relationship between neck pain and upper limb disability is poorly understood. In cross-sectional and longitudinal studies the prevalence of neck disorders has been linked with certain work place upper limb activities (Bjelle et al., 1981; Ohlsson et al., 1995; Andersen et al., 2003). In addition, there is evidence from longitudinal population studies that a history of shoulder disorders predicts poor long term outcome for subjects who have neck pain (Hoving et al., 2004; Bot et al., 2005). However, to the best of our knowledge there is no evidence supporting the intuitive view that the presence of neck pain may adversely affect upper limb function. It is not known whether upper limb disability predicts outcome for patients following conservative treatment of neck pain. It is the view of the author that clinicians rarely identify concurrent upper limb disability in patients with neck pain. At best clinicians may undertake range of motion testing on peripheral joints such as the shoulder or elbow. However, this in no way assesses functional ability since the correlation between range of motion and function appears weak (Roddey et al., 2005). It is also the view of the author that the presence of upper limb disability may limit treatment progress if it is not managed appropriately. This thesis is concerned with increasing understanding of the clinical relationship between neck pain and upper limb disability.

1.7 PHYSIOTHERAPY MANAGEMENT OF NECK PAIN

"Usual physiotherapy" and exercise based approaches are two common methods of delivering treatment to patients in a physiotherapy department.

Usual physiotherapy is multimodal and normally involves the delivery of advice and education plus a number of other possible treatments from a wide selection of passive and active treatment options. For example, this could include manual therapy, massage, specific or general exercise and physical modalities such as heat/cold, traction, electrotherapy, acupuncture. Choice of treatment is often based on the experience and preference of the physiotherapist undertaking assessment and treatment. It is suggested that multimodal approaches in physiotherapy (also known as usual physiotherapy) may be a beneficial way of approaching the management of neck pain (Moffett and McLean, 2006). However, it is the opinion of the author that this approach to neck pain management may offer relief of neck symptoms, without taking a more holistic view of the neck and upper limb complex. Current clinical practise seems to have no routine protocols for assessing and quantifying upper limb disability in patients with neck pain and therefore no recourse to upper limb rehabilitation. This may represent a deficit to current physiotherapy practise.

Exercise approaches vary greatly, but usually involve asking patients to undertake a range of specific and/or global exercises. The aim is to mobilise, strengthen or build up the endurance of specific regions of the body. There is some preliminary evidence to suggest that exercise is an effective method of managing neck pain (Sarig-Bahat, 2003; Moffett and McLean, 2006). However no evidence has been found which suggests that such exercise based approaches are commonly used in physiotherapy departments for the rehabilitation of patients with neck pain. A neck and upper limb exercise programme was developed by the author and piloted on a small group of neck pain patients with encouraging results. This exercise programme is the subject of investigation in this thesis.

In short, it is not known whether usual physiotherapy is more or less effective than a comprehensive neck and upper limb exercise programme for patients with neck pain. Research that investigates the effectiveness of usual physiotherapy compared with a comprehensive exercise programme for patients with neck pain is needed. This research forms the main focus of this thesis.

1.8 THE GENERAL AIMS AND STRUCTURE OF THIS THESIS

Neck pain is common, consumes considerable NHS resources and has a large socioeconomic impact, yet is an area that is poorly researched (Evans et al., 2002). In

particular, little evidence exists to either support or refute the use of physiotherapy group exercise programmes or usual physiotherapy regimes as a way of managing neck pain. The patients' physical, psychological and sociodemographic status may have an effect on outcome but as yet there is very little information about the prognostic factors for outcome. Upper limb disability may also have an effect on outcome. The main aims of the thesis are to:

i) Investigate the effectiveness of a neck and upper limb exercise programme compared with "usual physiotherapy".
ii) Investigate which patient psychological, socio-demographic, clinical and treatment preference variables are predictive of outcome.
iii) Determine the association between neck pain and upper limb disability.

To achieve these aims, this thesis is based on 4 methodological approaches:

i) A systematic review of the evidence regarding prognostic factors for the progression of non-specific neck pain, conservative management of neck pain, neck and upper limb outcome measures and variables which potentially predict treatment outcome for neck pain.
ii) Secondly, a randomised controlled study (GET UP neck pain trial) comparing a Graded Exercise Therapy with Usual Physiotherapy.
iii) Thirdly, an investigation of the predictive factors of outcome for neck pain patients receiving treatment in the GET UP neck pain trial analysed using general linear modelling.
iv) Finally, an investigation of the relationship between neck pain and upper limb disability analysed using linear regression modelling.

1.9 OUTLINE OF THIS THESIS

Chapter Two consists of a systematic review of the prognostic factors for the progression of non-specific neck pain to recurrent, persistent or disabling neck pain. It outlines the clinical implications and makes recommendations for further research. In the absence of evidence regarding predictors of treatment outcome, the findings in this chapter are used to facilitate the selection of predictor variables reviewed in Chapter Five and utilised in Chapter Seven.

Chapter Three reports the evidence for the conservative management of neck pain. Studies that investigated non-invasive, non-surgical, non-pharmacological management

options that are routinely available to physiotherapists, chiropractors or osteopaths are reviewed.

Chapter Four reviews a range of self administered questionnaires that measure 1) neck pain and disability and 2) upper limb disability that are appropriate for use in a mechanical neck pain population. The validity of these questionnaires is examined. Selection of a primary and secondary outcome measure for use in the GET UP neck pain trial is justified.

Chapter Five is a review and justification for use of variables that may potentially be predictive of outcome following treatment in the GET UP neck pain trial. Where appropriate the validity of patient completed questionnaires is examined.

Chapter Six reports a randomised controlled study comparing Graded Exercise Therapy (GET) and Usual Physiotherapy (UP) for patients with non-specific neck pain (GET UP neck pain trial). The results are discussed and implications for clinical practice and further research presented.

Chapter Seven presents the findings of a secondary analysis to investigate the patient psychological, sociodemographic and physical variables which predict outcome of treatment for patients participating in the GET UP neck pain trial. The findings are discussed and implications for clinical practice and further research presented.

Chapter Eight presents the findings of a secondary analysis to determine the relationship between neck dysfunction and upper limb disability for the participants in the GET UP neck pain trial. The findings are discussed and implications for clinical practice and further research presented.

Chapter Nine summarises the findings of this research in light of current research, draws conclusions, considers the implications and makes relevant recommendations. Future research directions are considered.

CHAPTER 2

PROGNOSTIC FACTORS FOR PROGRESSION OF NON-SPECIFIC NECK PAIN: A SYSTEMATIC REVIEW

2.1 INTRODUCTION

The research literature into factors that predict outcome following physiotherapy interventions for neck pain is sparse. Only one small study was found which identified that baseline pain intensity, well-being, expectations of treatment and duration of current episode predicted neck pain and disability score and pain intensity 12 months after conservative physiotherapy treatment (Kjellman et al., 2002). Factors that are prognostic of progression of neck pain in non-patient cohorts may be similar to those that predict treatment outcome in patient cohorts. Thus prognostic factors may provide some indication of variables that are potentially predictive of outcome following treatment.

Development and persistence of symptoms are probably related to multiple factors (Borghouts et al., 1998; Linton, 2000; Ariens et al., 2001). We were able to identify only two systematic reviews which investigated prognostic factors for the progression of non-specific neck pain (Borghouts et al., 1998; Linton 2000). The validity of the conclusions from these reviews was limited. The first review relied almost exclusively upon the results of observational and case-control studies (Borghouts et al., 1998). The second review was heavily influenced by weight of evidence from lumbar spine literature (Linton 2000). Since these reviews were completed, further prospective studies have been added to the body of literature relating to the progression of neck pain.

Prognostic factors can be divided into four major groups: physical, psychological, sociodemographic and clinical factors. The aim of this chapter is to systematically review and identify the most important prognostic factors that have been linked to the progression of non-specific neck pain. This information will facilitate the discussion and selection of factors that are potentially predictive of outcome following treatment.

2.2 METHOD

The systematic review guidelines produced by the NHS Centre for Reviews & Dissemination were used to conduct this review (CRD, 2001).

2.2.1 Data sources and search strategy

Online searches were conducted on AMED (1985-Sep 2005), CINAHL (1982-Sep 2005), EMBASE (1974-Sep 2005), MEDLINE (1966-Sep 2005), PsychINFO (1806-Sep 2005), PEDro and Cochrane Register of Systematic Reviews. Keywords used were: neck pain, cervical pain, odds ratio, predictor, risk factor, prognostic factor, probability, prognosis, progression, observational, prospective, cohort, follow-up.

The references of primary studies identified through the database search were scanned to identify relevant additional citations. Key journals (Journal of Clinical Epidemiology, Occupational & Environmental Medicine) were hand searched to identify relevant articles that were not yet indexed on the online databases. An internet search of Google and Google Scholar was also conducted to search for further papers. Duplicate articles were excluded. Unpublished manuscripts were not sought and investigators were not contacted for further information.

2.2.2 Study selection

A study was included if: (1) the study population consisted of patients with non-specific or musculoskeletal neck pain at baseline. Non-specific pain was defined as pain (with or without radiation into shoulder, arm or head) without a specific systemic disease being detected as the underlying cause of the complaint. The neck was defined as: the cervical spine, occiput region, cervico-thoracic junction as far as T4 and muscles originating from the cervical region acting on the head or shoulder girdle; (2) it was a prospective cohort study with a minimum follow-up period of 1 year; (3) it focussed on determinants of progression of neck pain; (4) it consisted of human subjects; (5) and was a full, peer reviewed report published in the English language.

A study was excluded if (1) it focussed on specific neck pain, such as whiplash associated disorder; (2) it evaluated musculoskeletal pain but did not analyse neck pain separately; (3) it evaluated a therapeutic intervention such as physiotherapy or surgery; (4) it was a case-control or cross sectional study. Case control designs may yield optimistic results related to bias in the selection of the control group, recall bias and

inaccuracies of retrospective data. Cross-sectional studies cannot determine whether the exposure or outcome came first; (5) it concerned patients with specific underlying pathology such as tumours, fractures, infection, inflammatory disorders, osteoporosis etc; (6) and neck pain was not present at baseline.

After completion of the search process, a three phase screening strategy was used to identify the articles to be reviewed. Firstly, one investigator (SMc) screened all the titles and abstracts identified by the search. All papers related to non-specific neck pain were retained. Secondly, two independent reviewers (SM and SMc) reviewed the titles and abstracts using the inclusion and exclusion criterion and selected potentially relevant studies. Finally, the full text articles were retrieved and both reviewers independently reviewed each of the retrieved articles to ensure that they met the inclusion/exclusion criterion for the review. In the event of any variations in opinion between the two reviewers, a third reviewer (JKM) reviewed the article and arbitrated until an agreement for inclusion or exclusion was reached.

2.2.3 Quality assessment of studies

There are no widely agreed quality criteria for assessing prognostic studies and several different scales and criteria have been developed (Altman, 1991). The quality assessment tool used here was adapted from two very similar assessment tools which have been used in previous systematic reviews of prognostic factors for whiplash associated disorders (Scholten-Peeters et al., 2003) and non-specific neck pain (Borghouts et al., 1998). The current tool was adapted to reflect the topic under review. (see Appendix 1 for the quality assessment tool). The original 16-item assessment tool was modified to include point B2 (size of population), to allow for assessment of studies based on cohort size. Population size has been used as a point of assessment in previous systematic reviews of cohort studies (Borghouts et al., 1998; Pincus et al., 2002) and is an important consideration in studies where multivariate analysis has been undertaken. Smaller studies, with large numbers of predictive variables, allow less confidence in the results of the analysis (Tabachnick and Fidell, 2001). There is no universal method of calculating a sample size for multivariate analysis, but sample sizes of 300 have been described as fair (Pincus et al., 2002). In line with this our review gave studies with sample sizes of more than 300 subjects a higher rating (Pincus et al., 2002).

The assessment tool consisted of 17 items examining six factors, namely study population, follow-up, treatment, prognostic factors, outcome and analysis. To determine the methodological quality of the studies in the review, each criterion was evaluated against pre-set standards, for the presence/absence of sufficient information and the likelihood of potential bias (see Appendix 2 for the pre-set standards). Each item had a yes, no and don't know option. If sufficient information was reported and bias considered unlikely, the criteria was positively rated (yes) and given a 1 point score. If information was reported but bias considered likely, the criteria was negatively rated (no) and given a zero score. When information was not clear or not reported, the criteria was rated inconclusive (don't know) and given a zero score. For each study an overall quality score was calculated by counting all positively rated criteria (1 point per criteria, maximum score 17 points). The assessment tool was piloted on three studies that were not involved in the review, and minor adjustments made to the pre-set standards for the purposes of clarification. Following this, the two reviewers (SMc and SM) independently assessed and scored the studies for the review. In the case of disagreement, consensus was sought between the two reviewers. If disagreement persisted, a third independent reviewer (EDG) made the final decision. A study was considered to be of good quality if it scored ≥ 9 points on the quality assessment scale. This is in line with that of a previous systematic review (Scholten-Peeters et al., 2003).

2.2.4 Data extraction

The two independent reviewers (SMc and SM) used a standardised form to extract information and data regarding the study population, inclusion and exclusion criteria, follow-up period, drop-out rates, type of prognostic factors, outcome measures and data on associations between prognostic factors and outcomes. In cases of disagreement, consensus was achieved by discussion. If consensus could not be reached a third reviewer made the final decision (see Appendix 3 for the standardised data-extraction form).

2.2.5 Data synthesis

The inter-observer agreement of quality assessment was derived by calculating % agreement and a kappa (κ) co-efficient to correct for chance agreement (Streiner and Norman 2003). Extracted information about the studies is presented in table format and structured to highlight similarities and differences between study outcomes. Qualitative conclusions in this review were based on levels of evidence previously used in several

Cochrane systematic reviews (Karjalainen et al., 2001; Verhagen et al., 2004) and other systematic reviews (Ariens et al., 2000; Ariens et al., 2001; Scholten-Peeters et al., 2003) (see Table 2.1).

Table 2.1: Levels of evidence for predictive factors

Level of Evidence	
Strong	Consistent findings from two or more high quality cohorts.
Moderate	Consistent findings from at least one high quality study and one or more low quality cohorts
Limited	findings of one high quality study or consistent findings in one or more low quality study
Conflicting	Inconsistent findings irrespective of study quality
No evidence	No studies found

Multivariate analysis estimates were used to establish the levels of evidence. If only univariate results were available, these were used to determine the levels of evidence instead. Significant associations ($p<0.05$) or clinically relevant risk estimates were used. The latter defined as estimates of Relative Risk (RR), Odds Ratio (OR) or Hazard Ratio (HR) ≤ 0.5 or ≥ 2.0 (van der Windt et al., 2000; Scholten-Peeters et al., 2003).

A negative effect of a prognostic factor implied an increased risk for the occurrence of persisting neck problem in the presence of that factor i.e. worse outcome. A positive effect of a prognostic factor implied a decreased risk for the occurrence of persisting neck problem in the presence of that factor i.e. better outcome. No effect of a prognostic factor implied that the presence of that factor neither increased nor decreased risk for the occurrence of persisting neck problem (Ariens et al., 2000).

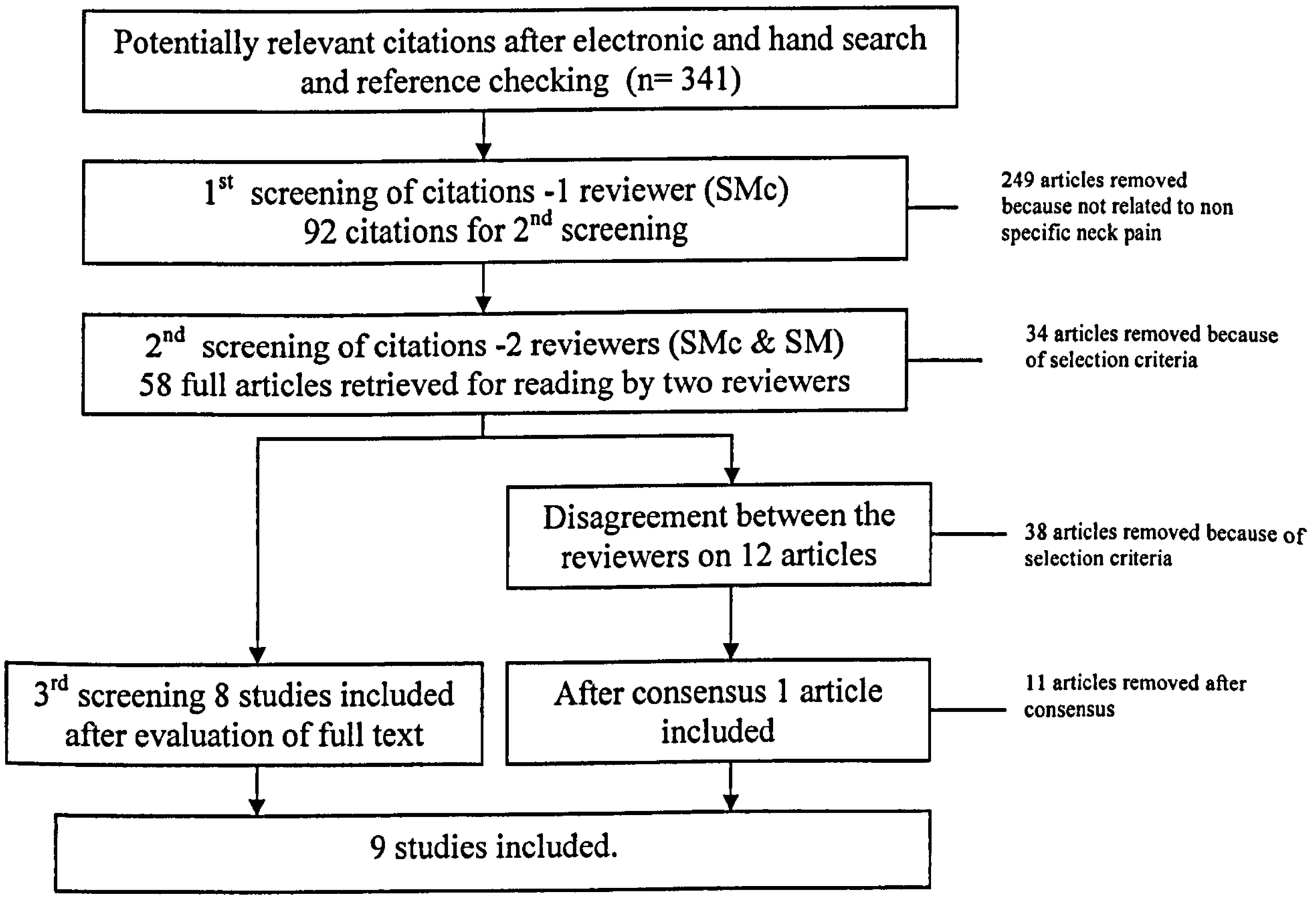
2.3 RESULTS

2.3.1 Selection of studies

The process of study selection is shown in the flow chart (Figure 2.1). The initial search yielded 341 citations. After the first screening of these abstracts by one reviewer

(SMc) 249 articles were removed for the following reasons; whiplash associated disorders (33), duplicates (33), reviews (6), surgical interventions (21), conservative interventions (11) or because they were not related to musculoskeletal disorders of the cervical spine (145). Ninety-two citations were put forward for second screening by both reviewers (SM & SMc). Using the inclusion and exclusion criteria 34 articles were excluded from further review. Thus a total of 58 studies were selected for inclusion and the full articles retrieved for ongoing selection. During the third screening of the full publications the two reviewers agreed to retain eight papers, agreed to exclude 38 papers and disagreed on the selection of 12 papers. During a consensus meeting of the two independent reviewers 11 of these 12 articles was excluded and one retained. In total nine papers were included in the review (Gore et al., 1987; Viikari-Juntura et al., 1994; Eriksen et al., 1999; Mikkelsson et al., 1999; Cassou et al., 2002; Hill et al., 2004; Hoving et al., 2004; Bot et al., 2005; Pernold et al., 2005). (see Appendix 4 for details of excluded studies).

Figure 2.1: Flow diagram of selection process of studies



2.3.2 Methodological quality

The reviewers reached agreement on 82% of the quality items assessed. The initial inter-observer agreement for each item ranged between $\kappa = 0.19$ (item C) and $\kappa = 1.0$ (item B2, D, G, M and N); the overall inter-observer agreement being $\kappa = 0.53$ with a standard error of 0.08. This represented moderate agreement between the two reviewers (Altman, 1991). Disagreements mainly related to reading errors or interpretation of the quality criteria list. These disagreements were easily resolved. Disagreement persisted on only three items (twice in item O; (Viikari-Juntura et al., 1994; Eriksen et al., 1999) and once in item P; (Viikari-Juntura et al., 1994)). The third reviewer made the final decision in each of these cases. The results of the quality assessment are shown in Table 2.2 below. The cohorts were ranked by methodological quality score; higher scores indicate better methodological quality.

Table 2.2: Results of Methodological Assessment

Cohort Name	A	B1	B2	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Quality Score
Bot et al (2005)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	17
Hill et al (2004)	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	16
Hoving et al (2004)	1	1	0	1	1	1	0	1	1	1	1	1	1	1	1	1	1	15
Eriksen et al (1999)	1	1	1	0	1	0	1	1	1	1	1	1	0	1	1	0	1	13
Pernold et al (2005)	1	0	1	1	1	1	1	1	1	1	0	1	1	1	1	0	0	13
Viikari-Juntura et al (1994)	0	1	1	0	1	1	1	1	1	1	0	1	0	1	1	1	1	13
Mikkelsen et al (1999)	0	1	0	0	1	1	0	1	1	1	1	0	1	1	1	0	1	11
Cassou et al (2002)	0	1	1	0	1	1	1	1	1	1	0	1	0	0	1	0	1	11
Gore et al (1987)	0	0	0	0	1	1	1	1	1	0	0	0	0	0	1	0	0	6

The quality scores ranged from 6 to 17, and eight of the nine of the studies achieved a score that indicated high quality. The most common methodological shortcomings related to poor description of the inception cohort (item A), poor description of the inclusion/exclusion criterion for subjects taking part in the study (item C), lack of standardization and validity of tools used to measure predictive variables (item J), clinical relevance of the outcome measures used (item L) and presentation of univariate analysis (item O). In all studies, prospective data collection (item G) over a 12-month period (item D), standardised treatment of the subjects (item H) and the presentation of descriptive statistics for the outcomes measured (item N) were apparent. The results of the nine included studies were often presented unclearly. Some studies only provided

significance levels without presenting crude or adjusted estimates of risk. Other studies presented risk estimates without stating whether these risks were significant. Two good quality studies (Cassou et al., 2002; Hoving et al., 2004) reported statistically significant multivariate findings, but did not state, as per our protocol, whether the significance level was at $p<0.05$ level or not. In both studies statistical methodology and results were well reported and led us to feel confident about their conclusions. These results were therefore retained to support the final levels of evidence. In some studies, it was unclear which confounding variables had been included in the multivariate analysis. This complicated interpretation of the findings.

2.3.3 Study Characteristics

The nine studies include in this review represented nine independent cohorts of patients. Of the nine studies, two recruited from occupational groups (Viikari-Juntura et al., 1994; Eriksen et al., 1999), two recruited from primary care practices (Hoving et al., 2004; Bot et al., 2005; Pernold et al., 2005), one recruited from a secondary care department (Gore et al., 1987), three recruited from the general population (Cassou et al., 2002; Hill et al., 2004; Pernold et al., 2005), and one recruited from a population of schoolchildren. The sample sizes varied from n= 183 (Hoving et al., 2004) to n= 21378 (Cassou et al., 2002). Six of the nine studies enrolled more than 300 subjects and three (33%) enrolled over 1000 subjects. The shortest follow-up period was set, a priori, at one year, whilst the longest follow-up period was approximately 10 years (Gore et al., 1987). The percentage of subjects lost to follow-up varied between 2.7% (Hoving et al., 2004) and 49.8% (Pernold et al., 2005), although in one study this figure was not made clear (Gore et al., 1987). In five of the nine studies the percentage of subjects lost to follow-up was less than 20% at one year. The main characteristics of the study populations are in Appendix 5.

2.3.4 Evidence of prognostic factors for the progression of neck pain

Appendix 5 also presents the range of prognostic factors and outcomes for each cohort, including the univariate and multivariate statistical results supporting each factor. About 150 different prognostic factors were examined ranging from number of hours watching the television to time spent on homework in adolescence to severity of neck pain/disability at baseline to fear avoidance beliefs. To facilitate interpretation, these prognostic variables were grouped into one of four categories, namely: physical, psychological, sociodemographic or clinical. Fourteen different outcome measures

were used. These were grouped into one of three outcome categories: symptoms, disability or recovery. The vast majority (71%) of outcomes related to measures of symptoms (intensity, duration or number of episodes). Disability included measures using a variety of neck specific pain and disability questionnaires. Work related outcomes, such as sickness absence, although important measures were only considered in one study. Recovery was measured using a global rating scale of the subjects perceived level of recovery. Only three studies utilised recovery or disability as an outcome measure (Hoving et al., 2004; Bot et al., 2005; Pernold et al., 2005). Low utilization of these measures limited the conclusions that could be drawn about the prognostic factors. Due to the heterogeneity of 1) the population, 2) the prognostic factors, 3) the outcome measures and 4) the available data, a qualitative analysis was performed.

2.3.5 Summary of evidence

Table 2.3 presents a summary of the available evidence for the significant prognostic factors at baseline arranged by prognostic category. This table also highlights the associations of these prognostic factors relative to the outcome categories i.e. symptoms, disability or recovery. Finally this table indicates the level of evidence which is associated with each prognostic factor. There is strong evidence that older age, longer duration of the current episode of neck pain, history of neck problems, shoulder problems or other musculoskeletal disorder such as back, knee or hip pain at baseline are independently prognostic of unfavourable outcome with regards to symptoms. Older age, longer duration of current episode of neck pain and history of other musculoskeletal disorders are strongly prognostic of unfavourable outcome with regards to neck related disability. A history of other musculoskeletal problems is predictive of poor recovery. The evidence for the predictive effect of greater neck symptoms at baseline and worse neck related disability at baseline is inconclusive. All the remaining variables highlighted in Table 2.3 have limited evidence of predictive ability for outcome on the basis that they each have one high quality study supporting them. There is strong evidence that regular sporting activity or exercise has a protective effect against progression of neck pain, although limited evidence suggests that cycling may be prognostic of poor outcome.

Table 2.3: Levels of evidence for prognostic factors for the progression of neck pain

Group	Prognostic Factor	Outcome	Author	+ findings	+ high quality	+ low quality	- findings	- high quality	- low quality	Level of evidence
Physical	Cycling	Symptoms	Hill				Hill	Hill		
	Regular physical or sporting activity	symptoms	Vikarii-Juntura (1994) Cassou (2002) Pernold (2005)	Vikarii-Juntura Cassou Pernold	Vikarii-Juntura Cassou Pernold					Strong
Psychological	High levels of worrying,	Symptoms	Bot (2005)				Bot	Bot		
Socio-demographic	Older age	Disability	Bot (2005) Hoving (2004)				Bot Hoving	Bot Hoving		Strong
	Older age	Symptoms	Hill (2004) Hoving (2005) Cassou (2002)				Hill Hoving Cassou	Hill Hoving Cassou		Strong
	Older age	Recovery	Hoving (2004)				Hoving	Hoving		
	Female gender	Symptoms	Eriksen (1999)				Eriksen	Eriksen		
	Not employed	Symptoms	Hill (2004)				Hill	Hill		
	Little influence on own work situation	Symptoms	Eriksen (1999)				Eriksen	Eriksen		
	Machine operator v office work	Symptoms	Vikarii-Juntura (1994)				Vikarii-Juntura	Vikarii-Juntura		
	Carpentry v office work	Symptoms	Vikarii-Juntura (1994)				Vikarii-Juntura	Vikarii-Juntura		
	Repetitive work at baseline	Symptoms	Cassou (2002)				Cassou	Cassou		
	High job demands	Symptoms	Cassou (2002)				Cassou	Cassou		
	Better perceived	Symptoms	Bot (2005)	Bot	Bot					

	health,									
	Poorer QoL scores	Symptoms	Bot (2005)				Bot	Bot		
	Poorer QoL scores,	Disability	Bot (2005)				Bot	Bot		
	More vitality	Disability	Bot (2005)	Bot	Bot					
Clinical	Greater intensity of neck symptoms at baseline	symptoms	Bot (2005) Hoving (2004) Gore (1987)	Bot	Bot		Hoving Gore	Hoving	Gore	Inconclusive
	Poorer neck function at baseline	Disability	Bot (2005) Hoving (2004)	Bot	Bot		Hoving	Hoving		Inconclusive
	Poorer neck function at baseline	Recovery	Hoving (2004)				Hoving	Hoving		
	Longer duration of current episodes of neck pain	Recovery	Bot (2005)				Bot	Bot		
	Longer duration of current episodes of neck pain	Symptoms	Bot (2005) Hoving (2004)				Bot Hoving	Bot Hoving		Strong
	Longer duration of current episodes of neck pain	Disability	Bot (2005) Hoving (2004)				Bot Hoving	Bot Hoving		Strong
	No change in neck pain for previous 2 weeks at baseline	Recovery	Hoving (2004)				Hoving	Hoving		
	No change in neck symptoms for 2 weeks at baseline	Disability	Hoving (2004)				Hoving	Hoving		
	History of neck symptoms	Recovery	Bot (2005)				Bot	Bot		
	History of neck problems	Symptoms	Bot (2005) Hoving (2004)				Bot Hoving	Bot Hoving		Strong

	History of neck trauma	Recovery	Hoving (2004)				Hoving	Hoving		
	History of neck trauma	Disability	Hoving (2004)				Hoving	Hoving		
	History of headaches in the previous year	Symptoms	Eriksen (1999)				Eriksen	Eriksen		
	History of other MSK disorders[1]	Symptoms	Cassou (2002) Hill (2004) Hoving (2004)				Cassou Hill Hoving	Cassou Hill Hoving		Strong
	History of other MSK disorders[1]	Recovery	Bot (2005) Hoving (2004)				Bot Hoving	Bot Hoving		Strong
	History of other MSK disorders[1]	Disability	Bot (2005) Hoving (2004)				Bot Hoving	Bot Hoving		Strong
	History of shoulder problems	Symptoms	Eriksen (1999) Bot (2005)				Eriksen Bot	Eriksen Bot		Strong
	Both shoulders affected	Recovery	Bot (2005)				Bot	Bot		
	Numbness in hands/fingers	Symptoms	Bot (2005)				Bot	Bot		
	Numbness in hands/fingers	Disability	Bot (2005)				Bot	Bot		
	Tendency to massage hands	Disability	Bot (2005)	Bot	Bot					

-ve findings represent an unfavourable change in the outcome measured, +ve findings represent a favourable change in the outcome measured

Note
1. Other musculoskeletal (MSK) disorders include knee, hip and low back pain

Table 2.3 highlights the low number of studies supporting each potential prognostic factor. The majority of prognostic factors fall into the clinical category. There is limited evidence for headaches, unchanging neck pain, numbness in the hands, and trauma to be associated with a poorer prognosis. Very few studies investigated physical, psychological and sociodemographic factors. One study found limited evidence that psychological factors (high levels of worrying) were prognostic of poor outcome (Bot et al., 2005). Limited evidence existed for nine further sociodemographic prognostic factors, namely: female gender, not being employed, little influence on own work situation, high job demand, repetitive work, some occupations, worse perceived health, lower quality of life scores and less vitality had limited evidence for being prognostic of poor outcome. Further high quality studies are required to substantiate the predictive nature of these factors.

2.4 DISCUSSION

This review summarised findings of nine prospective studies that investigated the predictive nature of around 150 physical, psychological, sociodemographic and clinical factors for the progression of non specific neck pain. The methodological quality of the studies was high; all but one exceeded our cut off for high quality (nine or more points out of 17). Overall there was strong evidence that older age, longer duration of the current episode, history of neck, shoulder or other musculoskeletal disorders predict unfavourable outcome. On the positive side, there was strong evidence from the cohort studies that participating in physical exercise is protective. This finding needs to be emphasised in order to encourage people with neck pain to remain as physically active as possible. It is a message which has important implications in the clinical setting.

There remains a lack of high quality research in this area. This may be an important avenue for research since many other factors have previously been identified as predictive for the progression of whiplash associated disorders and back pain (Linton 2000).

2.4.1 Limitations of this review

The possibility of publication bias cannot be excluded, since it is a recognized difficulty in systematic reviews that studies with significant results are more likely to be published and identified (Altman, 1991). Unpublished studies, studies from non-indexed journals,

relevant studies from other lesser known databases, and studies published in languages other than English were not included in the study.

The criteria used for quality assessment was based on a tool used by other studies. Overall it was a useful tool, however in this review it was felt that the inclusion of a quality criterion based on cohort size (item B2) was a necessary addition. Some of the criteria used arbitrary cut-off points e.g. cohort size (B2), length of follow-up (D), drop-out rate (E). These are important considerations where accuracy and confidence in the analysis and risk estimates are important (Altman, 1991; Laupacis et al., 1994; Tabachnick and Fidell, 2001) but determining a specific cut-off point is problematic and arbitrary (Tabachnick and Fidell, 2001). The tool would also benefit from a small number of amendments if used in future reviews of prospective cohort studies. Two items could be omitted from the quality assessment procedure. The inclusion criterion of studies for this review stated that studies should be prospective in design with a minimum one year follow-up period and therefore items D & G were not discriminating.

The levels of evidence in this review were based on the findings of multivariate analysis. When multivariate analysis was not available, univariate analysis was used. The use of univariate analyses may have biased the conclusion of the levels of evidence for the predictive factors, since univariate analysis does not adjust for confounding factors. This approach has been used before (Scholten-Peeters et al., 2003) and was appropriate since two out of the nine studies presented no multivariate data (Gore et al., 1987; Pernold et al., 2005), however the results from these two studies do not influence the main findings. One study (Viikari-Juntura et al., 1994) did not report the statistical significance level of their predictive factors. To deal with this situation, risk estimates (RRs, HRs, ORs) had to be ≤ 0.5 or ≥ 2.0 in order to be considered important enough to include in the final analysis for levels of evidence. This method has previously been used in two systematic reviews (van der Windt et al., 2000; Scholten-Peeters et al., 2003). Two studies (Cassou et al., 2002; Hoving et al., 2004) did not report the significance levels of their multivariate analysis, however the overall reporting was of a high standard and we felt confident to incorporate the results of both studies in the final results.

2.4.2 Outcome measures

This review considered three possible outcomes i.e. symptoms, disabilities and recovery. Symptoms were the most commonly used outcome. However the presence of symptoms may reveal little about functional capacity, since the correlation between disability and pain may be weak (Waddell, 1998; Ferrari and Schrader, 2001). Only three studies used functional outcomes such as disability or working capacity (Hoving et al., 2004; Bot et al., 2005; Pernold et al., 2005). These are important measures for future studies because of the economic and social impact that loss of working capacity and function brings to both the sufferer and society in general (Borghouts et al., 1999; SBU 2000).

2.4.3 Findings from previous systematic reviews

Two other systematic reviews were identified which investigated the prognostic factors for neck pain. Linton reviewed psychological risk and prognostic factors of back pain and neck pain (Linton 2000). He found strong evidence that psychosocial variables, including stress, distress, anxiety, mood and depression, fear-avoidance beliefs, coping strategies and pain behaviour are linked to the transition from acute to chronic pain and the development of long term disability. This differs from our systematic review which identified few psychological or sociodemographic prognostic variables. Linton drew his conclusions from 37 prospective studies, of which only five related to neck pain (Viikari-Juntura et al., 1991; Leino and Magni, 1993; Pietri-Taleb et al., 1994; Radanov et al., 1994; Radanov et al., 1994). Two of these related to whiplash. His review was powerfully influenced by evidence from lumbar spine research, so it may not be possible to generalise these findings to non-specific neck pain.

A second systematic review focussed on prognostic factors of non-specific neck pain (Borghouts et al., 1998). Despite the limited number of studies (only six reported on prognostic factors) and the generally lower quality of studies at that time, they reached one similar conclusion to the current review: that previous history of neck problems was associated with worse prognosis. All three reviews, including this current review, were limited in their ability to draw conclusions due to the low number of studies investigating prognostic factors for neck pain.

2.4.4 Clinical implications

Although the majority of neck pain patients may be expected to recover (Enthoven et al., 2004; Hoving et al., 2004), there are some indications that the clinical course of

neck pain follows a pattern of intermittent episodes of pain and disability over a period of years (Croft et al., 2001). The identification of prognostic factors within patient consultations may alert clinicians to those patients who may be more at risk of delayed recovery and pain and disability in the long term.

It is important to note that the more severe the symptoms are in the early stages (e.g. previous history of neck symptoms, longer duration of symptoms) then the stronger the likelihood of a poor outcome with regards to pain and disability in the years that follow. This may indicate that early advice and management strategies which aim to minimise initial pain and disability are of importance. For example the use of simple analgesics, heat, ice and the gradual return to normal physical activity should be encouraged. This is in line with recommendations set out in the neck book.

There is strong evidence that neck pain sufferers who do regular exercise are less likely to progress to recurrent, persistent or disabling neck problems. Pernold et al (2005) investigated 165 females with neck pain from a general Swedish population and reported that the pain intensity had improved significantly after five years in subjects undertaking medium and high intensity exercise, whilst non-exercisers had a small but non-significant improvement. Examples of medium intensity exercise were three or more hours of cycling or brisk walking every week. Examples of high intensity exercise were one or more hours per week of badminton, gymnastics, swimming at high intensity, jogging, skiing and mountain climbing (Pernold et al., 2005). In their study of 1832 men from an occupational setting, Viikari-Juntura et al (1994) found that the risk of persistently severe neck pain was decreased by half in male subjects who did two or more sessions of physical exercise per week compared with those who exercised less than once per week. Unfortunately they did not define what they meant by physical exercise or how long the sessions were. In a large scale (n=21378) study of a general French population, Cassou et al (2002) found that men who reported undertaking sporting activities were significantly more likely to have resolution of chronic neck and shoulder pain compared with those who reported doing no exercise. In women sporting factors did not emerge as a prognostic factor. Unfortunately they did not define what they meant by sporting activities or how much would be beneficial. In contrast Hill et al (2004) reported that subjects from a general neck pain population who reported engaging in cycling were at twice as much risk of developing persistent neck pain at one year follow-up compared with those who never cycled. On balance this indicates that

advice to undertake regular ongoing exercise should be emphasised to patients in order to control or improve their neck pain. It probably does not matter what form of exercise is recommended although cycling should be encouraged with slight caution. It is likely that exercise should be done on at least two occasions per week. Finally patients should be encouraged to start exercise gently and advised that there should be nothing to prevent them from gradually progressing to high intensity levels of exercise over a period of time. This evidence could also be used to counter the fears held by many neck pain sufferers that movement could be damaging and could lead to "re-injury".

Additionally, it is important for clinicians treating older patients (≥40y), those with other musculoskeletal disorders, and those with a previous history of neck or shoulder problems to recognise that these are risk factors for the progression of neck pain into recurrent, chronic or disabling neck pain. Clinicians need to identify which factors they may be able to influence, which factors may be influenced by other clinical specialities or the patient themselves, and to recognise which factors cannot be changed.

To date, the evidence for the predictive strength of many prognostic indicators is either limited or lacking. However, at this stage clinicians should not ignore these factors as potentially they may be important predisposing factors for progression of neck problems. Additionally, there is a gap in knowledge about factors that predict outcome following treatment of neck pain. Together these represent a major deficit in clinicians' understanding of neck pain. Firstly, poor identification of patients who are at risk of developing recurrent, persistent or chronic neck pain, limits the clinicians' ability to offer early intervention to those who may need it most. Secondly, poor evidence of predictors of treatment outcome for neck pain limits the clinicians' ability to tailor evidence based advice and treatment to the individual patient.

2.4.5 Recommendations

There is a need for further studies which investigate clinical, physical, psychological and sociodemographic prognostic factors for neck pain and predictive factors for treatment outcome.

It is important to obtain national or international consensus about the main methodological criteria which should be presented in prognostic studies, in a similar way to the CONSORT statement for randomised clinical trials (Moher et al. 2001). The

points covered in the quality assessment tool used in this review may represent a good foundation to build on.

2.5 CONCLUSIONS

Only a few clinically relevant prognostic factors were identified by this review. Strong evidence was found to link older age, longer duration of the current episode of neck pain, history of neck, shoulder or other musculoskeletal disorders to unfavourable outcome for non specific neck pain. There was strong evidence that participating in physical exercise is protective. There was a lack of high quality research investigating the predictive nature of clinical, physical, psychological and sociodemographic variables. These are important areas for further research.

This chapter reviews and summarises the evidence for progression of non-specific neck pain in subjects who are not undergoing treatment. It is not clear whether these factors would also predict outcome of physiotherapy treatment since research in this area is sparse. One study (Kjellman et al., 2002) identified that pain intensity, well being, expectations of treatment and duration of current episode predicted outcome of treatment for non-specific neck pain. Of these, only longer duration of the current episode predicts both progression of neck pain and outcome following treatment. The findings of this systematic review were used to inform the selection of predictor variables for outcome of participants in the GET UP neck pain trial.

The next chapter is a review of the literature relating of the conservative management of neck pain. It considers a wide range of treatment approaches that are routinely available to physiotherapists, chiropractors or osteopaths.

CHAPTER 3

EVIDENCE FOR THE CONSERVATIVE MANAGEMENT OF NECK PAIN: A LITERATURE REVIEW

3.1 INTRODUCTION

This chapter reviews the conservative management options that are within the scope of physiotherapy practice for patients with neck pain. Physiotherapy usually takes a multi-modal approach that may incorporate a wide range of conservative options. These usually include 1) diagnostic triage, 2) advice and education, 3) passive treatments such as electrotherapy modalities or manual therapy, which the physiotherapist performs on the patient and 4) active treatments such as exercise, which the patient undertakes under the supervision or advice of the physiotherapist. The remaining part of this chapter is divided into the four sections listed above.

3.1.1 Data sources and search strategy

Relevant studies were identified from online searches of MEDLINE, EMBASE, AMED, Psychinfo and PEDro between 1966 and May 2005. Keywords used included neck pain, cervical pain, physiotherapy, chiropractic, osteopathy, education, information, advice, cognitive-behaviour, psychosocial, manipulation, mobilisation, manual therapy, massage, modalities, electrotherapy, heat, ice, ultrasound, faradism, TENS, interferential, shortwave, laser, acupuncture, immobilisation, collars, traction, exercise, stretching, strengthening, endurance, proprioception.

3.1.2 Study selection

A study was included if: 1) the study population consisted of adults with mechanical neck pain, with or without referral into the shoulders, arms or head. Due to the limited number of articles related to neck pain, whiplash associated disorders and cervicogenic headache were included; 2) it was a systematic review, randomised controlled trial (RCT) or controlled clinical trial (CCT); 3) it involved conservative interventions that are routinely available to physiotherapists, chiropractors or osteopaths. Conservative interventions are defined here as non-invasive, non-surgical, non-pharmacological options. A study was excluded if it involved serious pathology, systemic disease, deteriorating neurological problems, inflammatory conditions, major trauma or non-

cervicogenic headaches. The author reviewed the titles and abstracts of the studies and retrieved all relevant citations. The evidence was considered en bloc since there was insufficient evidence to consider acute, sub-acute or chronic categories separately. The majority of evidence relates to chronic neck pain but where possible, the evidence to support management of acute neck pain is differentiated.

3.2 DIAGNOSTIC TRIAGE

Diagnostic triage is a management process rather than a treatment technique. Traditionally diagnostic triage is undertaken by a physician. However, more recently physiotherapists in the UK are often the first point of contact for the patient. Consequently, physiotherapists can expect to undertake diagnostic triage as part of their usual physiotherapy role. Patients with serious pathology (red flags) requiring the urgent attention of a consultant physician, and other conditions that are not appropriate for physiotherapy are screened out. In the rare event of finding serious pathology an emergency referral for specialist assessment must be made. Having excluded serious pathology the physiotherapist can confidently consider the problem to be simple or non-specific neck pain. The physiotherapist is then able to provide the patient with a meaningful explanation of the problem, reassurance, appropriate advice and relevant conservative treatment.

3.3 EDUCATION AND ADVICE

There is emerging evidence from the literature that appropriate written information can be an effective component in the management of musculoskeletal conditions (Burton et al., 1999; McClune et al., 2003), while poor information, or misinformation can adversely affect health behaviour and health outcomes (Cedraschi et al., 1998; Coulter, 1998). The array of written and oral education and advice options for neck pain is vast and may be delivered in a variety of ways e.g. individual or group teaching, leaflets or books, audio-tapes, internet sites, lectures, discussion, demonstration, practise, re-enforcement (Theis and Johnson, 1995). Unfortunately, the quality of this material is variable (Coulter, 1998; Gross et al., 2002). The therapist commonly provides patients with generalised biomechanical information (Moffett and McLean, 2006). However, various psychosocial and cognitive-behavioural factors including patients' beliefs, concerns and expectations have been identified as important for neck pain and should be addressed (Albright et al., 2001). The remainder of this section will review both patient education interventions and cognitive-behavioural therapy based interventions.

3.3.1 Patient education

A Cochrane systematic review of RCTs and CCTs investigated the efficacy of patient education strategies to reduce neck pain in adults with mechanical neck pain (Gross et al., 2002). These reviewers found three relevant RCTs which ranged from having weak to strong methodological quality. In one RCT, Kamwendo & Linton did not find significant reductions in pain using group instructional strategies (neck school) and exercise with or without psychological counselling compared to no treatment (Kamwendo and Linton, 1991). Koes et al. did not find a significant reduction in pain using individualised patient advice, anti-inflammatories and analgesics compared with placebo (Koes et al., 1992). However, McKinney found that advice which included demonstrated mobilization exercises, verbal and written instruction on posture correction, the use of a collar, heat sources, muscle relaxation and analgesics gave significant pain relief compared with general advice about mobilisation after a period of rest and use of analgesics at four weeks of treatment (McKinney, 1989). The first two studies were considered to have low statistical power due to the small number of subjects in the trials low quality. The third study was considered weak due to methodological flaws. Overall, Gross et al concluded that neither individual nor group patient education has been shown to be effective in reducing pain for mechanical neck disorders (Gross et al., 2002).

Two additional recent, high quality RCTs were also identified. The first study (Linton and Andersson 2000) investigated patients with acute and sub-acute neck and back pain (n=243). They compared three interventions: 1) an educational pamphlet offering advice about remaining active and thinking positively; 2) an extensive information programme with six instalments based on a traditional back school approach and 3) a group cognitive behavioural therapy programme delivered by a cognitive behavioural therapist for two hours, weekly, for six sessions. The sessions focussed on prevention of long-term disability. All three groups reported significant improvements in pain and fear-avoidance, although there were no significant differences between the groups. The pamphlet and information package groups both made significant improvements on pain catastrophising scores but the cognitive behavioural therapy group did not. However, neither of the groups receiving the pamphlet or information package were as effective as cognitive behavioural therapy at reducing the risk for a long-term sickness absence or decreasing physician/physiotherapy use (sickness absence was reduced by a factor of nine in the cognitive behavioural therapy group compared to the information groups).

The authors concluded that advice and education through a simple pamphlet or a comprehensive information package was not as effective as group cognitive behavioural therapy in lowering the risk of a long-term disability as measured by sickness absence and utilisation of health resources. The cognitive behavioural therapy programme was delivered by trained cognitive behavioural therapists and is not normally available to physiotherapists. However, the simple pamphlet and basic advice sessions were as beneficial at reducing pain and fear avoidance as cognitive behavioural therapy and this is within the scope of most physiotherapists. Basic advice sessions might be enhanced by the addition of information related to managing flare-ups/relapses and also longer term aims such as remaining physically active.

The second study (Horneij et al., 2001) undertook an RCT of nursing aides with neck, shoulder or back pain (n=282) in the preceding 12 months. Participants were randomised to one of three interventions: 1) an individualised education and exercise programme; 2) stress management and 3) no intervention. The study found that all three groups made non-significant improvements in neck and shoulder pain and perceived pain related interference with work and activities of daily living immediately after treatment and at 12 month follow-up. There were no differences in pain or disability between the groups at any stage. They concluded that the individualised education/exercise programme and the stress management programme were not effective in reducing neck pain or disability.

Thus there is conflicting evidence for the effectiveness of education for patients with neck pain. There is evidence from one high quality study that patient education may be effective in reducing pain and fear avoidance, but that it is generally less effective than cognitive behavioural therapy in lowering the risk of a long-term disability. The remaining evidence does not support the effectiveness of patient education strategies. This raises a number of quality and effectiveness issues for all clinicians to consider.

3.3.2 Cognitive behavioural interventions

Three RCTs have investigated the effectiveness of cognitive behavioural therapy to reduce neck pain and disability. As described in section 3.3.1 above Linton & Andersson's study of neck and back pain revealed that the risk of long-term sickness absence was significantly ($p<0.05$) reduced by a factor of nine in the group cognitive behavioural therapy programme by comparison with the other two groups receiving

information (Linton and Andersson 2000). The group cognitive behavioural therapy, delivered by trained cognitive behavioural therapists, also demonstrated a significant decrease in the use of physician care ($p<0.001$) and physical therapist care ($p<0.01$) compared with the other two groups. The authors conclude that group cognitive behavioural therapy is more effective than patient information at lowering the risk of long-term disability and health care utilisation in patients with neck pain. However, compared with cognitive behavioural therapy, the pamphlet and information session were as effective at reducing pain and fear avoidance and significantly more effective at reducing pain catastrophising scores.

Linton & Ryberg investigated a cognitive behavioural therapy programme in group of non-patients recruited from a general population study (n=253) who had experienced four or more episodes of neck or back pain symptoms in the preceding 12 months and less than 30 days off work (Linton and Ryberg 2001). Subjects were randomised to either: 1) standardised group cognitive behavioural therapy delivered by a cognitive behavioural therapist or 2) any usual treatment obtained from a general practitioner, physical therapist, chiropractor etc. At one year follow-up the cognitive behavioural therapy group demonstrated significantly better results on sickness absence ($p=0.032$) and number of pain free days ($p<0.05$). However, there were no within group or between group differences on measures of health care utilisation, pain experience, physical function, pain coping strategies, fear avoidance, anxiety and depression or coping strategies. The risk for long term sick leave during the follow-up period was reduced by a factor of three in the cognitive behavioural therapy group. The authors argued that group cognitive behavioural therapy produced a significant preventative effect with regard to disability (ie sickness absence). However, cognitive behavioural therapy was as ineffective as other treatments at changing pain, function and other psychological measures. This may be related to the fact that the subjects in this trial were from a non-patient group with relatively low levels of back and neck pain and were generally functioning well physically and emotionally. The effects of these interventions may have been greater in a patient group who were seeking treatment.

The third study was related to physiotherapy intervention for neck pain (Klaber Moffett et al., 2005). Patients (n=268) were randomised to receive either (1) usual physiotherapy, at the discretion of the physiotherapist or (2) a brief physiotherapy intervention (1-3 sessions) using cognitive behavioural principles to encourage self-

management and return to normal functional activities. Both groups made small but significant improvements at 12 month follow-up, but the usual physiotherapy group had significantly better (p=0.01) neck pain and disability (NPQ) scores compared with those receiving brief physiotherapy intervention.

There is some evidence for the use of cognitive behavioural interventions in the management of neck pain. Intensive cognitive behavioural therapy delivered by trained cognitive behavioural therapists may be useful at reducing sickness absence and health care utilisation. Brief physiotherapy intervention based on cognitive behavioural principles may be useful in reducing pain and disability. In many other regards cognitive behavioural interventions as a stand alone intervention may be no more effective than other education strategies or conventional treatments. However, it is possible that cognitive behavioural interventions may be more effective if delivered in combination with usual physiotherapy approaches to treatment. Further research in this area is required. Adequacy of training of the physiotherapists providing cognitive behavioural intervention may also be an important factor for getting good result with patients (Klaber Moffett et al., 2005).

3.3.3 Combination strategies

Evidence based booklets, namely The Whiplash Book (Burton et al., 2002) and The Neck Book (Waddell et al., 2004) have recently become available for neck pain patients. These provide a combination of patient education and cognitive behavioural advice. These booklets provide patients with information and advice on how to cope with their neck problem. The whiplash booklet was evaluated among 142 whiplash patients attending an accident and emergency department or a manipulative practice. The booklet was considered easy to read, understandable, believable and successful in conveying the main messages. The booklet also produced a significant improvement in patients' beliefs about whiplash (McClune et al., 2003). Further studies are required to evaluate the effectiveness of these booklets in reducing neck pain or disability

In summary, there is insufficient evidence to support the effectiveness of education and advice strategies for patients with neck pain. All clinicians should heed the warning that poor quality information may adversely affect health behaviour and outcomes (Cedraschi et al., 1998; Coulter, 1998). There is a need for further good quality studies of evidence based educational programs and cognitive behavioural interventions for

patients with neck pain, possibly as stand alone interventions but also as part of a multimodal programme of treatment (Swenson 2003).

3.4 PASSIVE TREATMENTS

3.4.1 Manual therapy (manipulation and mobilisation)

Manipulation and mobilisation are common place manual techniques, which physiotherapists may use in the management of neck disorders (Gross et al., 2002). Cervical manipulation is defined as the use of a localised high velocity, low amplitude passive thrust directed at specific joint(s) of the cervical spine to take them beyond their restricted range of movement (Harvey et al., 2003). Cervical mobilisation includes any manual therapy technique using low grade/velocity, small or large amplitude passive movement techniques or neuromuscular techniques directed at joint dysfunction that does not involve a high velocity thrust (Koes et al., 1991; Hurwitz et al., 1996).

Between 1991 and 2004, manual therapy for neck pain has been the subject of nine systematic reviews (Koes et al., 1991; Aker et al., 1996; Coulter, 1996; Hurwitz et al., 1996; Kjellman et al., 1999; Gross et al., 2002; Ernst, 2003; Bronfort et al., 2004; Bronfort et al., 2004). Koes et al identified 5 neck pain RCTs all of which were rated as low quality (Koes et al., 1991). The most common methodological problems were related to drop-out rates, small population sizes, lack of a placebo group and blinding of patients and reviewers. Consequently, the majority of these reviews were unable to draw any conclusions about the efficacy of manual therapy. Only four systematic reviews reached substantial findings. As recently as 1999, it was found that only one third of trials were rated as good quality (Kjellman et al., 1999). Since then the quality of trials has improved considerably. Trials have become larger, are of higher methodological quality and have longer term follow-ups (Gross et al., 2002). Consequently, the evidence in support of manipulation and mobilisation has become stronger and more conclusive. In their Cochrane review, Gross et al identified 33 trials investigating the efficacy of manipulation and mobilisation for neck pain and assessed 42% as being high quality (Gross et al., 2002).

From the four systematic reviews which reached any clinical conclusion, the evidence is summarised as follows:

- Multimodal care, which includes manipulation and/or mobilisation plus exercise, is beneficial in achieving pain reduction and patient satisfaction in acute and chronic

neck pain and cervicogenic headaches when compared with no treatment (Gross et al., 2002; Bronfort et al., 2004).

- Combined manipulation and mobilisation is effective in the short and long term when compared with no intervention for the treatment of cervicogenic headaches (Gross et al., 2002; Bronfort et al., 2004).
- Combined manipulation and mobilisation in combination is superior to general practitioner management for short-term pain reduction in chronic neck pain (Hurwitz et al., 1996; Bronfort et al., 2004).
- Manipulation is effective in the short term when compared to massage or placebo spinal manipulation for treatment of cervicogenic headaches (Bronfort et al., 2004).

In addition to these systematic reviews three additional RCTs were identified (Evans et al., 2002; Giles and Muller, 2003; Dziedzic et al., 2005).

In a low quality RCT, Giles & Muller randomised 115 patients with chronic spinal pain to one of three interventions: 1) medication; 2) needle acupuncture or 3) spinal manipulation (Giles and Muller 2003). At nine weeks follow-up none of the groups demonstrated significant improvement in neck disability scores. However, the groups receiving manipulation and acupuncture showed significant improvements in pain while those receiving medications did not improve. However, between groups analysis was not conducted and it is not known whether there was a significant between group differences. The validity of this study is limited and the results must be treated with caution. The study was based on a small population and it is not clear how many subjects had neck pain. In addition, 40% of subjects dropped out at the nine week follow-up.

A recent high quality RCT investigated the use of pulsed shortwave diathermy (Dziedzic et al., 2005). 350 patients with non specific neck pain were randomized to one of: 1) advice and exercise plus manual therapy; 2) advice and exercise plus pulsed shortwave or 3) advice and exercise alone. At six month follow-up all groups had a reduction of neck pain and disability. However, there were no statistically significant differences in mean changes between groups. The authors concluded that the addition of manual therapy did not provide any additional benefits over and above standard advice and exercise alone.

In a good quality trial, Evans et al. randomised 191 chronic neck pain patients to one of three treatments: 1) spinal manipulation combined with rehabilitative exercise; 2) rehabilitative exercise alone and 3) spinal manipulation alone (Evans et al., 2002). Ninety three percent of patients completed an 11-week intervention phase. 76% provided data at all evaluation time points over a two-year follow-up period. A significant difference in pain was observed in favour of both exercise groups ($p= 0.04$). However the group receiving combined spinal manipulation and rehabilitative exercise were significantly more satisfied with their care than the groups receiving rehabilitative exercise alone ($p = 0.02$) or spinal manipulation alone ($p < 0.001$). No significant between group differences were found for neck disability, general health status, global improvement or over the counter medication use. The results of this study did not demonstrate any advantages of spinal manipulation compared with rehabilitative exercise. The increased level of patient satisfaction with combined spinal manipulation/exercise provides support for a multimodal treatment approach.

Though not completely consistent, there is evidence from reviews and RCTs that multimodal care, incorporating manual therapy and exercise is a beneficial way of gaining pain relief and improving function for patients with mechanical neck disorders and cervicogenic headaches. Patients may be more satisfied with this kind of multimodal approach to treatment. On its own, manual therapy appears to have short term effects, although the evidence for long term effects is conflicting. Manual therapy is more effective than usual GP care, but appears to be no more effective than other forms of physiotherapy treatment.

3.4.2 Massage

Massage is an ancient form of treatment that is considered a manual therapy technique. Only one systematic review and one subsequent good quality RCT were found that investigated massage for the treatment of neck pain. In their systematic review, the Philadelphia Panel found no evidence for the efficacy of massage due to a lack of controlled trials (Albright et al., 2001). They recommended further well-designed trials investigating the adjunct and sole use of massage for patients with neck pain. In their study, Irnich et al. randomly allocated 177 chronic neck pain patients to one of three interventions: 1) acupuncture; 2) massage or 3) sham laser acupuncture (Irnich et al., 2001). Their outcome measures were pain on cervical movement, range of motion, pressure pain threshold, changes of spontaneous pain, global complaints and quality of

life (SF-36). These were measured at baseline, one week and three months after treatment. One week after treatment the acupuncture group showed a significantly greater improvement in motion related pain (p=0.0052) compared with massage, but not compared with sham laser (p=0.327). These results were not maintained after three months. There were no between group differences on any other outcome measures.

There is no evidence of efficacy for massage for patients with chronic neck pain. In line with the European guidelines for low back pain (Hildebrandt et al., 2004), massage is not recommended as a stand alone treatment for neck pain (Moffett and McLean, 2006). It may be worth considering the possibility that massage may lead to patient passivity, inactivity and disability behaviour (Swenson 2003). In some circumstances massage may be a useful adjunct treatment to support more active treatment programmes that encourage increased activity or return to normal activity (Moffett and McLean, 2006).

3.4.3 Physical modalities

Physiotherapists commonly include physical modalities in the belief that they reduce pain and inflammation. There are a wide array of modalities which are widely used e.g. heat, cold, ultrasound, faradism, TENS, interferential therapy, pulsed electromagnetic therapy, laser therapy etc. Between 1996 and 2004, physical medicine modalities for the treatment of neck pain were the subject of 8 systematic reviews (Aker et al., 1996; Belanger, 1996; Kjellman et al., 1999; Gross et al., 2000; Albright et al., 2001; Swenson, 2003; Bronfort et al., 2004; Verhagen et al., 2004). Overall there is limited evidence from small, single low quality studies, suggesting that laser therapy, therapeutic ultrasound and TENS are not effective for reducing neck pain (Aker et al., 1996; Gross et al., 2000; Albright et al., 2001). Not enough evidence exists to determine the effectiveness of other modalities i.e. heat, cold, faradism etc.

A previously mentioned study (section 3.4.1) investigated the use of pulsed shortwave diathermy (Dziedzic et al., 2005). 350 patients with non specific neck pain were randomized to: 1) advice and exercise plus manual therapy; 2) advice and exercise plus pulsed shortwave or 3) advice and exercise alone. Although all groups improved, there were no statistically significant differences between the groups. The authors concluded that the addition of pulsed shortwave did not provide any additional benefits in the treatment of neck disorders over and above the standard physiotherapy treatments provided.

In summary there is little high quality evidence investigating physical modalities for neck pain, whiplash or cervicogenic headaches. The little that does exist appears to suggest that they are not effective for reducing neck pain.

3.4.4 Acupuncture

Physiotherapists in the UK commonly use needle acupuncture for pain relief in the treatment of neck pain. Five systematic reviews (Aker et al., 1996; Kjellman et al., 1999; White and Ernst, 1999; Gross et al., 2000; Smith et al., 2000) identified between them 14 RCTs comparing needle or laser acupuncture versus a range of control procedures including sham acupuncture, sham TENS, diazepam, traction, SWD, and mobilisation in people with acute or chronic neck pain. White & Ernst reviewed all 14 studies and found no consistent difference between acupuncture and other treatments (White and Ernst, 1999). The outcomes of the 14 trials were equally balanced between positive and negative outcomes. The consensus from the five reviews was for no evidence of efficacy for acupuncture in the management of neck pain. In addition, Smith et al. concluded that higher quality studies were associated with negative findings (Smith et al., 2000).

In addition to systematic reviews, we identified three further trials of acupuncture for neck pain (Irnich et al., 2001; Giles and Muller, 2003; He et al., 2004). The first examined the effect of acupuncture treatment versus placebo electro-acupuncture on chronic neck and shoulder pain in 24 sedentary female workers at six month and three year follow-up (He et al., 2004). They reported positive treatment effects at six months and at three years for the patients receiving acupuncture. However due to the small number of subjects in this study the results should be treated cautiously.

As described in section 3.4.2 above, Irnich et al. randomly allocated 177 chronic neck pain patients to one of three interventions: 1) acupuncture; 2) massage or 3) sham laser acupuncture (Irnich et al., 2001). One week after treatment the acupuncture group showed a significantly greater improvement in motion related pain ($p=0.0052$) compared with massage, but not compared with sham laser ($p=0.327$). These results were not maintained after three months. There were no between group differences on any other outcome measures. They concluded that acupuncture was a more effective

short term treatment than massage for patients with chronic neck pain. However, acupuncture was no better than sham laser.

As described in section 3.4.1, Giles & Muller randomised 115 patients with chronic spinal pain to receive one of: 1) medication; 2) needle acupuncture or 3) spinal manipulation (Giles and Muller 2003). The groups receiving manipulation and acupuncture showed significant improvements in pain nine weeks after treatment. Between groups analysis was not conducted and it is not known whether one treatment was more effective than the other. Due to the small population and the high number of drop-outs the results of this study should be treated cautiously.

The results of these studies add little to the evidence gained from systematic reviews. Overall, there is insufficient evidence for the efficacy of acupuncture compared with other treatments in patients with acute or chronic neck pain. At best, acupuncture may provide short term relief of neck pain and enhance neck range of motion. Acupuncture may be a useful adjunct treatment that provides sufficient temporary pain relief to encourage more active treatment programmes that increase activity or allow return to normal activity. The use of acupuncture as a sole treatment can not be recommended (Moffett and McLean, 2006) since the use of passive modalities may lead to patient passivity, inactivity and disability behaviour (Swenson 2003). Further well-designed good quality studies are warranted (White and Ernst, 1999), especially in light of recent evidence to support the use of acupuncture for chronic LBP (Brinkhaus et al., 2006; Ratcliffe et al., 2006).

3.4.5 Immobilisation/ collars

A traditional conservative intervention for acute traumatic cervical injuries, cervical radiculopathy and severe neck pain is "immobilisation" with a hard collar or relative immobilisation with a soft neck collar. The rationale for use is based on clinical custom rather than scientific evidence (Moffett and McLean, 2006).

A Cochrane review of conservative treatments for whiplash-associated disorders (Verhagen et al., 2004) found one good quality study and six low quality studies looking at the efficacy of soft collars. Based on this evidence they concluded that there was no evidence that a soft collar is effective compared with no treatment. Secondly, there was limited evidence from one good quality study and a bank of low quality

studies that active interventions (exercise and activity) are more effective than a soft collar for patients with acute whiplash.

In one further small study, Persson & Lilja randomised 81 consecutive patients with cervical radicular pain and nerve root compression to one of: 1) surgical decompression and fusion; 2) physiotherapy or 3) neck collar (Persson and Lilja, 2001). In all groups, pain improved after four months and 12 months, although it is not clear whether this improvement was significant. After four months, pain was significantly better in the surgery group compared with the neck collar group. There was a no difference in pain between the physiotherapy group versus the cervical collar group. After 12 months there was no difference between the three groups. This study demonstrated no long term disadvantage of neck collar immobilisation compared with usual physiotherapy or surgery. However, this study was small and the results should be treated cautiously.

Although based on weak evidence the move away from immobilisation towards more active based treatment strategies and advice is in line with international guidelines for whiplash associated disorders (Spitzer et al., 1995) and the advice to patients set out in the Neck Book.

3.4.6 Traction

Cervical traction is a common modality for treating neck pain. Traction may be applied manually or mechanically, statically or intermittently. The choice of method is based on therapist preference and experience. We found six systematic reviews investigating the effectiveness of traction for neck pain (Spitzer et al., 1995; van der Heijden et al., 1995; Aker et al., 1996; Kjellman et al., 1999; Gross et al., 2000; Albright et al., 2001). Between them they identified five clinical studies which investigated traction compared with a range of other treatments e.g. sham traction, positioning, instruction in posture, neck collar, placebo tablets, untuned shortwave diathermy, analgesics, collar. The majority of the studies were low quality e.g. small population size, lack of randomisation, poor description of statistical procedure etc. All the studies found that there was no difference between traction and its comparison treatment on any measures. The conclusions drawn from the systematic reviews were that insufficient good quality evidence existed to make any recommendations regarding the use of traction as a stand alone treatment for acute or chronic neck pain.

3.5 ACTIVE INTERVENTIONS

Exercise is an integral part of the physiotherapy approach to managing patients with neck pain. There are many possible ways of classifying exercise approaches e.g. generalised exercise for neck and/or upper limb, cervical stabilisation, specific exercise approaches, functional restoration, proprioceptive rehabilitation etc. The evidence for such exercise based approaches for neck pain is mostly sparse. Hoving et al. undertook a criterion based appraisal of review articles on neck pain to assess the methodological quality, conclusions and concordance among reviews about the conservative treatment of neck disorders (Hoving et al., 2001). They analysed reviews in four basic categories of conservative care including exercise intervention. Four reviews examined the efficacy of exercise approaches (Gebhard et al., 1994; Spitzer et al., 1995; Jordan and Ostergaard, 1996; Gross et al., 1998). Of these only Spitzer et al. indicated that exercise therapy was beneficial for the treatment of neck pain (Spitzer et al., 1995). The remaining three reviews were inconclusive. Hoving et al. concluded that there was a lack of evidence from good quality primary studies on neck pain. In recent years there has been a substantial addition of good quality trials to the literature (Hoving et al., 2001).

The remainder of this section will review the evidence for:

- Generalised neck/upper limb exercise
- Cervical stabilisation exercises
- Specific exercise approaches
- Multidisciplinary rehabilitation/functional restoration
- Proprioceptive retraining

3.5.1 Generalised neck/upper limb exercise

Several systematic reviews suggest that there is too little information to support or refute the use of exercise programmes in treatment of neck pain (Aker et al., 1996; Gross et al., 2000; Hoving et al., 2001). Others suggest that neck/shoulder rehabilitation exercises appear to be emerging as an effective way of managing neck disorders (Spitzer et al., 1995; Jordan and Ostergaard, 1996; Kjellman et al., 1999; Albright et al., 2001). The lack of conclusive findings in this area has been related to a lack of good quality primary research. In recent years a substantial number of good quality studies have been published and four pertinent systematic reviews have been undertaken for mechanical neck disorders (Sarig-Bahat, 2003; Kay et al., 2005),

headaches (Bronfort et al., 2004) and whiplash associated disorders (Verhagen et al., 2004).

The first of these (Sarig-Bahat 2003) was a high quality review that focussed on exercise therapy for management of neck pain. A variety of exercise regimes were investigated, including stretching, strengthening, endurance, aerobic training, postural correction, neuromuscular control and movement awareness. Fifteen additional studies were identified that had not been included in earlier systematic reviews. Articles were assessed for quality using the PEDro scoring system and validated against published scores on the PEDro website (www.pedro.fhs.usyd.edu.au). They concluded that there was strong evidence supporting the effectiveness of proprioceptive exercise and dynamic resisted strengthening exercises of the neck and shoulder muscles for chronic and frequent neck disorders. Additionally, there was moderately strong evidence to support the use of early mobilizing exercises in acute whiplash patients. There was no evidence to support or refute the use of group exercise, neck schools or single sessions of extension-retraction exercise.

The most recent Cochrane systematic review (Kay et al., 2005) also focussed on exercise regimes for management of neck pain. They included 31 studies that encompassed a wide range of exercise options. 35% of these trials were rated as high in quality using a Jadad scale (Jadad et al., 1996). The authors found limited evidence from one low quality study of benefit for eye-fixation, strengthening, stretching and strengthening for neck disorders with headaches. There was limited evidence for home exercise programmes and active range of motion exercises for patients with acute neck problems. The evidence for stretching and strengthening exercise in chronic conditions was unclear. However, they found strong evidence from multiple high quality studies in favour of a multimodal approach for exercise in conjunction with manual therapy for sub-acute and chronic neck disorders with or without headaches. They found no evidence of difference between different exercise approaches.

A Cochrane systematic review of conservative treatments for whiplash associated disorders (Verhagen et al., 2004) reported on active forms of treatment compared with 1) no treatment and 2) passive forms of treatment. Active treatment included exercise, return to normal activity, and multimodal treatment that included the use of exercise. The majority of the evidence was for acute whiplash associated disorders and was

assessed as low quality. The authors concluded that there was limited evidence that both passive and active interventions seemed more effective than no treatment. They also concluded that there was a trend from low quality studies that active interventions were more effective than passive ones for acute whiplash associated disorders, although the results from high quality studies were conflicting.

Another Cochrane systematic review of conservative treatments for chronic/ recurrent headache (Bronfort et al., 2004) investigated the efficacy of exercise therapy and multimodal interventions incorporating exercise for the management of cervicogenic headache. They concluded that there was moderate evidence from one high quality study that low intensity exercise therapy was superior to no treatment in the long and short term for the management of chronic cervicogenic headaches. There was moderate evidence that combined low intensity exercise therapy and manual therapy was superior to no treatment in the long and short term for the management of chronic cervicogenic headaches.

In addition to these systematic reviews, two relevant randomised clinical trials were identified (Evans et al., 2002; Viljanen et al., 2003).

In a high quality RCT (Viljanen et al., 2003) to determine the effectiveness of dynamic muscle retraining and relaxation training, 393 female office workers with chronic neck pain were randomised to 12 weeks of: 1) dynamic muscle training; 2) relaxation training or 3) ordinary activity. Muscle training incorporated stretching exercises and dynamic exercises using dumbbells to work large muscles in the neck and shoulder region. Relaxation training comprised progressive relaxation, autogenic training, functional relaxation and system desensitisation. Both intervention groups received 30 minute supervised sessions, three times per week for 12 weeks. All groups improved but there were no significant differences in pain intensity, disability or sick leave between any of the groups post treatment, six month or at 12 month follow-up. The authors concluded that dynamic muscle training was no more effective than getting on with ordinary activity.

A high quality study (Evans et al., 2002) randomised 191 patients with chronic neck pain to 11 weeks of one of three treatments: 1) medX rehabilitation programme consisting of cervical strengthening exercises on a "medX" variable resistance, cervical

extension and rotation machine (medX); 2) an exercise programme combined with manipulative therapy (Ex/SMT). The exercises consisted of dumbbell exercises for upper limb and weighted head gear for cervical strengthening or 3) Spinal manipulative therapy alone (SMT). At two year follow-up, the study demonstrated a significant improvement on neck pain for Ex/SMT ($p=0.05$) and medX ($p=0.02$) compared with SMT alone. Patient's satisfaction with Ex/SMT was significantly higher than medX ($p=0.02$) or SMT ($p<0.001$). There were no significant between group differences for neck disability, general health status, improvement or OTC medication use. Given the relatively small population and a 25% drop-out rate it is possible that this trial did not retain enough power to pick up significant differences in these measures. This evidence supports the view that exercise is an effective treatment approach for managing neck pain. A multi-modal approach that includes exercise may be the most effective and satisfactory means of doing this.

Overall, the evidence from systematic reviews and trials increasingly support the use of exercise approaches for the management of neck pain although they do not appear to be consistently superior to other conservative treatment approaches. There appears to be little evidence to clearly favour one exercise approach over another. There is strong evidence that multimodal treatment approaches which incorporate exercise are beneficial for sub-acute and chronic neck disorders with or without associated headaches (Evans et al., 2002; Bronfort et al., 2004; Kay et al., 2005).

3.5.2 Cervical stabilisation exercises

Evidence suggests that in the presence of neck pain there is development of deep cervical flexor muscle dysfunction, a compensatory increase in superficial muscle activity around the neck and shoulder girdle and neck muscle fatigue under sustained low loads (Jull 2000). These dysfunctions may not be addressed by traditional exercise strategies that focus on strength and high-load endurance retraining. Re-education of these deep cervical postural muscles may be possible using specific stabilisation exercises. Clinically the popularity of such programmes has grown (O'Leary et al., 2003). The aim of these exercises is to correct imbalances of activity between deeply placed stabilising muscles and more superficially placed mobilising counterparts (Richardson et al., 1998). One high quality RCT investigated the effectiveness of manipulative therapy and a low-load stabilisation exercise program for cervicogenic headache when used alone and in combination compared with a control group (Jull et

al., 2002). They randomised 200 subjects into one of four groups: 1) manipulative therapy group; 2) stabilisation exercises group, 3) manipulative and stabilisation exercise group or 4) a control group. At 12-month follow-up, all three intervention groups had significantly improved headache frequency, headache intensity and neck pain and disability compared with the control group (all $p<0.05$). There was no difference between any of the intervention.

In summary, there is preliminary evidence from the one good quality clinical study (Jull et al., 2002) described above to support a stabilisation approach to rehabilitation of neck pain. This is in line with similar evidence in which retraining of deep postural muscles of the lumbar spine alleviated the symptoms of back pain and improved function (Hides et al., 1996; O'Sullivan et al., 1997; Hides et al., 2001).

3.5.3 Specific exercise approaches

The McKenzie method is a system to classify and treat neck pain based upon mechanical and symptom reactions to repeated movements in specific directions, the directional preference of the patient and a clinical phenomenon referred to as centralisation. It is advocated as an active form of treatment in which patients manage their own condition. Despite frequent use, supporting research evidence is very limited. One very small RCT (Kjellman and Oberg, 2002) compared McKenzie treatment to a general neck and shoulder exercise programme and a control group receiving low intensity ultrasound. 70 patients with simple, mechanical neck pain were randomised to one of the three groups. All three groups showed significant improvement in their pain and disability at three weeks, six months and 12 months, but there was no difference between the groups at any stage. This study can only be considered as a pilot study and from these findings it is not possible to support or refute the use of the McKenzie method for the management of neck pain.

The aims of Feldenkrais are to increase body awareness, co-ordination and control, breaking stereotyped movement and tension patterns. In their low quality study RCT, Lundblad et al compared Feldenkrais intervention with exercise based physiotherapy and a control group. 97 female workers with neck-shoulder complaints were randomised to one of the interventions. At approximately two months follow-up, Feldenkrais was associated with significant improvements in disability ($p=0.025$) compared with control (Lundblad et al., 1999). However this study had small numbers

in each intervention and a high drop out rate with only 58 participants completing the course of treatment. In addition their results are not based on intention to treat analysis. Due to the low overall quality of this study, the findings should be treated with caution.

Overall there is little evidence for the efficacy of specific exercise approaches to the management of neck pain. This is due to the lack of good quality trials investigating these approaches.

3.5.4 Multidisciplinary rehabilitation/ functional restoration

Functional restoration programmes, (also known as physical conditioning programs, work conditioning or work hardening) are undertaken by patients with the express aim of improving work status and function. Very little research has investigated the efficacy of these programmes for neck pain patients.

Karjalainen et al. undertook a systematic review of RCTs and CCTs appraising the effectiveness of bio-psychosocial rehabilitation for working age patients with neck and shoulder pain (Karjalainen et al., 2001). Only two low quality studies were found. Neither study demonstrated a difference between biopsychosocial rehabilitation and other interventions such as traditional care or care from a psychologist. Karjalainen et al concluded that there was little evidence for the use of bio-psychosocial rehabilitation for neck and shoulder pain. Schonstein et al. undertook a systematic review of RCTs comparing the effectiveness of functional restoration programs with other management strategies for workers with back and neck pain (Schonstein et al., 2003). They identified 18 relevant RCTs, however none of the studies were related to subjects with neck pain.

Currently there is no evidence of efficacy for multidisciplinary rehabilitation/ functional restoration approaches for patients with neck pain. The bulk of research in this area has been conducted with LBP patients. European guidelines found strong evidence that multidisciplinary bio-psychosocial rehabilitation programmes using a functional restoration approach were able to reduce pain, improve function and promote return to work in patients with chronic low back pain (Hildebrandt et al., 2004). Further research is needed for patients with neck pain.

3.5.5 Proprioceptive retraining

Proprioceptive retraining is not a treatment approach routinely used by physiotherapists and is more likely to be employed by specialised clinicians e.g. those working with balance disorders. Several authors have identified alterations in postural control and proprioception in patients with whiplash associated disorders (Heikkila and Astrom, 1996; Loudon et al., 1997) and chronic neck pain patients (Revel et al., 1991; Revel et al., 1994; Karlberg et al., 1995). Altered cervical proprioception may be an important factor contributing to symptoms associated with neck disorders (Revel et al., 1991; McLain, 1994). Cervical mechanoreceptors are essential for sensing cervical positions and movements and overall postural control via their connections to the visual and vestibular systems (Dutia, 1991; Gimse et al., 1996). The symptoms associated with altered cervical proprioception may be dizziness and light-headedness (Karlberg et al., 1995), balance disorders (Karlberg et al., 1995) or diminished neuromuscular protection of articular structures (Proske et al., 1988). The importance of the proprioceptive system as a pain modulator can not be ignored.

Sarig-Bahat, in her systematic review, reported strong evidence for the use of proprioceptive exercise for both chronic and frequent neck pain (Sarig-Bahat, 2003). In addition, we found two further studies that investigated the effect of proprioceptive rehabilitation exercises (Heikkila and Astrom, 1996; Humphreys and Irgens, 2002).

The first study investigated cervicocephalic kinesthetic sensibility in patients with whiplash injury and the effects of a rehabilitation programme (Heikkila and Astrom, 1996). Fourteen patients with whiplash injury and 34 healthy subjects participated in this study. Active head repositioning accuracy (HRA) was significantly less precise in the whiplash subjects compared to the control group. HRA in the whiplash group was more precise after a five week rehabilitation programme. This is a very small study on a convenience sample which merely suggests that cervicocephalic kinesthetic sensibility can be retrained in patients with whiplash. It is not known whether this resulted in a change of neck symptoms or disability.

Humphreys & Irgens conducted a prospective study on a convenience sample of 28 chronic neck pain subjects versus 28 age and gender matched, asymptomatic control subjects (Humphreys and Irgens, 2002). HRA was significantly reduced in neck pain subjects in comparison with control subjects ($p < 0.001$). Both symptomatic and

asymptomatic subjects were randomised to either a rehabilitative exercise or non-exercise group. Subjects receiving exercise intervention were trained to perform eye-head-neck co-ordination exercises. They were asked to perform the exercises twice daily over a four week period, and to keep a diary of exercise compliance and any associated symptoms. At four weeks follow-up the symptomatic exercise group reported a significant reduction in pain and significant improvement in HRA compared with the symptomatic non-exercise group (both $p < 0.001$). The authors concluded that proprioceptive exercises may be helpful in reducing pain and disability in chronic neck pain subjects. Due to the small numbers of subjects taking part in the trial, findings should be treated with caution.

Although the impact of the proprioceptive system on cervical pain and dysfunction is poorly understood, there is some evidence from reviews and low quality studies that proprioceptive rehabilitation may be helpful in the management of patients with neck pain. However this would require a greater understanding of proprioceptive dysfunction and rehabilitation strategies. Further research in this area is required.

3.6 CONCLUSION

There are only a limited number of good quality studies investigating the effectiveness of conservative management options for mechanical neck pain. The provision of good quality advice and education providing simple positive messages is central to the role of physiotherapists. However there is little evidence to support the effectiveness of this role. The majority of passive interventions has little support from research. Massage, physical modalities, acupuncture, immobilisation, traction are not researched in enough detail to make statements of efficacy. These interventions are at best adjunct techniques which may be used as part of a multimodal programme of rehabilitation. They may be employed as a means of producing pain relief, to support more active programmes of treatment that encourage patients to increase activity levels or return to normal activity. The exception to this is the use of mobilisation and manipulation. These techniques are effective in the short and long term for the management of acute and chronic neck disorders. They may be effectively employed either in combination with each other, or in combination with other forms of treatment such as exercise as part of a multimodal package of treatment.

Of all the conservative management options, active interventions based on exercise appear to have the strongest evidence base for the treatment of chronic neck pain. However, this evidence is not completely consistent and exercise based approaches are not necessarily superior to other conservative treatments. General neck and upper limb endurance training or dynamic strengthening programmes, cervical stabilisation exercises and proprioceptive exercise approaches appear to be more favourable exercise options than stretching, return to normal activity or no intervention. Additionally, multimodal treatment incorporating exercise based approaches in combination with other forms of treatment such as manipulation, mobilisation have also been found to be effective.

It is not known whether comprehensive exercise programmes incorporating endurance, strength, stabilisation and proprioceptive training are more effective in combination or in isolation. It is not known whether multimodal treatment such as that delivered by physiotherapists (also known as Usual Physiotherapy) is more or less effective than comprehensive exercise based approaches, for patients with neck pain. A randomised controlled trial comparing the effectiveness of usual physiotherapy and a comprehensive exercise based approach is needed. This research forms the focus of this thesis and is described in Chapter Seven.

The next chapter is a review and selection of neck outcome measures and upper limb outcome measures that will be used as primary and secondary measures of outcome for the RCT described in Chapter Seven.

CHAPTER 4

NECK AND UPPER LIMB OUTCOME MEASURES: A LITERATURE REVIEW

4.1 INTRODUCTION

There are many outcome measures which are pertinent to mechanical neck pain or upper limb dysfunctions. The majority evaluate both pain and disability. In relation to measuring change in pain and disability in patients over time, the quality of the chosen outcome measure is important. The quality of an outcome measure is related to its reliability, validity, responsiveness to change over time, applicability and practicality (Pietrobon et al., 2002). This chapter reviews and discusses the quality of neck outcome measures and upper limb outcome measures which are appropriate for use in patients with mechanical neck pain. It concludes by justifying the selection of one neck outcome measure and one upper limb outcome measure for use in the research component of this thesis.

4.1.1 Search strategy and inclusion/exclusion criterion for studies

The reliability, validity and responsiveness of neck outcome measures and upper limb outcome measures were reviewed using relevant good quality evidence. Outcome measures were included if they were self assessed, region specific (neck, shoulder or shoulder/upper limb) and included items on disability or physical functioning. Condition specific outcome measures were excluded (eg gleno-humeral instability, wheelchair users etc). Relevant articles, including reviews, reports and validation studies, were identified from computerised searches of MEDLINE, EMBASE, AMED, Psychinfo and PEDro between 1966 and June 2005. Keywords used were: neck, cervical, shoulder, upper limb, outcome measures, scales, questionnaire, index. The names of identified outcome measures were used as terms for a further search of the electronic databases. An internet search of Google and Google Scholar was also conducted to search for further papers. The author reviewed the titles and abstracts of the studies and retrieved all relevant citations. References of retrieved articles were screened for additional relevant studies.

4.2 NECK OUTCOME MEASURES

Seven self-administered neck outcome measures were identified, namely: Neck Disability Index (NDI); Northwick Park Neck Pain Questionnaire (NPQ); Copenhagen Neck Functional Disability Scale (CNFDS); Neck Pain and Disability Scale (NPADS); Neck Bournemouth Questionnaire (NBQ); Patient Specific Functional Scale (PSFS) and the Core Neck Pain Questionnaire (CNPQ). All outcome measures appeared suitable for patients with non-specific neck pain. They all measured pain and disability except the CNFDS (Jordan et al., 1998) which measured disability alone. These outcome measures have been subjected to varying degrees of recommended psychometric testing (Streiner and Norman 2003).

Table 4.1 compares the psychometric properties of each neck outcome measure and identifies the studies which validated each one. This table shows that four outcome measures, namely: The PSFS (Westaway et al., 1998), the CNPQ (White et al., 2004), the CNFDS (Jordan et al., 1998) and the NBQ (Bolton and Humphreys 2002) have undergone little validation. Of these tools only the NBQ has been revalidated since publication and this by the authors who originally developed it (Bolton 2004). Only the CNFDS has been used in further research and this was a study by the authors who developed the scale (Jordan et al., 1998). The PSFS is a self-administered questionnaire, but differs from the other scales. It is based on generating a problem list specific to each patient, instead of having patients check a general list of commonly encountered problems. Completion of the questionnaire is done jointly between clinician and patient, making it unsuitable for postal use. The questionnaire is well suited for identification of an individual's problems but not for making comparisons between different patient groups (Pietrobon et al., 2002). Therefore this questionnaire is probably more suitable for clinical rather than research purposes. These four measures are not suitable for this study and are given no further consideration.

The NPQ, the NDI and the NPADS are the most widely validated of the outcome measures and are now examined in greater detail.

4.2.1 The Northwick Park Neck Pain Questionnaire

The NPQ (Leak et al., 1994) is based on the Oswestry Low Back Pain Disability Questionnaire (ODI) (Fairbank and Pynsent 2000). It was developed and validated

Table 4.1 Comparison of psychometric properties of outcome measures for neck pain

Neck Questionnaires	Internal Consistency		Factor analysis	Test-retest reliability	Criterion validity	Construct validity	Responsiveness	Questionnaire content	References
	Item-total correlation	Cronbach's alpha							
Neck Disability Index Vernon & Moir (1991)	yes	yes	yes	yes	yes	yes	yes	Pain, other symptoms and disability	Vernon & Moir (1991); Hains et al (1998); Ackelman & Lindgren (2002); Hoving et al (2003); Wlodyka et al (2002; 2004)
Northwick Park Neck Pain Questionnaire Leak et al (1994)	yes	yes	no	yes	yes	yes	yes	Pain, other symptoms and disability	Leak et al (1994); Hoving et al (2003); Yeung et al (2004); Wlodyka et al (2002; 2004)
Neck Pain and Disability Score Wheeler et al (1999)	yes	yes	yes	yes	yes	yes	yes	Pain, other symptoms and disability	Wheeler et al (1999); Goolkasian et al (2002); Bicer et al (2004); Wlodyka et al (2002; 2004)
Copenhagen Neck Functional Disability Scale Jordan et al (1998)	yes	yes	no	yes	no	yes	yes	Disability	Jordan et al (1998)
The Neck Bournemouth Questionnaire Bolton & Humphreys (2002)	yes	yes	no	yes	no	yes	yes	Pain, other symptoms and disability	Bolton & Humphreys (2002); Bolton (2004)
The Patient Specific Functional Scale Westaway et al (1998)	no	no	no	yes	no	yes	yes	Pain and disability	Westaway et al (1998)
Core Neck Pain Questionnaire White et al (2004)	no	no	no	yes	no	yes	no	??	White et al (2004)

using a UK population. The questionnaire is composed of nine questions relating to symptoms i.e. pain intensity, pain frequency and pins and needles, and function i.e. sleeping, carrying, reading and watching TV, working/housework social activities and an optional driving function. Each question has five statements expressing progressive levels of functional disability. Each question scores between 0 to 4 with the resultant score being summated (maximum score 36, or 32 if the driving question is omitted) and then converted to a percentage to give an NPQ percentage score (Leak et al., 1994). **Reliability:** Test-retest reliability with a three day interval between tests indicated good short term levels of repeatability (Pearson r= 0.84; k=0.62, range 0.53 to 0.76) (Leak et al., 1994). A French version of NPQ also demonstrated good test-retest reliability (ICC =0.84) (Wlodyka et al., 2002). The internal consistency of the questionnaire was reported as good, but no statistical analysis was provided to support this view (Leak et al., 1994). This has been remedied in part by a Chinese NPQ which demonstrated good internal consistency (ICC=0.94; Cronbach's alpha=0.88) (Yeung et al., 2004). **Validity:** The correlation between the NDI and NPQ was high (r=0.88) demonstrating that the NPQ had good criterion related validity (Hoving et al., 2003). The Chinese NPQ correlated significantly with most of the sub-scores of the SF-36 (r ranging from -0.43 to -0.71) and a numeric rating scale (r = 0.69) indicating construct validity (Yeung et al., 2004). Content validity of the NPQ (and NDI) was assessed by comparing the scores and items of both questionnaires to the Problem Elicitation Technique (PET) (Hoving et al., 2003). The correlation between NPQ (and NDI) and PET was moderate (r=0.56) indicating the likelihood that they cover some of the same constructs. Of the 10 most commonly identified problems highlighted by patients completing the PET, only three were included in the NDI (work, driving and sleeping) and four in the NPQ (work, driving and sleeping and social activities). Other common problems highlighted by the PET, e.g. depression, frustration and anger, were not addressed by the NDI or NPQ. It was suggested that the NPQ and NDI measured similar constructs but that both lacked in assessment of emotional difficulties which are important features of the neck pain construct (Hoving et al., 2003). Additional measures of emotional function may be required to comprehensively measure neck related disability. **Responsiveness:** The NPQ demonstrated responsiveness to change in that NPQ change scores correlated linearly with question 10 of the NPQ, relating to global improvement in neck pain during follow-up evaluation of three days to one month (Leak et al., 1994). To date there are no known published figures of minimal clinically important differences. **Conclusions:** Among the strengths of the NPQ are reports of its use in different

populations and the fact that it has been validated against multiple measures of function, pain and clinical signs/symptoms. The NPQ was used recently in three recent high quality RCTs that investigated the efficacy of physiotherapy for patients with neck pain (Dziedzic et al., 2005; Klaber Moffett et al., 2005) and cervicogenic headaches (Jull et al., 2002). In addition it is easy for patients to complete, suitable for postal use, simple to score and provides a valid, reliable and responsive measure to evaluate outcome in patients with acute or chronic neck pain. The NPQ was considered an appropriate candidate as an outcome measure for this trial.

4.2.2 The Neck Disability Index (NDI)

The NDI (Vernon and Mior 1991), like the NPQ, was also based on the ODI. It is similar in style and content to the NPQ and was also developed and validated on a UK population. It asks 10 questions about neck pain and disability, with each question offering six statements expressing progressive levels of functional disability. Each question is scored between 0 and 5. The total NDI score is calculated by summing the scores of the 10 questions (maximum score 50) and converting it to a percentage. **Reliability:** A high degree of test-retest reliability was initially demonstrated on a sample of 17 whiplash patients ($r=0.89$, $p<0.05$) (Vernon and Mior 1991) and then again on a French NDI (ICC =0.93) (Wlodyka et al., 2002). The NDI was internally consistent for all 10 items (Cronbach's alpha coefficient >0.76 for each item) while the total index alpha co-efficient was calculated at 0.80 (Vernon and Mior 1991). **Validity:** Face validity was established through peer-review and patient feedback session (Vernon and Mior 1991). As with the NPQ, Hoving et al. expressed reservations about the content validity of the NDI regarding its ability to measure emotional difficulties related to neck pain. However they found that the NDI and NPQ were well correlated ($r=0.88$) demonstrating good criterion validity (Hoving et al., 2003). Construct validity was demonstrated between the NDI and a visual analogue scale (VAS) evaluating overall improvement ($r=0.6$) and McGill Pain Score ($r=0.7$) (Vernon and Mior 1991). **Responsiveness**: No studies were found which examined responsiveness to change of the NDI. A 10% change on the NDI was described as a clinically relevant change (Stratford et al., 1999). **Conclusions**: Among the strengths of the NDI are its reported use in different populations and the fact that it has been validated against multiple measures of function, pain and clinical signs/symptoms (Pietrobon et al., 2002). It has been used as an outcome measure in RCTs comparing the efficacy of different interventions (Evans et al., 2002; Kjellman and Oberg, 2002; Giles and Muller, 2003).

Similar to the NPQ, the NDI is easy for patients to complete, suitable for postal use, simple to score and provides a valid, reliable measure to evaluate outcome in patients with acute or chronic neck pain. The NDI was considered an appropriate candidate as an outcome measure for this trial.

4.2.3 The Neck Pain and Disability Scale (NPADS)

The NPADS (Wheeler et al., 1999) is a 20 item questionnaire based on the Million VAS (Million et al., 1981). Four dimensions to the scale have been identified, namely: neck problems, pain intensity, effects on emotion and cognition and interference with life activities (Pietrobon et al., 2002). Each question has a 5cm VAS graded from 0 (normal function) to 5 (worst possible situation). The scores of each item are summated to give a final NPADS score out of 100. **Reliability**: Excellent test-retest reliability was reported for this questionnaire ($r=0.97$; $p<0.01$) (Goolkasian et al., 2002) and a French translation (ICC =0.91) (Wlodyka et al., 2002). Good internal consistency was described, with coefficient alphas reported as 0.93 (Wheeler et al., 1999), 0.97 (Goolkasian et al., 2002) and 0.86 (Bicer et al., 2004) for all 20 items. However, it was suggested that the internal consistency calculation should be discounted since the NPADS is a multidimensional scale and calculation of a single alpha co-efficient is appropriate for correlation among items that measure one construct (Pietrobon et al., 2002). **Validity**: Face validity was evaluated by comparing scores of pain free volunteers with those of patients who had neck pain. Patients scored higher than pain free volunteers (Wheeler et al., 1999). Evidence for construct and criterion validity was provided by comparison with the ODI ($r=0.78$, $p<0.05$), the Pain Disability Index ($r=0.8$, $p<0.05$), and two psychological measures, namely; the Beck Depression Index ($r=0.52$, $p<0.05$) and the neuroticism scale of the Maudsley Personality Inventory ($r=0.33$, $p<0.05$) (Wheeler et al., 1999). Further evidence of criterion related validity was provided by comparison with the NDI ($r=0.72$) and Pain Disability Index ($r=0.74$) (Goolkasian et al., 2002). **Responsiveness:** The NPADS was responsive to change. Compared with NPQ and NDI change scores, changes in NPADS scores correlated highest with patient's overall assessment ($r=0.592$) making the NPADS the most responsive of the three questionnaires (Wlodyka et al., 2004). They concluded from this that the NPADS should be given preference over NPQ and NDI for use in clinical trials. The minimal clinically important difference has not been reported. **Conclusions**: The NPADS has not been extensively used for research purposes. In only one study has it been used by its authors to assess change after botulinum toxin injections for chronic

neck pain. To the best of our knowledge the NPADS has not yet been used on a British population. Nor has it been used to assess outcome following physiotherapy intervention. It is not as easy as the NPQ or NDI for patients to complete. It is not known whether it is suitable for postal use. Once completed it is simple to score. Although the NPADS was valid and responsive, some doubts were expressed about the way the reliability of the instrument was examined. These issues, coupled with the fact that it has not yet been extensively used for research purposes, raise doubts about the suitability of the NPDS as an appropriate outcome measure for this trial.

4.2.4 Conclusions

All the available neck outcome measures were limited in the extent to which they were psychometrically tested. The best available measures were the NPQ and the NDI. These are similar questionnaires, developed using similar patient groups, with similar strengths and weaknesses and with similar levels of validation. Both questionnaires may be limited in their ability to assess emotional difficulties related to neck pain. Nevertheless, both questionnaires appear to be validated against a variety of patient populations and against a variety of measures of pain disability and symptoms. They have been used in physiotherapy research of treatment effectiveness, are easy to complete and score, suitable for postal use and responsive to change. Researchers at the Institute of Rehabilitation have previously used the NPQ for neck related research, which provides access to information about mean NPQ scores and standard deviations in a similar study population. For these reasons, the NPQ was selected as the primary outcome measure for the current study.

4.3 UPPER LIMB OUTCOME MEASURES

Altogether 10 self-administered upper limb outcome measures were identified, namely: Disabilities of the Arm, Shoulder and Hand (DASH); Shoulder Pain and Disability Index (SPADI); The American Shoulder and Elbow Surgeons Evaluation Form (ASES); UK Shoulder Disability Questionnaire (SDQ - UK); Dutch Shoulder Disability Questionnaire (SDQ - NL); Simple Shoulder Test (SST); Shoulder Rating Questionnaire (SRQ); Shoulder Severity Index (SSI); Subjective Shoulder Rating System (SSRS) and Oxford Shoulder Score (OSS). These outcome measures appear suitable for patient populations with non-specific shoulder or upper limb dysfunction. To our knowledge none has been validated for the assessment of upper limb disability

in a population with neck pain. These outcome measures have been subject to varying degrees of recommended psychometric testing (Streiner and Norman 2003).

Table 4.2 compares the psychometric properties of each upper limb outcome measure and identifies the studies which validated each one. Table 4.2 shows that all the scales are limited in the extent to which they have been validated. The most widely validated of the scales are the DASH, SPADI and the ASES. These three scales also appear to be the most widely used upper limb questionnaires for research purposes. The other scales have been subjected to little psychometric testing and will not be considered further.

4.3.1 The Disabilities of Arm, Shoulder and Hand (DASH)

The DASH (Hudak et al., 1996) was developed as a regional outcome measure which considers the upper extremity as a single functional unit. This gives it wide applicability and allows for comparison across a variety of upper extremity conditions. It is a 30 item questionnaire measuring physical and social function and upper limb symptoms. There is also an optional sport and work specific section. Scoring for each item is a five point Likert scale with 1 indicating no difficulty and 5 indicating an inability to manage. The scores for all 30 responses are summed giving a score out of 150. The score is transformed to a DASH score out of 100, by subtracting 30 and dividing by 1.2. Higher scores indicate greater disability (McConnell et al., 1999).
Reliability: Preliminary work on the reliability of the DASH (internal consistency alpha coefficient ≈ 0.96, test-retest reliability ICC ≈ 0.92) has been carried out by those who developed it (Hudak et al., 1996; Marx et al., 1999; McConnell et al., 1999). This excellent level of internal consistency and test-retest reliability was replicated by other validation studies (Turchin et al., 1998; Beaton et al., 2001; Durand et al., 2005). The DASH has been translated into other languages including German, French, Dutch, Swedish, Spanish, Taiwanese and Chinese. These also demonstrated excellent levels of internal consistency and test-retest reliability (Atroshi et al., 2000; Rosales et al., 2002; Veehof et al., 2002; Offenbacher et al., 2003; Lee et al., 2004; Liang et al., 2004).
Validity: Content and face validity of the DASH in English and other languages was assured by including a variety of language and upper limb experts in the development process (McConnell et al., 1999; Lee et al., 2004; Durand et al., 2005). A thorough review of the literature was also conducted to ensure that the original DASH measured

Table 4.2 Comparison of psychometric properties of upper limb outcome measures

Neck Questionnaires	Internal Consistency		Factor analysis	Test-retest reliability	Criterion validity	Construct validity	Response to change over time	Questionnaire content	References
	Item-total correlation	Cronbach's alpha							
Disabilities of the Arm, Shoulder and Hand (DASH) Hudak et al (1996)	yes	yes	yes	yes	yes	yes	yes	Pain, other symptoms and disability	Hudak et al (1996); Upper Extremity Collaborative Group (1996); McConnell et al (1999); Navsarikar et al (1999); Atroshi et al (2000); Beaton et al (2001); Dubert et al (2001); Veehof et al (2002); SooHoo et al (2002); Rosales et al (2002); Gummesson et al (2003); Offenbacher et al (2003); Germann et al (2003); Liang et al (2004); Durand et al (2005); Lee et al (2005)
Shoulder Pain and Disability Index (SPADI) Roach et al (1991)	no	yes	yes	yes	yes	yes	yes	Pain and disability	Roach et al (1991); Williams et al (1995); Beaton & Richards (1996); Beaton et al (1998); Heald et al (1997);Roddey et al (2000); Beaton et al (2001); Cook et al (2001); Paul et al (2004)
The American Shoulder and Elbow Surgeons Evaluation Form (ASES) Richards et al (1994)	no	yes	no	yes	yes	yes	yes	Pain and disability	Richards et al (1994); Romeo et al (1996); Beaton & Richards (1996); Beaton et al (1998); Cook et al (2001); Michener et al (2002); Sallay et al (2003)
UK Shoulder Disability Questionnaire (SDQ - UK) Croft et al (1994)	no	no	no	no	no	yes	no		Croft et al (1994); Paul et al (2004)
Dutch Shoulder Disability Questionnaire (SDQ - NL) Van der Windt et al (1998)	no	no	no	no	no	yes	no		Van der Windt et al (1998); van der Heijden et al (2000); Paul et al (2004)

Simple Shoulder Test (SST) Lippitt et al (1993)	no	doubtful	yes	no	no	yes	no		Lippitt et al (1993); Beaton & Richards (1996); Roddey et al (2000); Cook et al (2001); Romeo et al (2004); Beaton et al (1998);
Shoulder Rating Questionnaire (SRQ) L'Insalata et al (1997)	no	doubtful	no	no	no	doubtful	no		L'Insalata et al (1997); Paul et al (2004); Vermeulen et al (2005)
Shoulder Severity Index (SSI) Patte (1987)	no	no	no	no	no	yes	no		Patte (1987); Beaton & Richards (1996); Beaton et al (1998);
Subjective Shoulder Rating System (SSRS) Kohn & Geyer (1997)	no	no	no	no	no	doubtful	no		Kohn & Geyer (1997); Beaton & Richards (1996); Beaton et al (1998);
Oxford Shoulder Score (OSS) Dawson et al (1996)	no	doubtful	no	no	no	yes	no		Dawson et al (1996)

all relevant issues (McConnell et al., 1999). Evidence of criterion and construct validity of the DASH was provided by comparison with a number of different upper limb and generic measures of health and well-being. The DASH and SPADI subscale scores correlated highly with each other (Spearman's r= 0.82 for SPADI pain; r= 0.87 for SPADI disability) indicating that the questionnaires measured similar constructs. DASH scores correlated against physician rated level of severity (ANOVA, F=19.85, p<0.0001), patient rated level of severity (ANOVA, F=16.08, p<0.0001), ability to work or not (t test, t=8.33, p<0.0001), the modified ASES (Pearson's, r=-0.81) the SF-36 (Pearson's r=0.73) and SF 36 subcales (Pearson's r range -0.36 to -0.62) (Hudak et al., 1996; Turchin et al., 1998; SooHoo et al., 2002). The DASH in other languages has consistently demonstrated good face, construct, criterion and content validity (Atroshi et al., 2000; Veehof et al., 2002; Offenbacher et al., 2003; Lee et al., 2004; Liang et al., 2004). **Responsiveness:** The DASH detected changes of disability over time in patients with a variety of upper-extremity musculoskeletal disorders (Gummesson et al., 2003. Further studies showed that the responsiveness of the DASH is comparable with other condition specific questionnaires such as Boston and Brigham (carpal tunnel) Questionnaire (Beaton et al., 2001; Greenslade et al., 2004) and the Patient Rated Wrist Evaluation (MacDermid et al., 2000; MacDermid and Tottenham, 2004). A 10 to 15 point change in mean DASH score is considered a minimal clinically important difference (Beaton et al., 2001; Hunsaker et al., 2002; Gummesson et al., 2003). **Conclusion:** The DASH appeared to be the most widely used and researched of the upper limb outcome measure. It was validated in multiple languages and found to be a valid, reliable and responsive measure of outcome in patients with a wide variety of upper limb musculoskeletal disorders. It is easy for patients to complete, suitable for postal use, and relatively simple to score. Therefore as a measure of neck related upper limb disability the DASH was considered an appropriate candidate as a secondary outcome measure for this trial.

4.3.2 The Shoulder Pain and Disability Index (SPADI)

The SPADI (Roach et al., 1991) was developed to measure pain and disability in non-specific shoulder pathology. It consists of 13 items divided into two subscales: pain (5 items) and disability (8 items). The response format for each question is a 10cm VAS anchored at each end by "no pain/difficulty" and "worst pain imaginable/so difficult required help". A score is calculated for each item ranging from 0-11. The subscale scores are calculated by adding up the scores for that subscale and dividing by the

maximum score possible for the items that were applicable to the subject. Any item that was marked by the patient as not applicable was not included in the scoring. This number was converted to a percentage. Scores in each subscale range from 0-100. Higher scores indicate greater levels of impairment. The total SPADI score is determined by averaging the pain and disability subscale scores, giving a total score range from 0-100. Each of the domains is equally weighted (Roach et al., 1991). **Reliability:** Test-retest reliability of the SPADI ranged from moderate (ICC=0.66) (Roach et al., 1991) to excellent (ICC=0.91) (Beaton and Richards 1998). The studies showed the internal consistency of the SPADI and both its subscales to be high (Cronbach's alpha total score=0.95; pain subscale=0.86; disability subscale=0.93) (Roach et al., 1991). This level of consistency has been replicated in other studies (Roddey et al., 2000). **Validity:** Content validity and face validity of the SPADI was facilitated by including a number of clinicians in the development process (Roach et al., 1991). The SPADI had broadly similar levels of criterion related validity to a number of other shoulder outcome measures (v SRQ, r=0.83; v SDQ-UK, r= 0.57; v SDQ-NL, r= 0.33; v SST, r= 0.74; v ASES, r= 0.77; v SSI, r= 0.79; v SSRS, r= 0.50) (Beaton and Richards, 1998; Paul et al., 2004; Placzek et al., 2004). This suggested that the SPADI measured broadly similar constructs to other shoulder outcome measures. In addition, the SPADI discriminated between levels of shoulder severity compared with a global rating of shoulder severity (ANOVA, F=19.69, $p < 0.0001$) (Beaton and Richards 1998). The SPADI also correlated against a number of general quality of life scales including the SF 20 (r=-0.25 to r= -0.50), the Health Assessment Questionnaire (r=0.61), the Sickness Impact Profile (SIP) (r= 0.57) and the SF 36 (r= 0.67) (Williams et al., 1995; Heald et al., 1997; Beaton and Richards, 1998). **Responsiveness:** The responsiveness of the SPADI was adequately demonstrated by calculating standardised response means for patients completing a global perceived measure of improvement (SRM = 1.38 and 1.23) (Beaton and Richards, 1996; Heald et al., 1997; Beaton and Richards, 1998). The SPADI was more responsive for assessing changes in shoulder disability than general measures of disability, e.g. the SIP total score (SRM = 0.79) or the pain and physical subscales of the SF-36 (SRM = 0.91 and 0.55 respectively) (Beaton and Richards, 1996; Heald et al., 1997; Beaton and Richards, 1998). The SPADI was also more responsive than other specific measures of shoulder disability compared with patient rated change e.g. the SPADI (Spearman's r=0.61) was more highly correlated than the SDQ-NL (r=0.58) and the SDQ-UK (r=0.54), but not as highly correlated as the SRQ (r=0.68) (Paul et al., 2004). A change score of 10% was

calculated as being a minimal clinically important difference. **Conclusion:** The SPADI is a valid, reliable and responsive instrument that provides a standardised measure of outcome in patients with a variety of non-specific shoulder disorders. It is easy for patients to complete, suitable for postal use, and simple to score. Although the SPADI has not been validated for use in a neck pain population, as a measure of neck related upper limb disability the SPADI was considered an appropriate candidate as a secondary outcome measure for this trial.

4.3.3 American Shoulder and Elbow Surgeons Evaluation Form (ASES)

The ASES (Richards et al., 1994) was developed in 1993 to standardise the assessment of shoulder function in subjects who were potential surgery cases. It incorporates two sections. The first part is completed by a clinician but is not scored. The second part is a patient self-evaluation and consists of 11 items. These 11 items are divided into two areas: pain (one item) and function (10 items). The response to the pain item is a 10cm VAS anchored at each end by "0= no pain at all" and "10= pain as bad as it can be". Each of the functional items have four response options scored from 0 (unable to do) to 3 (not difficult). The pain score and function composite score are equally weighted (maximum 50 points each) and combined to give a maximum score out of 100 (Richards et al., 1994). Consequently, the ASES is more heavily weighted towards pain assessment than the SPADI and DASH. The ASES has not been as strongly validated as the SPADI or the DASH. **Reliability:** Test-retest reliability was excellent in three studies with ICC scores ranging from 0.84 to 0.96 (Beaton and Richards, 1998; Michener et al., 2002; Sallay and Reed, 2003). It also compared favourably with other upper limb outcome measures, namely SPADI, SSI and SST (Beaton and Richards 1998). One study demonstrated an acceptable level of internal consistency (Cronbach alpha = 0.86) (Michener et al., 2002). **Validity:** Good levels of criterion related validity were demonstrated against a range of upper limb outcome measures including University of Pennsylvania Shoulder Score, SPADI, SST, SSRS, and SSI) (Pearson's r ranging from 0.73 to 0.79) (Beaton and Richards, 1998; Michener et al., 2002). Construct validity is generally lacking since two studies compared the ASES with the SF-36 and found variable levels of correlation (r=0.4 and r=0.67) (Beaton and Richards, 1998; Michener et al., 2002). However, there was evidence that the ASES discriminated between levels of shoulder severity (ANOVA, $F=12.11$, $p < 0.0001$) (Beaton and Richards 1998). **Responsiveness:** Responsiveness of the ASES was demonstrated in two studies with a standardized response mean (SRM) ranging between

0.93 and 1.5 (Beaton and Richards, 1998; Michener et al., 2002). This compared favourably with other shoulder questionnaires (SPADI, SSI and SST) (0.87< SRM < 1.23) (Beaton and Richards 1998). The minimal clinically important difference was calculated as being 6.4 ASES points (Michener et al., 2002). **Conclusion:** The ASES is the most weakly tested of the three upper limb outcome measures. By comparison to the SPADI and DASH, the ASES is more heavily weighted towards pain assessment and less so towards upper limb disability. For these reasons, the ASES was not considered appropriate for use in this study.

4.3.4 Conclusions

Overall, the DASH was more extensively validated than the SPADI. The DASH and SPADI subscale scores were well correlated with each other indicating that the questionnaires measured very similar constructs (Beaton et al., 2001). The responsiveness of the DASH (SRM = +/- 0.78) was slightly better than the SPADI (SRM= +/- 0.62) for patients with a range of upper limb dysfunctions. However, the same study demonstrated that the DASH had greater validity and responsiveness in both proximal and distal disorders, confirming its usefulness across the whole upper extremity (Beaton et al., 2001). The SPADI was developed for assessment of shoulder pain and disability, which gives it less utility. Overall the DASH received better ratings for its psychometric properties than the SPADI (Bot et al., 2004). Although the DASH has not been validated on a neck pain population, many North American clinics indicated that the tool was used for clinical purposes with a neck pain population (McConnell et al., 1999). Additionally, the Institute of Work and Health (www.dash.on.ca) confirmed that the DASH was likely to be suitable for the measurement of upper limb disability in a neck pain population. The DASH was therefore the upper limb outcome measure of choice for our trial.

4.4 CONCLUSIONS

This chapter reviewed the reliability, validity and responsiveness of a range of neck outcome measures and upper limb outcome measures. The NPQ and the NDI were equally matched as measures of neck outcome. The Institute of Rehabilitation used the NPQ in previous neck research, which allowed us access to information about mean NPQ scores and standard deviation for a similar study population. For these reasons, the NPQ was selected as the primary outcome measure for the GET UP neck pain trial. The DASH was the most extensively validated upper limb outcome measure and

considered the most useful tool across the whole upper extremity. For these reasons the DASH was selected as a secondary outcome measure of upper limb disability for the GET UP neck pain trial.

The next chapter is a review and selection of variables that will be used as predictors of outcome in the GET UP neck pain trial.

CHAPTER 5

A REVIEW AND JUSTIFICATION FOR THE USE OF POTENTIALLY PREDICTIVE VARIABLES OF TREATMENT OUTCOME IN THE GET UP NECK PAIN TRIAL: A SYSTEMATIC REVIEW

5.1 INTRODUCTION

The ability to predict outcome following treatment is important for two main reasons. Firstly, patients at risk of poorest outcome can be identified and targeted with appropriate early management strategies (Sterling et al., 2005). Secondly, patients can be streamlined towards appropriate interventions thereby maximising outcome for individual patients (Harvey and Cooper, 2005). This area of research has received little attention to date. No research has been found that investigated predictors of outcome following conservative intervention for patients with non-specific neck pain. Some studies have indicated that psychological, sociodemographic and physical variables play an important role in recovery or non-recovery from whiplash related neck pain (Cote et al., 2001; Scholten-Peeters et al., 2003; Sterling et al., 2005). One aim of this thesis is to identify those psychological, sociodemographic and physical variables which predict outcome of physiotherapy intervention for patients with non-specific neck pain.

Chapter Three reported on prognostic factors which predicted progression of non specific neck pain. There was strong evidence of unfavourable outcome associated with older age, longer duration of the current episode of neck pain, previous history of neck problems, co-existing shoulder problems and other musculoskeletal disorders. In contrast, there was strong evidence that regular exercise predicted good outcome. There was limited evidence of unfavourable outcome for headaches, unchanging neck pain, numbness in the hands, trauma, high levels of worrying, female gender, not being employed, little influence on own work situation, high job demand, repetitive work, some occupations, worse perceived health, lower quality of life scores and less. There was conflicting evidence that baseline measures of pain and disability predicted outcome. There was an absence of high quality research investigating the predictive nature of psychological factors.

Based on these findings, this chapter reviews and discusses a range of psychological, sociodemographic and physical variables which may predict treatment outcome for patients with mechanical neck pain. Where relevant, the reliability and validity of appropriate measurement tools are reviewed. These variables will be considered for their ability to predict outcome in the GET UP neck pain trial.

The variables under review are as follows:

- Age
- Gender
- Fear avoidance beliefs
- Pain self efficacy
- Coping strategies
- Anxiety and depression
- Upper limb disability
- Current smoking status
- Material and social deprivation
- Physical activity

5.1.1 Search strategy and inclusion/exclusion criteria for studies

Part of this chapter is concerned with the selection of assessment tools for psychological, sociodemographic, physical variables. The reliability, validity and responsiveness of appropriate tools were reviewed using relevant good quality evidence. Assessment tools were of interest if they were self assessed and suitable for use in a population with musculoskeletal disorders. Relevant articles, including reviews, reports and validation studies, were identified from computerised searches of MEDLINE, EMBASE, AMED, Psychinfo and PEDro between 1966 and December 2005. Keywords used included: neck, musculoskeletal pain, age, gender, fear avoidance, kinesiophobia, fear, pain self efficacy, coping, coping strategies, anxiety, depression, upper limb, shoulder, smoking, deprivation. The names of identified of known measures were also used as terms for a further search of the electronic databases.

5.2 AGE

There is strong evidence that age is associated with the onset of neck pain. Several good quality longitudinal studies have indicated that subjects in the age range 45-55 are twice as likely to develop neck pain as their younger counterparts (Niedhammer et al.,

1994; Pietri-Taleb et al., 1994; Leclerc et al., 1999; Viikari-Juntura et al., 2001; Gerr et al., 2002; Korhonen et al., 2003). The incidence with age is thought to follow a similar pattern to low back pain i.e. there is steadily increased prevalence until the 55-64 year age group and then the prevalence rate levels out (Brattberg et al., 1989; Badley and Tennant, 1992; Andersson et al., 1993). In addition there is strong evidence from good quality prospective studies (Cassou et al., 2002; Hill et al., 2004; Hoving et al., 2004) that older age is linked to the development of chronic, persistent or disabling problems in subjects who suffer from non-specific neck pain (see Chapter Three). The predictive validity of age for outcome following treatment of neck pain is not known. There is some evidence that older age is associated with poorer outcome for patients with chronic LBP

It is therefore concluded that age may predict the outcome of physiotherapy treatment and may be valuable as a potential predictive variable.

5.3 GENDER

It has been hypothesized that gender may predict treatment outcome for patients with chronic musculoskeletal disorders (McGeary et al., 2003. Research suggests that there are gender differences in pain perception that may be related to biological, psychological and social factors (Unruh, 1996; Berkley, 1997; Unruh et al., 1999). Researchers tend to agree that the incidence of neck pain is higher in women than men (Makela et al., 1991; Cote et al., 1998). Several good quality prospective studies identified that women were nearly twice as likely to develop neck pain as men (Leclerc et al., 1999; Viikari-Juntura et al., 2001; Gerr et al., 2002; Korhonen et al., 2003). Women were also more likely to report multiple locations of pain, such as pain in the neck, shoulder, arm, and thigh (Andersson et al., 1993). Additionally, women with neck pain were more likely to develop chronic, persistent or recurrent symptoms than men (Eriksen et al., 1999). Although women had a higher incidence of neck pain and were more likely to consult a GP (Croft et al., 2001), the predictive validity of gender regarding treatment outcome for neck pain is not known. However, women with chronic spinal pain may be more likely to respond positively to multidisciplinary and cognitive behavioural interventions than men (Jensen and Bodin, 1998; Jensen et al., 2001).

It is therefore concluded that gender may be predictive of outcome of physiotherapy treatment and may be valuable as a potential predictive variable.

5.4 FEAR AVOIDANCE BELIEFS

The fear avoidance model of exaggerated pain perception was developed to explain why some individuals with acute pain progressed to chronic pain, whereas others were able to recover (Lethem et al., 1983; Slade et al., 1983). The model proposed that fear of pain or re-injury led to the avoidance of particular movements or activities (Vlaeyen and Linton 2000). Individuals mostly confront their pain/injury and resume activities in a graded manner, eventually returning to normal levels of activity. Avoidance is a maladaptive response where potentially painful activities are avoided. Avoidance may exacerbate the fear and result in development of exaggerated pain perceptions, continued disability, and adverse psychological consequences (Lethem et al., 1983; Slade et al., 1983; Vlaeyen and Linton, 2000). Fear avoidance may also play an important role in "deconditioning syndromes" (Vlaeyen and Linton 2000). A number of studies have demonstrated that fear avoidance beliefs are an important psychosocial predictor of disability among patients with LBP and musculoskeletal pain (Klenerman et al., 1995; Crombez et al., 1999; Vlaeyen and Crombez, 1999; Denison et al., 2004; Grotle et al., 2006). A comprehensive review concluded that fear avoidance beliefs are related to the onset and maintenance of disability in musculoskeletal pain (Vlaeyen and Linton 2000). Others suggested that the role of fear avoidance beliefs still needs clarification (Pincus et al., 2002) since several studies have shown that fear avoidance beliefs have no predictive value (Burton et al., 1995; Kovacs et al., 2005; Sieben et al., 2005). Several studies have also shown that high fear avoidance beliefs predicted poor outcome following intervention for LBP (Fritz and George, 2002; Burton et al., 2004; Al-Obaidi et al., 2005). Although there is some preliminary indication that patients with high fear avoidance beliefs may specifically benefit from targeted approaches such as the Back to Fitness exercise programme (Klaber Moffett et al., 2004).

In the cervical spine, fear avoidance beliefs have been the subject of limited investigation. In a prospective study of 163 patients with neck or back pain (George et al., 2001) weaker associations were reported between fear avoidance beliefs scores and disability for patients with neck pain compared with patients with LBP. Patients with cervical pain were also more likely to report lower disability scores and lower fear avoidance levels regarding physical activity than patients with LBP. In a study of 90

people reporting acute neck or head pain after a motor vehicle collision, high baseline neck disability and high fear avoidance scores predicted outcome 6 months later (Nederhand et al., 2004). Using these variables they could correctly classify 83.3% of cases with chronic disability. This evidence suggests that although fear avoidance beliefs may predict outcome, the impact may be less profound in neck pain than LBP. This hypothesis requires further clarification. No evidence was found related to the predictive validity of fear avoidance beliefs with regards outcome following intervention for neck pain.

The Tampa Scale of Kinesiophobia (TSK) (Kori et al., 1990) is a measure for fear of movement, re-injury and increased pain. It is suitable for use with musculoskeletal pain (Crombez et al., 1999) and has been used for a number of studies related to neck pain (George et al., 2001; Nederhand et al., 2004). It consists of 17 questions which are scored on a four point scale ranging from "1=strongly disagree" to "4=strongly agree". The scores on item 4, 8, 12 and 16 are reversed. A total TSK score is calculated by summing the score from all 17 items giving a total score range from 17 to 68 (Swinkels-Meewisse et al., 2003). TSK scores larger than the median of 40 may be considered as elevated (Crombez et al., 1999). Overall the TSK has been shown to be both valid and reliable. Good test-retest reliability and good to high internal consistency has been demonstrated in several studies (French et al., 2002; Swinkels-Meewisse et al., 2003; Lundberg et al., 2004; Bunketorp et al., 2005; Burwinkle et al., 2005; Woby et al., 2005). The TSK has both face and content validity (Lundberg et al., 2004). TSK total scores correlated strongly with other fear measures, catastrophising, a simple behavioural test and measures of disability (Vlaeyen et al., 1995; Crombez et al., 1999; French et al., 2002; Swinkels-Meewisse et al., 2003; Roelofs et al., 2004), indicating good construct and criterion related validity. It is easy to complete and score and suitable for postal use. The TSK is considered a reliable, valid and appropriate measure of fear avoidance for this trial.

It is concluded that fear avoidance beliefs may predict outcome of physiotherapy treatment and may be valuable as a potential predictive variable.

5.5 PAIN SELF EFFICACY

Self-efficacy is defined as the personal conviction that one can successfully achieve specific outcomes or behaviours in a given situation (Bandura, 1977; Bandura, 1982).

The strength of a person's self-efficacy determines the amount of effort and persistence an individual will exert in trying to cope with difficult situations (Levin et al., 1996). Individuals who have high levels of self-efficacy are more likely to persevere in the face of failure, work harder on difficult tasks and exhibit fewer symptoms of anxiety than individuals with low levels of self-efficacy (Levin et al., 1996). Self-efficacy beliefs have been used to try to explain many of the behaviours and disabilities in patients with persistent or chronic pain (Jensen et al., 1991; Turk et al., 1996). In this pain self efficacy (PSE) model, a person who believes that they can cope with pain is more likely to engage in painful activities (Ayre and Tyson 2001). PSE has been shown to be an important predictor of pain intensity, pain behaviours and disability in patients with chronic musculoskeletal conditions (Buescher et al., 1991; Buckelew et al., 1994; Estlander et al., 1994; Lacker et al., 1996; Arnstein et al., 1999; Strahl et al., 2000; Ayre and Tyson, 2001; Denison et al., 2004). Studies of chronic pain patients have also suggested that self-efficacy is a predictor of treatment outcome in chronic pain patients (Kores et al., 1990). Coupled with this, low self efficacy may lead to non-compliance with treatment (Coughlan et al., 1995; Levin et al., 1996).

There are few studies investigating the effect of self-efficacy in a neck pain population. One study investigated the predictive value of a range of psychometric instruments for the development and persistence of back, neck and shoulder pain at one and two years follow-up (Estlander et al., 1998). This included psychological distress, depression, self-efficacy beliefs, subjective work prognosis, disability, and work characteristics. However, in this study the best predictor of future pain was disability at baseline. None of the psychometric measures, including self-efficacy beliefs predicted future pain.

The Pain Self-efficacy Questionnaire (PSEQ) (Nicholas, 1994) is a 10 item self report questionnaire measuring the strength of patients' beliefs about their ability to accomplish a range of activities despite his/her pain. Patients rate how confident they are that they can do each of 10 functions at present, despite their pain, by selecting a number on a seven point scale, where "0=not at all confident" and "6=completely confident". Total scores range from 0 to 60. Higher scores indicate stronger pain self efficacy beliefs (Nicholas, 1994; Gibson and Strong, 1996). The PSEQ was shown to have good test-retest reliability and internal consistency (Nicholas, 1994; Gibson and Strong, 1996). High correlations between PSEQ scores and perceived capacity for work related tasks and other measures of self efficacy indicated good construct and criterion

related validity (Nicholas, 1994). The PSEQ is easy to complete and score and suitable for postal use and is considered a reliable, valid and appropriate measure of PSE for this trial.

We concluded that PSE may be predictive of outcome of physiotherapy treatment and may be valuable as a potential predictive variable.

5.6 COPING STRATEGIES

Individuals vary in their ability to cope with pain and commonly use strategies described as active (adaptive) or passive (maladaptive) coping strategies (Rosenstiel et al., 1983; Brown and Nicassio, 1987). Active strategies, such as taking exercise, thinking positively or ignoring the pain, require the individual to take responsibility for managing their own situation by attempting to control the pain or function despite the pain (Jensen et al., 1991). Passive strategies, such as catastrophising, decreasing activity or relying on medication, involve withdrawal or dependency on others for the control of pain e.g. doctors (Jensen et al., 1991). There is strong evidence that pain coping strategies are associated with various outcome measures of pain intensity, psychosocial disability and physical functioning in a wide variety of conditions (Turner and Clancy, 1986; Brown and Nicassio, 1987; Flor and Turk, 1988; Jensen and Karoly, 1991; Jensen et al., 1992; Geisser et al., 1994; Jensen et al., 1994; Dozois et al., 1996). High levels of passive coping strategies were found to predict poor outcome (Klenerman et al., 1995; Steultjens et al., 2001; Carroll et al., 2002). In particular, high levels of catastrophising (fearing or expecting the worst) predicted increased pain, physical disability and psychosocial dysfunction in patients with a range of chronic pain problems (Estlander, 1989; Jensen et al., 1992; Geisser et al., 1994; Burton et al., 1995; Hill et al., 1995; Turner et al., 2000; Severeijns et al., 2001; Tan et al., 2001).

There is little evidence for the predictive nature of coping strategies for outcome of neck pain. One small study of patients (n=54) suffering from chronic neck and arm pain demonstrated that baseline catastrophising scores predicted changes of pain intensity following treatment with radio frequency lesioning of the cervical spinal dorsal root ganglion (Samwell et al., 2000). A second study surveyed individuals (n=571) with non-disabling neck and/or low back pain (n=571). After 12 months they found that passive coping strongly and independently predicted disabling neck and/or back pain. Those using moderate to high levels of passive coping strategies were at a five-fold

increased risk of developing disabling pain (Mercado et al., 2005). This study did not undertake a separate analysis of the neck pain subjects. No evidence was found regarding the predictive validity of coping strategies following conservative intervention.

The Coping Strategies Questionnaire (CSQ) (Rosenstiel et al., 1983) is the most widely used and best validated measure of pain coping strategies (Jensen et al., 1991; Riley and Robinson, 1997; Tan et al., 2001). It consists of 42 questions, assessing seven different coping strategies, namely: diverting attention, reinterpreting the pain sensation, catastrophising, ignoring sensations, praying or hoping, coping self-statements, increased behavioural activities. The catastrophising subscale of the CSQ measures negative self-statements and catastrophising thoughts in patients with chronic pain (Rosenstiel et al., 1983; Denison et al., 2004). Using a seven point scale for each question, subjects indicate how often they use a particular strategy where "0=never", "3=sometimes" and "6=always". A coping score for each subscale is calculated by summing the scores in each category (Rosenstiel et al., 1983; Lin 1998). The CSQ has been shown to have good reliability and internally consistency (Rosenstiel and Keefe, 1983; Keefe et al., 1989; Main and Waddell, 1991). Internal consistency coefficients ranged from 0.57 to 0.89 (Keefe et al., 1987; Gil et al., 1989; Spinhoven et al., 1989). Several studies demonstrated the construct, concurrent and content validity of the CSQ (Rosenstiel and Keefe, 1983; Keefe et al., 1987; Keefe et al., 1989; Jensen and Karoly, 1991; Main and Waddell, 1991; Dozois et al., 1996). The CSQ measures six cognitive and one behavioural coping strategy and has received criticism for not measuring enough of a patient's behavioural coping strategies (Tan et al., 2001). Despite this, it demonstrates excellent utility as a measure of coping strategies and is widely used in research (Tan et al., 2001).

We concluded that coping strategies may be predictive of outcome of physiotherapy treatment and may be valuable as a potential predictive variable.

5.7 ANXIETY AND DEPRESSION

Psychological distress, such as symptoms of anxiety and depression, is prevalent in populations with chronic pain (Romano and Turner, 1985; Burton et al., 1995; McWilliams et al., 2004) and may interfere with a person's capacity to participate in rehabilitation (Croft et al., 1996; Papageorgiou et al., 1997). Initial reaction to an injury

is often recognised in terms of anxiety, shock and fear rather than depression (Lazarus and Folkmann, 1984). It is possible with the passage of time and failure of treatment that a patient's coping skills will become exhausted and depression may appear (Gatchel and Gardea, 1999). If it is possible to avoid painful activities or compensate by changing activities, then patients are unlikely to become depressed. If however the pain is severe, frequent, widespread, disabling or uncontrolled then depression may be more likely to follow (Dworkin et al., 1990; Schiaffino et al., 1991; Nicassio and Wallston, 1992; Cairns et al., 1996). Psychological distress, anxiety and depression were found to be related to pain and disability in a number of musculoskeletal disorders.

Also, a large number of studies documented that distress, anxiety and depression predicted new LBP, pain severity, disability and pain behaviour (Greenough, 1993; Burton et al., 1995; Williams et al., 1995; Croft et al., 1996; McCracken et al., 1996; Burton et al., 2004; Grotle et al., 2006). One study calculated that 16% of new episodes of LBP in the general population may be attributable to psychological distress (Croft et al., 1996). Distress and depression were strongly implicated in the transition from acute to chronic LBP pain (Linton 2000; Pincus et al., 2002). Distressed LBP patients were 5.2 times more likely to remain disabled or get worse than there non-distressed counterparts (Main et al, 1992). A large (n=1953) two year prospective study of mechanical and psychosocial risk factors for the development of new onset forearm pain found that psychological distress was an important predictor of onset of forearm pain (RR=2.4, 95% CI=1.5 to 3.8) (Macfarlane et al., 2000). A second, smaller (n=107) prospective study identified that lower levels of depression predicted better outcome and increased pain relief following treatment for patients with orofacial pain (Riley et al., 2001).

There is little evidence for anxiety or depression as predictors of outcome of neck pain. In a cross-sectional study the presence of anxiety and depression was associated with higher levels of neck disability (Luo et al., 2004). In a large prospective study (n=790), depression was a strong and independent predictor for the onset of an episode of intense disabling neck and/or low back pain at six and 12 month follow-up (Carroll et al., 2004). By comparison with the least depressed patients, the most depressed patients had a four fold increased risk of developing troublesome pain (HRR=3.97; 95% CI 1.81 to 8.72). Estlander et al (1998) conducted a prospective study of 452 subjects. Pain in the shoulder, neck and low back during the preceding year was assessed at baseline, one

year and two years follow-up. A range of psychological variables e.g. distress and depression were also assessed at baseline. These researchers found that the best predictor of future pain was disability at baseline; the psychometric measures did not predict pain at follow-up (Estlander et al., 1998). They found no evidence regarding the predictive validity of anxiety and depression with regards outcome following intervention.

The Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983) is a frequently used clinical and research tool designed to identify possible and probable cases of anxiety disorders and depression among patients in non-psychiatric hospital clinics (Bjelland et al., 2002). It is divided into an anxiety subscale and depression subscale each containing seven items. The subscales are independent of each other. Each item is answered by the patient on a four point (0–3) response. Scores for each mood category are calculated by summing the scores of each item in the subscale so the possible scores for the anxiety and depression subscales range from 0 to 21. A score of 0 to 7 on either subscale is considered within normal limits, 8 to 10 suggests the probable presence of the disorder and a score of 11 or more indicates the presence of the mood disorder (Snaith 2003). A systematic review of the literature revealed that the HADS is reliable and valid (Bjelland et al., 2002). They found it was sensitive and specific on both subscales at a cut off score of more than eight points (Bjelland et al., 2002). They concluded that the HADS performed well in assessing symptom, severity and cases of anxiety and depression in both somatic, psychiatric and primary care patients and in the general population.

We concluded that anxiety and depression may be predictive of outcome of physiotherapy treatment and may be valuable as a potential predictive variable.

5.8 UPPER LIMB DISABILITY

The relationship between neck pain and upper limb function is poorly understood. The neck and upper limb are mechanically, anatomically and physiologically linked, thus it might be expected that a problem in one region may give rise to a problem in the other. Clinically this is perhaps intuitive, however little evidence was found to support this view. The prevalence of neck disorders was shown to rise with increased percentage of time spent with shoulders abducted or raised (Bjelle et al., 1981; Ohlsson et al., 1995). In addition there was limited evidence that the development of neck pain was causally

linked with work place upper limb activities such as highly repetitive shoulder movements (Andersen et al., 2003), intensive manual handling (Grooten et al., 2004), very slow or very fast arm speed (Lauren et al., 1997) and poor maximal strength of shoulder elevation (Jonsson et al., 1988). Our systematic review (see Chapter Two) identified strong evidence that the presence of shoulder problems was prognostic of recurrent, persistent or disabling neck pain in patients with non-specific neck pain. It is hypothesized that certain upper limb activities or disorders may predispose the development and progression of neck problems. It is not known whether the presence of upper limb disability predicts the outcome for patients with neck pain following conservative treatment.

The Disabilities of Arm, Shoulder, Hand questionnaire (DASH) is a frequently used clinical and research tool for measuring upper limb disability. Its strengths, limitations and use are described in Chapter Four (section 4.3.1).

We concluded that upper limb disability may be predictive of outcome of physiotherapy treatment and may be valuable as a potential predictive variable.

5.9 CURRENT SMOKING STATUS

Smoking is widely documented as causing delayed healing. Smoking was shown to adversely affect bone mineral density, lumbar disc disease, the rate of hip fractures, and the dynamics of bone and wound healing (Porter and Hanley, 2001). It has been suggested that smoking may contribute to degeneration of musculoskeletal structures because of its effect on the blood vessel supply to the affected area (Kane et al., 2006). Several prospective studies identified smoking as a risk factor for the development and persistence of musculoskeletal disorders (Eriksen et al., 1999; Feldman et al., 1999; Thomas, 1999; Power et al., 2001), although systematic reviews suggested that this was not always consistent (Leboeuf-Yde and Yashin, 1995; Leboeuf-Yde, 1999). Smoking also predicted poor outcome following conservative intervention in back pain (Bendix et al., 1998).

In addition, several prospective studies identified smoking as a weak risk factor for the development of neck pain (Viikari-Juntura et al., 1994; Viikari-Juntura et al., 2001; Korhonen et al., 2003). Although, in women, smoking habits more strongly predicted the development of neck-shoulder symptoms (OR=1.8, 95% CI=1.14 to 2.82, former

versus never smokers) (Feveile et al., 2002). Only one good quality study was found which investigated the predictive nature of smoking in relation to the progression of neck pain to chronic, recurrent, persistent or disabling neck pain. In a prospective study (n=1832) on the effects of occupational and individual factors on neck trouble, current smoking status independently predicted the development of severe neck trouble (OR=1.4; 95% CI= 0.7 to 2.8; current smoking v not smoking) (Viikari-Juntura et al., 1994). One small study identified that smoking predicted worse neck and arm pain and disability following cervical surgery compared with not smoking (Peolsson et al., 2006). It is not known whether smoking status predicts the outcome for patients with neck pain following conservative treatment.

We concluded that smoking may be predictive of outcome of physiotherapy treatment and may be valuable as a potential predictive variable.

5.10 MATERIAL AND SOCIAL DEPRIVATION

It is well recognised that social deprivation plays a major role in the aetiology and outcome of many health disorders (Marmot and McDowall, 1986; Watt, 1996) and it has been suggested that socioeconomic status should be treated as a confounding variable in all clinical trials (Schecter et al., 2001). There is increasing awareness that deprivation may influence the course of musculoskeletal disorders (Carr and Klaber Moffett, 2005). Musculoskeletal pain and disability have been shown to be significantly higher for those living in areas of social deprivation (Urwin et al., 1998; Brekke et al., 1999; Harrison et al., 2005) and several studies have shown that the consequent impact is greatest among deprived populations (Croft and Rigby, 1994; Brekke et al., 1999; ERAS, 2000; Brekke et al., 2002). Those living in areas of social deprivation are less likely to utilise health resources (Kim et al., 2004) and more likely to discharge themselves from treatment (Self et al., 2005). Very few randomised controlled trials have been conducted in socially deprived areas (Watt, 1996). However, to make matters more difficult non-responders in trials are more likely to come from socially deprived areas (Urwin et al., 1998). Only a few studies provide preliminary evidence of a link between social deprivation and poor outcome for patients with rheumatoid arthritis and chronic low back pain (McEntegart et al., 1997; Carr and Klaber Moffett, 2005), although these findings are not consistent (Harrison et al., 2005). As far as we are aware, the effect of deprivation on outcome for neck pain patients undergoing physiotherapy management has not been investigated.

At the time of this study the Townsend material deprivation score was considered the best indicator of social and material deprivation currently available (http://www.devon.gov.uk/dris/commstat/townsend.html, 2005). This deprivation score is calculated from four Census 2001 variables, namely: unemployment (lack of material resources and insecurity), overcrowding (material living conditions), lack of owner occupied accommodation (a proxy for wealth) and lack of car ownership (a proxy indicator of income). The Townsend score is derived by summing the standardised scores (z scores) for the four variables. The resulting scores range from -4.9441 to 20.6000, with the mean score equal to zero. Scores greater than zero indicate greater levels of material deprivation (Townsend et al., 1988). Townsend scores were calculated by converting postcodes to ward codes and then from ward codes to Townsend scores. These data tables are available through Manchester University (http://www.mimas.ac.uk).

We concluded that deprivation level may be predictive of outcome of physiotherapy treatment and may be valuable as a potential predictive variable.

5.11 EXERCISE/PHYSICAL ACTIVITY

Research has demonstrated the low level of participation in exercise among the UK population (Department of Health, 1998). National statistics suggests that about two thirds of the population do not engage in exercise. In particular women are less active than men and older age groups are less active than younger age groups (Department of Health, 1998). The health benefits of physical activity and exercise are extremely well reported. Physical activity and exercise plays a major role in management of a range of health conditions such as obesity, heart disease, diabetes, osteoporosis and LBP. Exercise has been shown to influence the course of a range of musculoskeletal disorders including back pain (Frost et al., 1995; Hurwitz et al., 2005), knee pain (Deyle et al., 2005; van Gool et al., 2005) and shoulder pain (Geraets et al., 2005). People with musculoskeletal disorders who do exercise report less pain, increased range of motion, increased muscle strength, endurance and power less disability, less sickness absence, improved health status etc. Exercise also serves to protect joints through improved cartilage and joint health and stronger structures.

In Chapter Three, section 3.5 it was reported that active exercise based interventions such as neck and upper limb endurance training, dynamic strengthening programmes, cervical stabilisation exercises were effective ways of managing patients with neck pain. In Chapter Two, section 2.4.4 it was reported that neck pain sufferers who engage in regular general exercise are less likely to progress to recurrent, persistent or disabling neck problems than their counterparts who do no exercise. This suggests that any form of physical activity is also likely to be beneficial for patients with neck pain. As far as we are aware, the effect of prior physical activity on outcome for neck pain patients undergoing physiotherapy management has not been investigated. Therefore it is not clear whether a prior level of physical activity in patients with neck pain predicts the outcome of physiotherapy intervention.

We concluded that physical activity may be predictive of outcome of physiotherapy treatment and may be valuable as a potential predictive variable.

5.12 CONCLUSIONS

This chapter reviewed psychological, sociodemographic and physical variables which may predict treatment outcome for patients with neck pain. It would appear that health outcomes for a wide range of musculoskeletal conditions are dependant on a number of factors. All the variables identified here have shown ability to predict outcome for a range of musculoskeletal conditions, low back pain in particular. There is little evidence in relation to their predictive ability regarding neck pain. Consequently, their contribution to the maintenance of neck pain and disability is unknown. In particular it is not known whether these variables predict outcome for neck pain patients attending physiotherapy. The ability of these variables to predict treatment outcome will be investigated within the GET UP neck pain trial.

The next chapter outlines the methodology and results of a randomised controlled trial comparing Graded Exercise Treatment and Usual Physiotherapy for patients with neck pain (GET UP neck pain trial).

CHAPTER 6

A RANDOMISED CONTROLLED TRIAL COMPARING GRADED EXERCISE TREATMENT AND USUAL PHYSIOTHERAPY FOR PATIENTS WITH NON SPECIFIC NECK PAIN (THE GET UP NECK PAIN TRIAL)

6.1 INTRODUCTION

Chapter Three of this thesis highlighted the lack of good quality research investigating the effectiveness of conservative management options for mechanical neck pain. The strongest evidence is currently related to multimodal packages of treatment (usual physiotherapy) and exercise based strategies. There is some evidence to suggest that usual physiotherapy may be effectively employed on patients with neck pain (see section 3.4.1). Usual physiotherapy offers a broad range of treatments, including some specific exercise based approaches such as McKenzie exercises in combination with other passive treatments, advice and education. With regards to exercise, the strongest evidence of effectiveness currently lies with strategies focussing on general neck and upper limb endurance training, dynamic strengthening programmes, cervical stabilisation exercises and proprioceptive exercise (see section 3.5). An exercise programme that incorporates all these aspects may be an effective way of managing neck pain. As far as we are aware this kind of neck and upper limb exercise based approach to the management of neck pain has not previously been investigated.

To date, no research has been found which compares the effectiveness of a neck and upper limb exercise programme with usual physiotherapy for patients with neck pain. Research of this kind has been identified as a priority (Chartered Society of Physiotherapy, 2002). This chapter describes a randomised controlled trial which investigated the effectiveness of a neck and upper limb exercise programme, based on stabilisation, endurance and strengthening principles, compared with usual physiotherapy for neck pain patients referred to a physiotherapy department.

6.1.1 Aim

The aim of this study was to investigate, at six weeks and six months, the effectiveness of a group neck and upper limb graded exercise programme compared with usual

physiotherapy for a group of patients referred to a physiotherapy department with neck pain.

6.1.2 Hypothesis

H^0 - the null hypothesis – There is no difference in pain and function, at six weeks and six months, between patients receiving the group neck and upper limb graded exercise programme and those receiving usual physiotherapy.

H^1 - the alternative hypothesis - There is a difference in pain and function, at six weeks and six months, between patients receiving the group neck and upper limb graded exercise programme and those receiving usual physiotherapy.

6.2 METHODS

6.2.1 Study design

This was a multi-centre Randomised Controlled Trial that recruited neck pain patients from the physiotherapy departments in Hull, High Wycombe, Nottingham and Grimsby. Patients were randomised to either, 1) a graded neck and upper limb exercise class (GET) or, 2) usual physiotherapy (UP). Patients were stratified to these interventions according to treatment centre and NPQ scores; stratification by NPQ scores ensured that each intervention had approximately equal numbers of patients with high and low neck pain and disability, stratification by treatment centre ensured that each centre had approximately equal numbers of patients in each treatment group.

6.2.2 Ethical approval and research governance approval

Initially single centre ethics approval was gained from two research and ethics committees: Hull & East Riding Research & Ethics Committee and Mid & South Buckinghamshire. This allowed Hull and East Yorkshire Hospitals NHS Trust and Wycombe Primary Care NHS Trust to participate in the research. In order to include Nottingham City Hospital NHS Trust and North Lincolnshire and Goole NHS Trust in the trial, multi-centre ethics approval was later sought and gained from the Hull & East Riding Research & Ethics Committee. Letters of ethics approval are at Appendix 6.

Research approval was sought and gained from the Research Governance Departments at Hull and East Yorkshire Hospitals NHS Trust, Wycombe Primary Care NHS Trust, Nottingham City Hospital NHS Trust and North Lincolnshire and Goole NHS Trust.

Finally, support to undertake the research was sought and gained from the physiotherapy managers of the participating Trusts. Letters of support and approval are attached at Appendix 7.

6.2.3 The study sample

One hundred and fifty one neck pain patients were recruited from the waiting list of physiotherapy departments at Hull and East Yorkshire NHS Trust, Wycombe Primary Care NHS Trust, Nottingham City Hospital NHS Trust and North Lincolnshire and Goole NHS Trust. Patients were randomised to either, 1) a graded neck and upper limb exercise class (GET) or, 2) usual physiotherapy (UP).

6.2.4 Sample size/ power calculations

Sample size calculations were based on the use of the NPQ. When the trial was set up no published figures of minimal clinically important differences were found. For the purposes of calculating sample sizes previous research suggested that a change of about 5% was clinically relevant (Klaber Moffett et al., 2005). As discussed in section 4.2.2 of Chapter Four, the NPQ and NDI are similar questionnaires and a 10% change on the NDI is considered clinically relevant (Stratford et al., 1999). In this study we hoped to detect a difference in mean NPQ scores of 2.5 points (or 6.9 percentage point change when NPQ score is converted to a 0-100 scale) between the groups after six months. Based on previous similar research (Klaber Moffett et al., 2005), the within-group standard deviation was 5.00. Therefore, for two-tailed, two-sample t-tests carried out with a 5% significance level, 64 patients were required in each group to achieve 80% power (Machin et al., 1997). Within-patient correlations of 0.6 to 0.75 are typical (Machin et al., 1997). Therefore adjusting for planned analysis of covariance and assuming conservatively a within-patient correlation of 0.5, leads to a total of 48 patients in each group. However, allowing for a possible attrition rate of 25%, a conservative estimate based on previous experience (Klaber Moffett et al., 2005), leads back to a target total of 64 patients to be recruited in each group. Furthermore, for the purposes of further statistical analysis using multivariate techniques, we proposed to recruit 150 patients in total.

6.2.5 Inclusion/exclusion criteria

Patients were considered for inclusion in the trial if they: 1) had sub-acute or chronic mechanical neck pain with or without referred symptoms into the head or upper limbs.

The neck was defined as that region bounded above by a horizontal line through the most inferior part of the occiput, bounded below by a horizontal line through T2 and bounded laterally by a vertical line through the medial border of the scapula. Mechanical neck pain was defined as being reproduced by neck movements, provocation tests or sustained postures, 2) were at least 18 years of age and 3) were able to travel independently to the physiotherapy department.

Patients were excluded from the trial if they: 1) had a neck condition requiring urgent treatment, 2) had any potentially serious conditions e.g. systemic disease, progressive or worsening neurological disorders, inflammatory conditions or major trauma, 3) had any previous traumatic injury to the affected upper limb(s) and shoulder girdle(s) resulting in current or prolonged disability, 4) were unable or unwilling to complete the self-administered questionnaires, 5) were unable to get on/off a bed independently, 6) were unable to participate in an exercise class or 7) had received physiotherapy or specific exercise for neck pain either at the time of entry to the study or in the three months prior to that point.

6.2.6 Recruitment of the study sample

Potentially eligible patients with neck pain on the waiting list of participating physiotherapy departments were invited to participate in this study. A letter containing the following information was sent to the patient:

- An invitation to take part in the study (Appendix 8)
- Information about the study (Appendix 9).
- Introductory information about the Institute of Rehabilitation (Appendix 10).
- A freepost card to drop in the post if they did not wish to have further information about the study (Appendix 11).
- A comment to inform the patient that if we did not receive the freepost card we would contact the patient by phone in order to discuss the study, conduct a brief screening interview and invite them to meet the trial co-ordinator and to fill in questionnaires if they were interested in participating in the study.

If the patient did not wish to know any more about the study they were invited to return a pre-paid slip saying that they did not wish to be contacted or invited to participate. Participants, who were happy to be contacted, were telephoned by the trial co-ordinator who explained the study to them, checked whether the patient was suitable for the study

and invited them to consider participating. A telephone checklist (see Appendix 12) was completed for each patient, to ensure the standardisation of the information given and to ensure the relevant inclusion/exclusion criterion were covered. If the patient, in principle, verbally consented to take part in the trial, they were given an appointment to meet the trial co-ordinator (assessor) face-to-face in the physiotherapy department.

At the first appointment the trial co-ordinator (assessor):

a. Checked that the patient understood the nature of the trial and answered any questions.
b. Confirmed the patient's eligibility for the trial by completing a checklist of clinical and demographic questions (Appendix 13).
c. Obtained informed written consent from the patient (Appendix 14).
d. Instructed patients how to complete the baseline questionnaire (Appendix 15).
e. Allocated the patient a unique trial reference number.
f. Randomised the patient to one of the intervention groups using the agreed randomisation protocol.
g. Organised the appropriate appointment and paperwork for the patient to attend their appointment.

After entry to the trial, the patient's GP and/or consultant received written information about the trial (Appendix 16) and were invited to comment.

6.2.7 Randomisation procedure

Patients entering the study were randomised to one of two interventions using a series of sealed, opaque envelopes. Patients were stratified according to treatment centre and NPQ scores. Therefore, each treatment centre had its own series of pre-prepared randomly sequenced envelopes. Each series of envelopes were divided into high and low NPQ scores, where high scores were ≥ 15 and low scores were ≤ 14. This score was derived from data collected during previous neck pain studies run at the Institute of Rehabilitation. The interventions were referred to as GET and UP, where GET stands for graded exercise therapy and UP stands for usual physiotherapy. The two interventions were randomised in blocks of three and four using a computerised number generating programme in order to ensure that the numbers allocated to each intervention remained close to each other at each of the different centres. Each patient received only one of the interventions.

A statistician (EDG) generated the randomisation sequence using computer software package R1.9. A student (AG) prepared each series of randomisation envelopes. Both people work at the Institute of Rehabilitation, but neither was involved in the recruitment, assessment or treatment of patients.

6.2.8 Blinding

It was not possible to blind patients to which treatment they received. However, patients were made aware that both interventions were considered active physiotherapy treatments and that neither treatment was known to be better than the other. It was not possible to blind the assessors (MM, CP, SMc) to which treatment the patient received, however assessors were not involved in the delivery of the interventions at any of the centres. Additionally, these independent assessors only became aware of which intervention the patient received after baseline data collection. The assessors were instructed to remain passive about the treatment allocation, when they opened the envelopes. Thereafter, all the follow-up data was collected through patient completed questionnaires via the postal system.

6.2.9 The interventions

6.2.9.1 Graded exercise treatment (GET)

Patients randomised to GET received an information sheet about the exercise group (see Appendix 17) from the assessor at the end of the initial assessment. They were asked to attend 12 (minimum of six) sessions over a six week period. Qualified physiotherapists, ranging from junior to superintendent physiotherapists, supervised the classes. These physiotherapists received standardised training from the principal investigator (SMc) to ensure a consistent approach to the delivery of the exercise class. (This training is described at section 6.2.11) A class at each site was monitored at regular intervals to ensure consistency of approach between sites. Feedback was provided to class leaders as necessary.

The exercise sheet used for the exercise class is in Appendix 18.

Briefly the exercise class consisted of three phases:

- warm-up exercises
- range of movement exercises for neck, trunk and upper limb
- endurance training for the upper limb and shoulder girdle

Patients began each session with warm-up exercises and range of movement exercises. In this phase compensatory movement patterns were discussed and re-educated and patients learned how to control segmental and global orientation of their spinal curves in posture. Varying levels of physical ability and confidence were expected and recognised, so patients were encouraged to progress to the endurance phase of training when they felt ready. In this phase there were eight exercises which were conducted for one minute each (one set), with a weight of the patients choice, at a speed of the patient's choosing. Patients were encouraged to progress from one set of endurance exercises to a maximum of three sets as they felt able. The length of each exercise session varied between 30-60 minutes as the patient's ability allowed. All the exercises were modifiable to allow patients to perform all exercise in a pain-free manner. Typical compensatory strategies and permitted modifications for each exercise are shown at Appendix 19. In the unlikely event that a patient experienced an adverse event as a consequence of exercise, the patient was able to stop GET and have usual physiotherapy. Clinicians also had the discretion to withdraw patients from the class. Follow-up data continued to be collected on these patients

6.2.9.2 Usual physiotherapy (UP)

The receptionist at the physiotherapy department gave patients who were randomised to UP their physiotherapy appointments in the usual way.

UP interventions were at the discretion of the individual physiotherapist. Possible management options included manual therapy, neural and muscle treatments, modalities and individualised exercise. Assessment session lasted between 40-60 minutes and follow-up treatment lasted 20-30 minutes. The number of times the patient attended for treatment was at the discretion of the individual physiotherapist. The number of treatment session for each patient was recorded for post hoc comparison with GET, however it was anticipated that patients would be seen approximately six times. Patients randomised into this group were not eligible to take part in the supervised group exercise programme in the physiotherapy department.

Trained, qualified physiotherapists, ranging from junior to superintendent in grade, provided the UP intervention. In contrast to the physiotherapists delivering GET no additional training was given.

The treatment received by these patients was collected using a treatment record form (see Appendix 20). This was obtained from the physiotherapy notes on completion of treatment in order to calculate number of treatments, collate the different treatments given and to check the extent to which upper limb training was administered.

6.2.10 Clinical and admin staff delivering the interventions

The reception staff and musculoskeletal physiotherapists at each of the departments were involved in the trial process. A total of seven receptionists and 32 physiotherapists were involved during the recruitment phase of the trial. For pragmatic reasons it was not possible to select trial staff according to grades or level of training. Accordingly, the physiotherapists delivering the UP intervention ranged from junior to superintendent II. In order to take into account departmental staffing variations, each physiotherapist completed a brief curriculum vitae to indicate grade, level of experience and the extent of formal training in neck and upper limb physiotherapy. A copy of the blank CV is at Appendix 21. These physiotherapists only received information about the trial.

Two/three physiotherapists from each site volunteered to deliver GET and ranged from junior to superintendent II. Each physiotherapist in this group received information about the trial and formal training on the delivery of the GET.

6.2.11 Training and information delivered to staff

All physiotherapists and reception staff who were involved in the trial attended a 30 minute information giving session in the physiotherapy department of each participating Trust. The information imparted by the Principal Investigator (SMc) included:

- The purpose and aim of the study.
- The interventions available within the study.
- Brief outline of the trial procedures.
- Tasks that reception staff would be asked to perform to facilitate the trial processes (Appendix 22).
- Tasks that physiotherapists would be asked to perform to facilitate the trial processes (Appendix 23).
- All staff were given the opportunity to ask questions.

The reception staff and the lead physiotherapist at each centre were given 30 minutes of additional training about the exact administrative processes they would be asked to undertake.

6.2.11.1 Graded exercise treatment training

The physiotherapists delivering GET received four sessions of additional theoretical and practical training from the Principal Investigator, which consisted of:

Session 1 (2 hours):	• Theoretical principles underpinning stabilisation training with specific reference to cervical stabilisation. • Practical assessment and re-education of deep cervical flexor function in lying, sitting and standing.
Session 2 (2 hours)	• Overall view of phases and purposes of exercise class. • Review of assessment and re-education of deep cervical flexion function. • Practical review of each exercise in the class, including common compensation strategies used by patients, common helpful re-education strategies and permitted modifications.
Session 3 (1 hour):	• Observation of class to check fidelity of the treatment delivery. This was an opportunity to receive practical tips with trial patients and to ask further questions as required.
Session 4 (adhoc):	• Additional training and opportunity to ask questions informally.

6.2.12 Outcome measure and data collection – baseline and follow-up

The data were collected, in the absence of the trial co-ordinator or any physiotherapist, using self-administered questionnaires at three points of time: baseline, at end of treatment (approximately six weeks) and at six months (the primary endpoint). The primary outcome measures for this study were the NPQ and the DASH.

6.2.12.1 Baseline data

At baseline a booklet of questionnaires was administered to all trial patients (see Appendix 15). These took about 25-35 minutes to complete. The questionnaire consisted of six sections; two were baseline measures of pain and disability and four

were standard psychological measures used as potential predictors of outcome. The sections were as follows:

Section 1	Northwick Park Neck Pain Questionnaire (NPQ) (Leak et al., 1994) - a measure of neck related pain and disability (see Chapter Four, section 4.2.1)
Section 2	Disabilities of the Arm, Shoulder and Hand (DASH)(Hudak et al., 1996) - a measure upper limb disability (see Chapter Four, section 4.3.1)
Section 3	Tampa Scale for Kinesiophobia (TSK) (Kori et al., 1990) - a measure of beliefs about fear of movement, exercise and re-injury (see Chapter Five, section 5.4)
Section 4	Hospital Anxiety and Depression Scale (HAD)(Zigmond and Snaith, 1983) - a tool designed to identify possible and probable cases of anxiety disorders and depression among patients in non-psychiatric hospital clinics (see Chapter Five, section 5.7)
Section 5	Pain Self Efficacy Questionnaire (PSEQ) (Nicholas 1994) - a measure of the strength of patients' beliefs about their ability to accomplish a range of activities despite his/her pain. (see Chapter Five, section 5.5)
Section 6	Coping Strategies Questionnaire (CSQ) (Rosenstiel et al., 1983) - a measure of seven common strategies used by patients to help them cope with pain. (see Chapter Five, section 5.6)

In addition to this information the trial co-ordinator collected clinical and demographic information about the patient during the initial assessment (Appendix 13). The above-mentioned questionnaires are standardised and widely used for research purposes. They are appropriate for use in this patient group. The validity and reliability of these questionnaires is discussed in Chapters Four and Five of this thesis.

6.2.12.2 Follow-up data

At follow-up the postal questionnaire consisted of three sections as follows:

Section 1	Northwick Park Neck Pain Questionnaire (NPQ)(Leak et al., 1994)
Section 2	Disabilities of the Arm, Shoulder and Hand (DASH) (Hudak et al., 1996)
Section 3	Cost Analysis Information

This questionnaire, which was presented in short booklet format, is shown at Appendix 24 and details the specific questions used for cost analysis. The booklet took about 5-10 minutes to complete. The cost analysis is not reported on since it is not the subject of this thesis.

Prior to sending out requests for follow-up data, the trial co-ordinator made a courtesy phone call to find out how the patient was getting on and to let them know that a questionnaire would be delivered within the next few days. A letter, a follow-up questionnaire and freepost envelope were sent through the post. Patients were asked to complete the questionnaire and return them to the Institute of Rehabilitation using the freepost envelope. A maximum of two further written reminders were sent in order to increase the return rate. In cases where questionnaires were not returned, a final telephone interview was conducted where possible and only sections one & three were completed.

This process was completed for each patient after treatment had been completed (approximately six weeks) and at six months.

6.2.13 Data analysis

Data collected at baseline, six weeks and six months were scanned onto an excel database and from there onto a statistics package (SPSS 13.0 for Windows). The assessment of data was undertaken at the Institute of Rehabilitation in Hull, independent of the clinics involved. During the screening process, some discrepancies in the data were obvious i.e. duplicate and missing answers. Missing items and multiple entries in the questionnaires were checked independently by two people. Where patients made two choices to indicate an in-between answer, we dealt with this by inserting the mean score. Global scores for each variable were calculated by summing scores from multiple items on the baseline and follow-up questionnaires. In cases of missing items, global scores were prorated from the scores for available items. In cases where insufficient items had been scored to predict mean scores, these were left as missing items.

Descriptive statistics such as mean values and ranges of data collected at baseline were compared for the two interventions. Independent t-tests and chi-square tests were used to investigate for any statistically significant differences between the two intervention groups at baseline. Repeated measures analysis of variance (ANOVA) was used to test

for differences between the graded exercise group and the usual physiotherapy group on each of the outcome measures at the different time points. After this, any variables that were statistically different between the two groups at baseline were entered as covariates in the ANCOVA. A p value of less than 0.05 was considered a statistically significant level.

All possible cases were included in the analysis. This included those who completed treatment as per protocol, those who were randomised to an intervention but did not attend their treatment (DNA), those who were randomised to a treatment but did not complete treatment as per protocol (DNCT), those subjects who withdrew from the trial, and finally any patients who deviated from their randomised allocation. Missing data was not imputed. This meets most of the components of intention to treat analysis (ITT) and henceforth will be described as an ITT analysis.

6.3 RESULTS

6.3.1 Study population

6.3.1.1 Recruitment

Recruitment of participants began in February 2004. Recruitment was slower than expected for several reasons and recruiting was extended until July 2005. 483 patients with neck pain were referred for possible inclusion into the trial. One hundred and fifty one patients were eventually recruited into the study, representing an overall inclusion rate of 31.3%. Of the 151 patients recruited to the trial, 76 were randomised to usual physiotherapy and 75 to graded exercise treatment. Figure 6.1 below is a consort flow-chart showing their progress through the trial. Six month follow-up began in August 2004 and continued until January 2006. At six months 34 (22.5%) patients were lost to follow-up (see section 6.3.4.2).

Figure 6.1 Consort flow-chart of participants in the GET UP neck pain trial

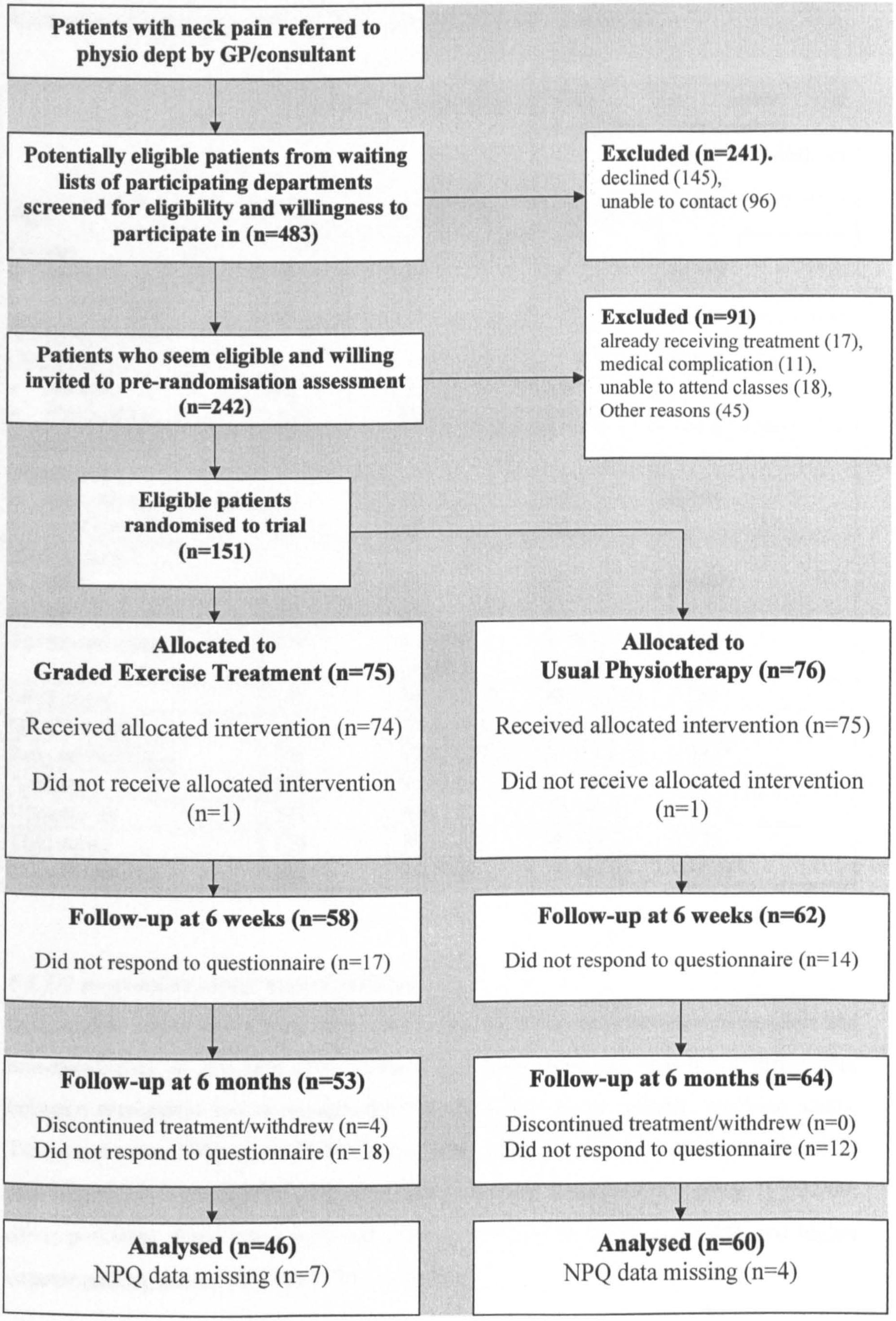


Table 6.1 Baseline characteristics of trial responders and trial non-responders.

Values are means (standard deviations) unless otherwise indicated

	Frequency	Responders	Non-responders	p value of independent samples t-test or χ^2 test
Age	151	54.2(14.4)	52.6(14.3)	0.557
Gender • female (frequency) • male (frequency)	 90 61	 67 50	 23 11	 0.277
Smoking status (frequency) • smokers • non-smokers	 43 107	 33 84	 10 23	0.814
Exercise levels (frequency) • more than once per week • never exercise	 60 84	 43 68	 17 16	 0.191
Intervention • GET • UP	 75 76	 53 64	 22 12	 0.046*
Townsend score	150	1.3156 (4.003)	2.2897 (4.6487)	0.231
NPQ score	151	38.1(15.7)	40.9(12.0)	0.263
DASH score	142	30.2(19.8)	33.8(16.2)	0.363
Pain self efficacy	145	38.5(15.7)	32.8(13.3)	0.042*
Anxiety	151	9.3(1.9)	8.8(1.4)	0.229
Depression	149	9.8(2.5)	10.3(2.7)	0.303
TSK score	139	35.5(7.3)	36.0(8.1)	0.723
Catastrophising	141	9.3(7.0)	14.6(6.8)	<0.001*

6.3.1.2 Responders versus non-responders

Independent t-tests and χ^2 tests were used to test for differences between responders and non-responders in this trial (see Table 6.1). There were no significant differences between responders and non-responders on measures of age, gender, smoking status, Townsend score, NPQ score, DASH score, TSK score, anxiety or depression. However non-responders were significantly more likely to come from the GET group {χ^2=3.969; df=1; p=0.046}, have lower pain self efficacy {t(63,459)=2.079, p=0.042} and higher catastrophising scores {t(139)=-3.741, p<0.001}.

Table 6.2 Baseline characteristics of participants in each intervention of the GET UP neck pain trial. Values are means (standard deviations) unless otherwise indicated

	Frequency	Graded Exercise Treatment (n=75)	Usual Physiotherapy (n=76)
Age	151	54.2 (13.8)	53.5 (15.1)
Female (frequency)	90	44	46
Male (frequency)	61	31	30
Smoking status (frequency)			
• smokers	43	22	21
• non-smokers	107	53	54
Exercise levels [1]			
• more than once per week	60	29	31
• never exercise	84	44	40
Social deprivation score	150	2.0416 (4.300)	1.044 (3.989)
Treatment (frequency)			
• Expressed a preference	82	38	44
• Preferred UP	41	17	24
• Preferred GET	34	18	16
• No preference	67	34	33
NPQ score (0-100)	151	39.1 (14.4)	38.4 (15.6)
DASH score (0-100)	141	31.0 (18.2)	31.1 (20.1)
QVAS (0-100)	150	62.0 (15.9)	59.8 (17.4)
Pain self efficacy (0-100)	145	36.9 (15.1)	37.4 (15.6)
Anxiety	151	9.4 (1.7)	9.0 (1.8)
Depression	149	9.9 (2.6)	9.8 (2.5)
Tampa Scale of Kinesiophobia (17-68)	139	36.1 (8.2)	35.1 (6.7)
Coping Strategies			
• diverting attention	143	14.5 (8.2)	13.7 (9.0)
• reinterpreting pain sensation	142	9.8 (7.8)	9.7 (8.1)
• catastrophising	141	10.7 (7.2)	10.2 (7.4)
• ignoring sensations	148	17.2 (8.0)	16.5 (8.1)
• praying and hoping	141	15.9 (9.5)	17.6 (8.5)
• coping self statements	143	24.4 (5.9)	23.6 (7.0)
• increased behaviour	143	17.3 (7.6)	17.5 (7.3)

1. Any form of exercise or activity which raises the heartbeat or gets the patient slightly out of breath

6.3.2 Baseline data

Table 6.2 above shows baseline clinical and demographic characteristics of patients allocated to each intervention group. Independent sample t-tests and chi square tests were used to check for any statistically significant differences between the groups in each intervention and no significant difference between the groups for any of the baseline characteristics were found. Therefore secondary analysis of covariance adjusting for baseline variables was not deemed necessary.

6.3.3 Results - intention to treat analysis

Table 6.3 Mean NPQ and DASH scores (and standard deviations) at baseline, six weeks and six month follow-up.

	Graded Exercise Treatment		Usual Physiotherapy	
	NPQ score mean (SD)	DASH score mean (SD)	NPQ score mean (SD)	DASH score mean (SD)
Baseline	39.1 (14.4) (n=75)	31.0 (18.2) (n=69)	38.4 (15.6) (n=76)	31.5 (20.1) (n=73)
6 week follow-up	37.6 (18.2) (n=58)	35.3 (22.3) (n=57)	33.3 (19.3) (n=62)	26.1 (19.4) (n=61)
6 month follow-up	34.1 (18.6) (n=53)	32.8 (21.0) (n=49)	30.7 (21.5) (n=64)	27.6 (21.9) (n=60)

Note: lower scores indicate less disability

Table 6.3 shows the mean NPQ and DASH scores at baseline, six week and six month follow-up. For our primary outcome measure, the NPQ score, both treatment groups improved at six weeks, with a further improvement at six months. The group allocated to GET improved by 1.5 points at six week follow-up and by 5.0 points at six month follow-up. The group undertaking UP improved by 5.1 points at six week follow-up and by 7.7 points at six month follow-up. Boxplot analysis of the data revealed two outliers; both from GET intervention (see Appendix 25). Neither were extreme values i.e. more than three box lengths away from the box. In addition the data sets were normally distributed. Therefore the removal of any cases and transformation of the data was not required and the assumptions for ANOVA were met. A repeated measures ANOVA was performed with intervention type as the between subjects factor. The data sets failed Mauchly's test of sphericity and we therefore used the Greenhouse-Geisser Test to be more conservative in our analysis. Analysis showed that there was no significant difference in change between the two intervention groups over time

[Greenhouse-Geisser adjusted F(1.531,159.223) =1.119, p=0.317] (see Table 6.4 below). Further analysis showed that both groups improved significantly over time [Greenhouse-Geisser adjusted F(1.531,159.223)=5.118; p=0.013] (see Table 6.4). Analysis of residuals from ANOVA was approximately normally distributed and the assumptions for ANOVA were therefore met (see Appendix 25). As discussed in section 6.2.4, a change of approximately 6.9 NPQ points was considered a clinically important difference. The UP group achieved this by the six month follow-up, but the GET group did not. There were no statistically significant differences between the two interventions at any stage of the follow-up period. These results indicated that both interventions reduced neck pain and disability; UP had the greater effect, but the difference between the two interventions was not statistically significant. Appendix 25 contains boxplot analysis, SPSS analysis of repeated measures ANOVA for NPQ scores and analysis of residuals.

Table 6.4 Type III sum of squares and tests of within-subjects effects on repeated measures ANOVA for NPQ score and NPQ score v intervention

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
NPQ	Greenhouse-Geisser	1549.691	1.531	1012.217	5.118	.013
NPQ*coderx[1]	Greenhouse-Geisser	338.684	1.531	221.219	1.119	.317
Error (NPQ)	Greenhouse-Geisser	31489.544	159.223	197.771		

1. Coderx=intervention type

For our secondary outcome measure Table 6.3 above shows the mean DASH score. Patients allocated to UP showed an improvement in the DASH score of about 5.4 points at six weeks. However, they showed a small deterioration of the DASH scores by six month follow-up, although they maintained a small overall improvement of 3.9 points by comparison with baseline. Notably, the patients allocated to GET reported higher DASH score at six weeks, before returning to near baseline score at six month follow-up. Boxplot analysis revealed that the data sets were normally distributed and that there were no extreme cases (see Appendix 26). A repeated measures ANOVA was performed with intervention type as the between subjects factor. The data sets failed Mauchly's test of sphericity and we again used the Greenhouse-Geisser Test to be more conservative in our analysis. Analysis showed that there was no significant difference between the two intervention groups [Greenhouse-Geisser adjusted F(1.353,124.439)=1.762, p=0.185](see Table 6.5 below). Further analysis showed that

DASH scores did not improve significantly in either treatment group [Greenhouse-Geisser adjusted F(1.353,124.439)=0.05; p=0.890](see Table 6.5). Analysis of residuals from ANOVA was normally distributed and the assumptions for ANOVA were therefore met (see Appendix 26). These results indicated that neither intervention was effective at reducing upper limb disability associated with neck pain. Appendix 26 contains boxplot analysis, full SPSS analysis of repeated measures ANOVA for DASH scores and analysis of residuals.

Table 6.5 Type III sum of squares and tests of within-subjects effects on repeated measures ANOVA for DASH scores and DASH score v intervention

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
DASH	Greenhouse-Geisser	17.315	1.353	12.801	.050	.890
DASH * coderx[1]	Greenhouse-Geisser	614.588	1.353	454.375	1.762	.185
Error(DASH)	Greenhouse-Geisser	32088.839	124.439	257.868		

1. Coderx=intervention type

6.3.4 Quality assurances

6.3.4.1 Participant v non participants analysis

Four hundred and eighty three patients with neck pain were referred for possible inclusion into the trial. Of these, 151 patients were recruited into the study, representing an overall inclusion rate of 31.3%. Of those excluded, 241 were excluded during the first telephone interview with the trial co-ordinator. There were many reasons for being excluded at this stage. Typical reasons given were not wanting to commit themselves to being in a trial, work or family commitment, being unable to attend an exercise class at set times or because we were unable to contact them. A further 91 were excluded during the face-to-face assessment with the trial assessor. Typical reasons for exclusion at this stage were being unable to attend the exercise class, medical complications or that they were already receiving treatment. See the consort flow-chart at figure 6.1 above.

Table 6.6 Sociodemographic characteristics of the trial participants compared with non-participants. Values are frequencies (percentages) or means (standard deviations)

	Referred to trial (frequency)	Participants	Non participants	Significance level
Gender				
• Males	176	60 (34.1)	116 (65.9)	p=0.369
• Females	302	91 (20.2)	211 (79.8)	
Centres				
• Hull	246	81 (32.9)	165 (67.1)	
• Wycombe	106	34 (32.1)	72 (67.9)	p=0.092
• Grimsby	72	26 (36.1)	46 (63.9)	
• Nottingham	58	10 (17.2)	48 (82.8)	
Age (in years)	475	54.25 (14.63)	49.98 (16.09)	p=0.006
Townsend Score	480	1.5364 (4.1617)	2.3592 (4.5691)	p=0.061

Independent t tests and chi-square tests were used to test for differences between participants and non-participants in the trial. Except for age, the participants and non-participants were similar (see Table 6.6). Compared to non-participants, participants were significantly older {participants mean age 54.25(14.63), non participants mean age 49.98(16.09), p=0.006}. There were several other slight differences between participants and non-participants. Participants were more likely to be male and come from less materially deprived neighbourhoods, although these differences were not significant. Recruitment rates from each centre were about equal, although at one of the four centres difficulties were experienced converting eligible patients into study participants. Reasons for this were not clear. With the exception of age, the participants in this study appear to be similar to non-participants.

6.3.4.2 Loss to follow-up

Figure 6.1 above shows the drop outs during the course of the trial. At six weeks 31 (20.5%) patients were lost to follow-up. At six months 34 (22.5%) were lost to follow-up. Loss to follow-up was higher in the GET group. At six weeks loss to follow-up was 17 (22.6%) in the GET group and 14 (18.4%) in the UP group. At six months these figures were 22 (29%) and 12 (15.8%) respectively.

All losses to follow-up were related to drop outs or withdrawals. The majority of drop outs occurred because we were no longer able to contact the patient by telephone or because the questionnaires were not returned to us. Four people withdrew from the

trial; one withdrew for personal reasons and three withdrew for health reasons not related to the trial. Of the patients who withdrew for health reasons, one patient fractured a wrist and was no longer able to participate in GET, a second had a cardiovascular accident (CVA) and was admitted to hospital, the third was admitted to hospital for planned cardiac bypass surgery. All the withdrawals were unrelated to treatment but came from the GET group. No serious adverse events were reported.

6.3.4.3 Responders versus non participants/ non-responders

Further analysis was conducted to investigate whether the trial responders were representative of the general neck pain population referred to this trial. Independent t-tests and χ^2 tests were used to test for differences between responders and non participants/ non-responders in this trial. The results of this analysis are shown at Table 6.7. There was no significant difference between responders and non participants/ non-responders on gender. However responders were significantly more likely to be older (mean age in years responders = 55.6 (14.2) v non participants/ non-responders = 49.9 (16.0); {t(473)=3.425, p=0.001}) and to be less materially deprived (mean Townsend score responders = 1.3156 (4.003) v non participants/ non-responders = 2.3527 (4.5702); {t(478) = -2.191, p=0.029}. This indicated that the trial responders are significantly different from the general neck pain population on age and sociodemographic status. This may have implications regarding whether the results of this study are generalisable to the wider neck pain population.

Table 6.7 Baseline characteristics of responders at six months v non-responders and non-participants. Values are means (standard deviations) or frequencies (percentage)

	Referred to trial (frequency)	Subjects who completed NPQ at 6 months	Non-participants and non-responders at 6 months	P values of independent samples t-tests or χ^2 test
Townsend score	480	1.3156 (4.003)	2.3527 (4.5702)	p=0.029
Age	475	55.6 (14.2)	49.9 (16.0)	p=0.001
Gender				
• Male	176	47 (26.7)	129 (73.3)	p=0.387
• female	302	70 (23.2)	232 (76.8)	
Centres				
• Hull	246	62 (25.2)	184 (74.8)	
• Wycombe	106	26 (24.5)	80 (75.5)	p=0.095
• Grimsby	72	22 (30.6)	50 (69.4)	
• Nottingham	58	7 (12.1)	51 (87.9)	

6.3.4.4 Usual physiotherapy treatment received

Physiotherapists treated their patients in the usual way using their own clinical judgement and recorded treatment sessions in physiotherapy notes. Once treatment was completed details of the types of treatment were recorded for each patient on the individual treatment record form at Appendix 20. Appendix 27 collates the treatment delivered to the patients randomised to the UP group. Nine patients did not attend the physiotherapy department for initial assessment. A further 12 patients did not complete treatment. Fifty five patients completed usual physiotherapy treatment as per protocol. The majority of patients received specific neck exercises, mobilisation treatment and a home exercise programme. These findings are similar to reports of usual physiotherapy treatments in another study (Klaber Moffett et al., 2005). Upper limb strengthening exercises and advice to undertake general exercise was minimal within the group allocated to Usual Physiotherapy, indicating that the two interventions delivered in this study were different as intended in the protocol.

6.3.4.5 Graded exercise treatment received

The Principal Investigator followed up several classes on each site over the course of a year with ad hoc visits to improve consistency of approach on all sites. This was an opportunity to answer any questions and provide support to the physiotherapists undertaking GET. On all sites, all physiotherapists were adhering to the agreed guidelines for the class. The physiotherapist kept a record of the number of times patients attended the GET intervention. These results are collated in Appendix 28. Thirty five patients completed the treatment programme as per protocol i.e. they attended a minimum of six exercise classes. Fourteen patients did not attend treatment (DNA). One patient inadvertently received the UP treatment programme instead of GET and four withdrew from treatment; one for personal reasons and three for health reasons unrelated to the trial (see section 6.3.4.2). A further 23 patients did not complete the GET treatment programme i.e. they attended but completed less than six sessions of treatment (DNCT). The reason for DNAs and DNCTs is not known.

6.3.4.6 Sub-group analysis

Table 6.8 below shows the mean NPQ and DASH scores at baseline, six weeks and six month follow-up for sub groups of patients randomised to receive GET. These subgroups are divided into four main categories; namely those that 1) completed

treatment (≥ 6 sessions), 2) begun but did not complete treatment (< 6 sessions), 3) did not attend for treatment and 4) others.

Table 6.8 Results of subgroup analysis for graded exercise treatment. Results are given as mean (standard deviation)

Subgroup	Treatment completed as protocol	Treatment begun but not completed (DNCTs)	Did not attend treatment (DNA)	Others[1]	Whole group (ITT[2])
NPQ score at baseline	38.4 (15.9) (n=35)	37.5 (14.1) (n=23)	43.3 (12.9) (n=12)	40.9 (7.4) (n=5)	39.1 (14.4) (n=75)
NPQ score at 6 week follow-up	33.8 (15.1) (n=33)	47.3 (20.0) (n=17)	36.5 (21.6) (n=4)	29.8 (21.7) (n=4)	37.7 (18.2) (n=58)
NPQ score at 6 month follow-up	29.6 (18.7) (n=32)	40.9 (17.9) (n=17)	41.2 (12.0) (n=4)	No scores available	34.1 (18.6) (n=53)
DASH score at baseline	30.7 (20.6) (n=34)	30.1 (17.1) (n=21)	33.0 (15.6) (n=10)	32.8 (9.4) (n=4)	31.0 (18.2) (n=69)
DASH score at 6 week follow-up	29.8 (21.5) (n=32)	45.5 (21.5) (n=17)	41.6 (19.2) (n=4)	30.0 (24.7) (n=4)	35.3 (22.3) (n=57)
DASH score at 6 month follow-up	28.3 (18.2) (n=31)	40.6 (24.5) (n=15)	40.6 (24.7) (n=3)	No scores available	32.8 (21.0) (n=49)

1. Four patients withdrew from the trial and one received UP inadvertently
2. ITT = intention to treat

These results show that the subgroup who completed treatment as per protocol improved 8.8 points on the NPQ at six month follow-up. This compares favourably with the findings of the intention to treat analysis (5.0 point improvement at six months). The subgroup who completed treatment also improved 2.4 points on the DASH at six month follow-up. This also compares favourably with the intention to treat analysis in which patients at first demonstrated a worsening of DASH score before returning to near baseline level at six month follow-up (deterioration of 1.8 points). A notable finding of the subgroup analysis relates to those patients who began but did not complete treatment (DNCTs). Twenty three patients (31%) attended at least one GET session but did not complete six sessions. The results in Table 6.8 suggest that according to the data returned by 17 patients, GET patients who did not complete treatment reported more neck pain at follow-up. These NPQ scores deteriorated by approximately 10 points at six week follow-up, before reducing to near baseline level at six month follow-up. DASH scores also deteriorated by 15 points at six week follow-up. Although DASH scores reduce again by six month follow-up, they remain elevated

by comparison with baseline. These results suggest that a proportion of patients may deteriorate with GET.

Table 6.9 Results of subgroup analysis for usual physiotherapy

Subgroup	Treatment completed as protocol	Treatment begun but not completed	Did not attend (DNA) treatment	Others[1]	Whole group (ITT[2])
NPQ score at baseline	40.3 (15.4) (n=55)	33.9 (16.9) (n=12)	34.0 (14.9) (n=7)	27.8 (7.9) (n=2)	38.4 (15.6) (n=76)
NPQ score at 6 week follow-up	33.7 (19.4) (n=49)	36.7 (23.7) (n=6)	27.8 (18.0) (n=4)	23.6 (2.0) (n=2)	33.3 (19.3) (n=62)
NPQ score at 6 month follow-up	31.3 (20.8) (n=51)	31.4 (29.9) (n=7)	27.8 (20.5) (n=4)	16.7 (15.7) (n=2)	30.6 (21.4) (n=64)
DASH score at baseline	33.7 (20.0) (n=52)	24.1 (19.2) (n=12)	27.6 (21.9) (n=7)	15.8 (13.0) (n=2)	31.1 (20.1) (n=73)
DASH score at 6 week follow-up	27.0 (20.1) (n=49)	29.6 (17.3) (n=7)	13.1 (9.4) (n=4)	10.3 (0.00) (n=1)	26.1 (19.4) (n=61)
DASH score at 6 month follow-up	29.6 (22.7) (n=48)	27.2 (20.1) (n=6)	13.1 (9.6) (n=4)	8.8 (8.8) (n=2)	27.5 (21.9) (n=60)

1. Two patients received GET inadvertently
2. ITT= intention to treat

Table 6.9 shows the mean NPQ and DASH scores at baseline, six weeks and six month follow-up for sub groups of patients randomised to receive UP. These results show that the subgroup who completed treatment as per protocol improved 9.0 points on the NPQ at six month follow-up. This compares favourably with the findings of the intention to treat analysis (7.7 point improvement at six months). This subgroup also improved 4.7 points on the DASH at six month follow-up. This compares favourably with the intention to treat analysis (4.1 point improvement at six months). For patients who began but did not complete UP treatment there is a similar pattern to those randomised to GET. Twelve patients (15.8%) attended at least one UP session and discharged themselves before completing treatment. The results suggest that NPQ scores deteriorate at six week follow-up before returning to baseline level at six month follow-up. The DASH scores also deteriorate after six weeks and remain elevated by comparison with baseline at six months. These results suggest that a proportion of patients may also deteriorate with UP. However only about half these patients returned follow-up questionnaires, therefore these conclusions must be treated with caution.

In summary, patients who completed treatment had reduced neck pain and upper limb disability at both six weeks and six months by comparison with baseline. Both groups improved by a clinically important amount; however GET was subject to a greater drop out rate from treatment. A total of 35 patients from both intervention groups did not complete treatment. Due to the high loss to follow-up data in this group of patients conclusions must be made cautiously, however it seems possible that these patients may have deteriorated as a consequence of treatment. A total of 19 patients did not attend treatment at all. Again conclusions should be made cautiously but the results suggest that these patients may have improved, possibly spontaneously.

6.3.4.7 Treatment completed v treatment not completed

In total 54 patients did not attend treatment (DNA) or failed to complete treatment (DNCT). Independent sample t-tests and chi-square tests were used to investigate for statistically significant differences in baseline characteristics between patients who completed treatment as per protocol and patients who did not complete treatment (i.e. DNAs and DNCTs). The table of these results are shown at Table 6.10 below. The two groups were significantly different on two baseline variables, namely age and Townsend scores. Patients who failed to complete treatment were significantly younger (mean age=50.8 (13.4)) than those who completed treatment (mean age=55.7 (14.2)) {t(142)=2.054; p=0.042}. Patients who failed to complete treatment had significantly higher Townsend scores (mean Townsend score=2.7687 (4.6478)) compared with those who completed treatment (mean Townsend score=0.8310 (3.7035)) {t(141)= -2.745; p=0.007}. This indicates that those from more materially deprived areas were less likely to attend their initial assessment (DNA) or complete treatment (DNCT) than those from less materially deprived areas.

Table 6.10 Baseline characteristics of patients who completed treatment as per protocol and those who did not complete treatment. Values are means (standard deviations) unless otherwise stated

	Completed treatment (n=90)	Did not complete treatment (n=54)	p value of independent samples t-test or χ^2 test
Age	55.7(14.2)	50.8(13.4)	0.042*
Female (frequency)	51	35	0.334
Male (frequency)	39	19	
• smokers	25	16	0.844
• non-smokers	64	38	
• exercise more than once per week	36	22	0.922
• never exercise	49	31	
Social deprivation score	0.8310(3.7035)	2.7687(4.6478)	0.007*
• Expressed a preference	50	28	0.187
• Preferred UP	29	9	
• Preferred GET	18	15	
• No preference	38	25	
NPQ score (0-100)	39.6(15.6)	37.5(14.6)	0.445
DASH score (0-100)	32.5(20.2)	28.9(17.8)	0.276
QVAS (0-100)	60.6(17.4)	60.3(15.4)	0.934
Pain self efficacy (0-100)	37.9(16.2)	35.8(14.4)	0.432
Anxiety	9.2(1.8)	9.3(1.9)	0.795
Depression	9.8(2.6)	10.0(2.5)	0.642
Tampa Scale of Kinesiophobia (17-68)	35.0(6.7)	35.8(8.3)	0.576
Coping Strategies			
• diverting attention	14.4(9.0)	13.4(8.0)	0.518
• reinterpreting pain sensation	10.4(8.2)	9.1(7.5)	0.366
• catastrophising	9.6(7.1)	12.0(7.5)	0.065
• ignoring sensations	17.5(8.3)	16.0(7.9)	0.285
• praying and hoping	17.4(9.4)	15.7(8.1)	0.252
• coping self statements	24.2(6.7)	23.8(6.0)	0.736
• increased behaviour	18.0(8.0)	16.1(6.5)	0.154

However, patients' preference for treatment may also have influenced their adherence to treatment (Torgerson and Sibbald, 1998; Klaber Moffett et al., 2005). In this study we were interested in whether the patients preference for treatment had an impact on outcome. Patients were asked whether they had a preference for UP, GET, brief intervention, a home exercise programme or whether they had no preference. Resentful demoralisation due to disappointment may have occurred when they did not receive their preferred treatment (Torgerson and Sibbald, 1998). This may have led to poor adherence to treatment. Conversely, patients receiving their preferred treatment may have adhered with treatment more stringently (Torgerson and Sibbald, 1998). Table 6.11 shows the frequency of treatment completers and non-completers by comparison with matching of treatment to patients treatment preference. Analysis using crosstabulation and chi-square analysis indicated that matching of patient preference with actual intervention received did not significantly influence whether the patient was a treatment completer or non-completer [χ^2=0.997, df=2; p=0.613]. In other words, resentful demoralisation does not seem to have occurred.

Table 6.11 Frequency (percentages) of completers and non-completers by matching of treatment received to patient preference.

	Total	Treatment completed	Treatment not completed	Significance level χ^2
Treatment matched to preference	44 (100%)	27 (61%)	17 (39%)	p=0.613
Treatment not matched to preference	33 (100%)	23 (70%)	10 (30%)	
No preference	67 (100%)	40 (60%)	27 (40%)	
Total	144(100%)	90 (62%)	54 (38%)	

6.4 DISCUSSION

This chapter reports the findings from a multi-centre randomised controlled trial investigating the effectiveness of a neck and upper limb exercise class (GET) compared with usual physiotherapy (UP). This study demonstrated that there was no significant difference in neck pain and function, as measured by the NPQ and the DASH, at six weeks or six months between patients receiving GET and those receiving UP. Both interventions reduced NPQ scores by a statistically significant amount. The NPQ scores for the GET group reduced slightly by 5.0% while those in the UP group reduced by

7.7% at six months follow-up. Two earlier studies suggested that a 5.0% change on the NPQ represented a clinically important change (Dziedsic et al., 2005; Klaber Moffett et al., 2005). By that standard, both GET and UP produced a clinically important change in neck pain and disability. However, DASH scores did not change significantly in either intervention group during the follow-up period. In fact, somewhat surprisingly DASH scores deteriorated at six week follow-up in those receiving the GET intervention before returning to baseline levels (see Table 6.3). Although this figure appears to be skewed by the patients who did not complete treatment (DNCT) (see Table 6.8). Patients who completed treatment as per protocol showed similar improvements in neck pain (about 9.0%) regardless of intervention type, although GET was subject to a large drop-out rate. Overall, the results of this study suggest that UP was effective at reducing neck related pain and disability. GET was an effective alternative treatment for some neck pain patients, especially for those patients who were able to adhere to the treatment protocol of a minimum six sessions.

The findings of this study are in line with the findings of other trials investigating usual physiotherapy for the management of neck pain. A randomised controlled trial comparing usual physiotherapy with a brief physiotherapy intervention (Klaber Moffett et al., 2005) found that the usual physiotherapy group improved significantly on the NPQ by about 6% at three months and 7.8 % at 12 months. A second randomised controlled study (Dziedzic et al., 2005) demonstrated that their interventions, namely (1) advice and neck exercises, (2) advice, neck exercises and manual therapy and (3) advice, neck exercises and pulsed shortwave diathermy, achieved improvements of approximately 10-11% on NPQ scores at six month follow-up. Their advice, neck exercises and manual therapy intervention varied from usual physiotherapy only in regard to the use of modalities such as electrotherapy, acupuncture, heat and ice etc. The GET UP neck pain trial supports the view reported in Chapter Three, section 3.4.1 and 3.5 that usual physiotherapy or multimodal care (incorporating manual therapy and neck exercises) is effective for the management of neck pain.

The improvement of NPQ score in the GET group was found to be clinically meaningful and statistically significant. However this improvement was small. Therefore the GET UP neck pain trial provides weak support for the findings reported in Chapter Three, section 3.5 favouring exercise approaches involving strengthening, endurance training or cervical stabilisation for the management of neck pain. This study

supports the rationale that exercise based treatments are effective at reducing neck pain and disability in particular groups of patients i.e. those patients who complete treatment as per protocol. Neck pain patients should therefore be assessed to see whether exercise based interventions are appropriate to meet their clinical need. However the criteria for making such decisions in clinical practice are lacking and need further research. Patients should also be assessed for willingness to participate in an exercise programme.

6.4.1 Strengths of the study

This randomised controlled study has been designed, conducted, analysed and interpreted in accordance with the recommendations of the CONSORT statement (Moher et al., 2001). This study achieved its recruitment target of 150 patients and had a good rate of follow-up (77.5% at six months). Outcomes were self assessed using postal questionnaires, eliminating the possibility of therapist or assessor bias. The use of broad inclusion criterion ensured that the trial participants were representative of the typical group of non-specific neck pain patients referred to the physiotherapy departments involved with this trial.

6.4.2 Limitations of the study

At one physiotherapy department there were staffing issues which may have affected the trial patients in both interventions. A high turnover of staff in that department meant that several patients in the UP group were treated by more than one member of staff. Those in the GET group had a number of different staff co-ordinating the group. Training and support as per section 6.2.11 was given to all members of staff involved on the trial in order to ensure that patient treatment was not adversely affected. However, this situation does reflect the current limited resources of many NHS physiotherapy departments.

Loss to follow-up was greater in the GET group (29%) than the UP group (16%). In addition, less than half of the patients in the GET group (47%) completed treatment as per protocol. For the UP group adherence was better (72%). Many barriers to initiating and adhering to an exercise programme have been identified. Firstly, programme organisation and leadership may be an important factor that determines whether patients in an exercise group stick with the programme or drop out (Boyette et al., 1997). Although the trial physiotherapists were motivated volunteers and adhered to the programme, it was clear that some physiotherapists were more naturally orientated to

managing and leading a class than others. Training for the physiotherapists to run the GET group in most cases was less than one day. This may not be sufficient training in order to become proficient in the running of an exercise class. In addition, physiotherapy training at undergraduate and postgraduate level is mainly aimed at the delivery of usual physiotherapy and little time is dedicated to learning the skills of managing a class situation. Secondly, 84 out of 151 (55.6%) patients in this trial reported that they were doing no exercise at baseline assessment (see Table 6.2). This is in line with national statistics which suggests that about two thirds of the population do not engage in exercise. Although all the patients in the GET UP neck pain trial reported that they were willing to be randomised to either intervention, they may have been less motivated to adhere with GET than UP. Thirdly, the GET UP neck pain trial identified that patients from a more deprived background were significantly less likely to adhere or complete treatment than those from a less deprived areas (see section 6.3.4.7). This is in line with previous research which indicates that patients from deprived backgrounds are more likely to discharge themselves from treatment (Department of Health, 1998). The population in the GET UP neck pain trial was more deprived than average for the UK, with those allocated to GET being slightly but not significantly more deprived than those allocated to UP (see Table 6.2). This may explain the poor overall adherence with both interventions and in particular the poorer adherence rate with GET. Finally many other barriers to engaging in an exercise programme have been identified. Some of these may also be related to deprivation levels. These include poor education, poor history of exercise, perceived physical frailty, perceived poor health, social support, readiness to change, self efficacy (Duncan and McAuley, 1993; Courneya and McAuley, 1995; Hellman, 1997; Rhodes et al., 1999). In consequence, asking patients to initiate and adhere to an exercise programme is an enormous challenge for health professionals. However it is a challenge which can not be ignored since many studies, including the GET UP neck pain trial, have shown that adhering to an exercise programme improves pain and function in many musculoskeletal conditions (Boyette et al., 1997; van Gool et al., 2005). In addition Chapter Two, section 2.3.5 reports on strong evidence that adhering to regular ongoing physical activity protects people with neck pain from progression of that neck pain. Helping patients to overcome barriers to participation may be an important element to improving patient adherence with an exercise programme. Motivating and encouraging patients to adhere to exercise is critical to the effectiveness of the programme. Physiotherapists that run exercise

classes may benefit from additional training regarding barriers to exercise and methods to identify and overcome those barriers.

Randomisation of patients to treatment using numbered, sealed opaque envelopes is an acknowledged method of randomisation in controlled trials. The method is now considered methodologically weak since there is a possibility that the envelope randomisation process may be compromised. Where possible distance randomisation should be the method of choice. This method was chosen due to financial constraints.

None of the physiotherapists had the opportunity to practice running an exercise class prior to the commencement of the trial. This may have had an impact on the confidence of the physiotherapist to run the class, which may be important since patient confidence and trust in the physiotherapist's ability may be a key component in the effectiveness of treatment (Thom and Campbell, 1997; Thom et al., 2002). In addition the amount of training received by the physiotherapists may have been insufficient to ensure the effectiveness of the approach. In view of the high attrition rate, potential barriers to attendance and possible low motivation to participate in exercise in this socially deprived population, more intensive and continuing education for the physiotherapists may have resulted in greater success. How much training is required is not clear but one study showed that a two day education course for physical therapists was not associated with improvement in clinical outcomes for patients with neck pain. However an ongoing improvement project for physical therapists resulted in greater clinical improvement for patients with neck pain.

The participants in GET were asked to attend between six and 12 sessions of treatment. In general the influence of exercise intensity, frequency of exercise, number of sessions and programme duration on outcome remains unknown. However 6-12 sessions may not be sufficient to effect an optimal change in pain or function for the patients participating in GET. Some LBP studies which have demonstrated good clinical outcome have used more prolonged periods of exercise intervention e.g. twice a week for 3 months (Manniche et al., 1993; Mannion et al., 1999). In addition our own pilot study (see Chapter One, section 1.1) indicated that patients were generally slow to get going with exercise and that the bulk of improvements occurred in the later stages of the programme.

6.4.3 Implications for clinical practice

The GET UP neck pain trial demonstrated that GET and UP produced a small (GET 5.0%; UP 7.7%) but significant reduction in pain and disability for patients with non-specific neck pain at six month follow-up. Therefore both interventions are feasible management options in a physiotherapy department setting. GET was appropriate for patients who completed treatment as per protocol but due to the high levels of non-adherence it should not be considered a simple method of managing neck pain. Problems with adherence to exercise are well documented (Crook et al., 1998; Campbell et al., 2001). The organisational, physiotherapist and patient barriers coupled with the training implications are outlined in section 6.4.2 above and may influence the effectiveness of the approach. Clinicians must give careful consideration as to how best to employ and maximise adherence and the effectiveness of the approach.

Patients taking part in GET reported higher mean DASH score at the six week point, indicating a deterioration of upper limb disability, before returning to baseline level at six months. This figure appears to be skewed by the patients who did not complete treatment (see Table 6.8). Given that this group of patients were selected because of the non-specific nature of their neck symptoms, were asked to exercise at their own individual pace and increased their activity at their own chosen speed, it seems unlikely that these patients were harmed. Two possible explanations are presented. Firstly, post exercise muscle soreness is common especially where the exercise is unfamiliar (Zainuddin et al., 2005). It generally develops within 24 hours of exercise, peaks after 24-48 hours and lasts for around five to seven days after the exercise has been conducted (Hilbert et al., 2003). This possibility of post exercise soreness was carefully explained to all patients taking part in the exercise group, that it was quite normal for people undertaking exercise and patients were encouraged to discuss any concerns in this regard with the physiotherapist co-ordinating the class. The majority of patients in this trial were not used to doing any form of exercise and post exercise muscle soreness, in combination with their neck pain may have enhanced discomfort and resulted in some patients perceiving the exercise intervention as not beneficial. A second possibility is that participation in an exercise class may have highlighted a deficit in upper limb dysfunction which the patients were hitherto unaware. This may have lead to the patient developing the perception that their problem was getting worse not better. Clinically it may be important for physiotherapists to tackle these issues proactively in order to allay any unexpressed concerns that the patient may have. These arguments

coupled with the previous discussions related to overcoming barriers and motivation to exercise (see section 6.4.2) lead to our suggestion that treatments which incorporate general exercise may be more effectively pursued by initially assessing patients in UP. This would give physiotherapists the opportunity to identify upper limb disability, discuss exercise options with the patient, elicit any concerns and tackle them proactively and reinforce the benefits of exercise, prior to the patient undertaking an exercise programme.

Secondary analysis has revealed that both interventions had a high non completion rate. A large number of patients in the GET group (n=23 or 31%, see Table 6.8) and the UP group (n=12 or 16%, see Table 6.9) started treatment but did not complete treatment as per protocol. There is some indication that in this group neck pain and upper limb disability may have been exacerbated as a consequence of treatment. These findings should concern physiotherapists working in outpatient departments, since non completion of treatment is a common occurrence. Clinicians generally have little information regarding this group of patients but should consider whether the reasons for non completion of treatment is related to actual deterioration of the patients condition, perceived deterioration due to post exercise or post treatment soreness or for some other reason. These features of treatment should be carefully explained to patients, to re-assure them that this is a normal reaction to exercise and does not mean that they are harming their necks. In addition it is judicious for physiotherapists to apply gentle and graded assessment and intervention techniques, particularly in the early stages of treatment when patients are adjusting to new movement and new exercises which may be perceived as threatening. This may be particularly relevant for patients who do no exercise, are very stiff or limited in their movements or fearful of movement.

Finally, this study demonstrated that younger patients were less likely to attend their first treatment or complete treatment than older patients (see section 6.3.4.7). This may have been due to family or work commitments, which might mean that conventional appointment times may not fit with the lifestyle of younger patients. In addition patients from more materially deprived backgrounds were less likely to attend their first treatment or complete treatment. This supports the findings of previous research which suggests that those living in areas of social deprivation are less likely to utilise health resources (Kim et al., 2004). They are more likely to fail to attend their first appointment and terminate treatment early (Self et al., 2005. There is very little

evidence looking at the reasons for high attrition from physiotherapy and therefore this phenomenon is poorly understood. There is some evidence from psychotherapy research that social support, social resources, racial status, education and income are sociodemographic variables that predict attrition (Wierzbicki and Pekarik, 1993; Self et al., 2005. Physiotherapy departments with low treatment completion rates that treat patients from these social backgrounds may wish to review clinical and administrative management processes in order to meet the specific needs of their patient population. For example, preliminary evidence from audit suggests that a triage service, located in an area of social deprivation, focussing on a brief intervention of early advice and self management options results in a reduced number of patients who did not attend for treatment (personal communication, Tomlinson et al., 2006).

Six sessions of an exercise programme may not be sufficient in order to bring about major changes in function, especially in longstanding cases or in patients with high levels of fear. Other successful LBP exercise programmes have used substantially more sessions e.g. 24 sessions (Manniche et al., 1993; Mannion et al., 1999). Our own pilot study (see Chapter One, section 1.1) identified that benefits were more apparent in the later stages of the programme (session 9-12) once patients had progressed to the endurance phase of the programme. Physiotherapy departments running exercise based rehabilitation programmes should give due consideration to how many sessions they include in their exercise programmes and how they facilitate their patients to maintain active lifestyles once the formal programme has ended.

6.4.4 Implications for research

Exercise based approaches to the management of neck pain have been shown to be effective (see Chapter Three, section 3.5). The GET UP neck pain trial demonstrated that patients who completed GET as per protocol derived as much benefit as those completing UP, albeit only a modest amount. The exercise programme might be improved in two possible ways. Firstly combining exercise based rehabilitation with usual physiotherapy may enhance effectiveness. This has been shown to be a beneficial combination in studies for OA knee (Deyle et al., 2005), back pain (Bronfort et al., 1996) and cervicogenic headache and neck pain (Jull et al., 2002). Secondly, there is evidence from chronic LBP research that intensive multidisciplinary biopsychosocial rehabilitation with functional restoration improves outcome by comparison with other

forms of outpatient rehabilitation (Schonstein et al., 2003). Both of these interventions should be further investigated for the neck pain population.

The identification of subgroups of neck pain patients that benefit from different interventions has been identified as a research priority (Harvey & Cooper, 2005) in order to achieve better targeted and more effective treatment. Such research could also be used to identify potential procedural improvements in the way usual physiotherapy and exercise based interventions are delivered clinically.

There is increasing evidence that social deprivation plays a significant role in the development, prevalence and course of musculoskeletal disorders (Urwin et al., 1998; Brekke et al., 1999; Carr and Klaber Moffett, 2005). Very few randomised controlled trials have been conducted in socially deprived areas (Watt, 1996) but the GET UP neck pain trial indicated that social deprivation is linked to attrition from physiotherapy (see section 6.3.4.7). There is preliminary evidence of a link between social deprivation and poor outcome for patients with rheumatoid arthritis and chronic low back pain (McEntegart et al., 1997; Carr et al., 2005). In line with previous opinion (Schecter et al., 2001), it is recommended that material and social deprivation should be treated as a confounding variable in all musculoskeletal clinical trials (Carr and Klaber Moffett, 2005).

6.5 CONCLUSIONS

This study demonstrated that GET and UP produced small but significant reductions in pain and disability for patients with non-specific neck pain at six month follow-up. UP had better adherence levels from patients and generally produced slightly better results. GET had a high attrition rate, but those who completed treatment as per protocol derived reduction in neck pain and disability comparable with those receiving UP. Both approaches are appropriate for use in clinical practice. Adherence issues, particularly for GET, cannot be ignored since many studies have shown that adhering to an exercise programme can improve pain and function in many musculoskeletal conditions. Exercise programmes should not be considered a simple method of managing neck pain, since there are many organisational, physiotherapist and patient barriers which may influence the effectiveness of the approach. Specific targeted strategies may be needed in order to address the barriers to adherence and maximise the effectiveness of the

approach. Clinicians need to carefully consider how best to employ exercise rehabilitation in order to maximise treatment outcome for their patients.

The next chapter will identify which patients are more likely to benefit from each of the treatment packages offered in the GET UP neck pain trial.

CHAPTER 7

AN INVESTIGATION OF PSYCHOLOGICAL, SOCIO-DEMOGRAPHIC AND PHYSICAL VARIABLES WHICH PREDICT TREATMENT OUTCOME IN THE GET UP NECK PAIN TRIAL: A SECONDARY ANALYSIS

7.1 INTRODUCTION

The randomised controlled trial described in the previous chapter demonstrated that usual physiotherapy (UP) was effective at reducing neck pain and disability in a group of patients referred for physiotherapy. Graded exercise therapy (GET) was effective at reducing neck pain and disability in the group of patients who completed treatment, but not upper limb disability. As discussed in Chapter Five, section 5.1, identification of patients that are more likely to benefit from these treatments could allow resources to be targeted appropriately in order to maximise treatment outcome (Harvey and Cooper, 2005). Equally, patients identified as being at risk of poorest outcome could be reviewed for more appropriate management strategies (Sterling et al., 2005). For example in Chapter Six, section 6.3.4.7 patients from socially deprived backgrounds were more likely to have a high attrition rate from physiotherapy and may benefit from more targeted approaches. To date little is known about the relationship between patient baseline characteristics and outcome of treatment for non-specific neck pain. However there is some indication that psychological, sociodemographic and physical variables predict treatment outcome for whiplash associated disorder (Sterling et al., 2005) and low back pain (Bendix et al., 1998; Jensen et al., 2001; Al-Obaidi et al., 2005). This chapter presents a secondary analysis to identify baseline characteristics which predict outcome of treatment for participants in the GET UP neck pain trial.

7.1.1 Aim

The aim of this secondary analysis was to investigate the effect of baseline psychological, socio-demographic, physical and treatment variables on outcome at six months for neck pain patients who participated in the randomised controlled trial described in Chapter Six. It was hypothesized that a range of variables could predict treatment outcome in a group of patients with neck pain. Furthermore, it was hypothesized that some variables could interact with type of intervention received to

predict treatment outcome. That is, some patients with certain baseline characteristics may achieve significantly better outcome with one treatment compared with the other.

7.1.2 Hypothesis

H^0 - the null hypothesis

a. Psychological, socio-demographic, physical and treatment variables at baseline are not predictive of outcome at six months for neck pain patients receiving physiotherapy interventions.
b. There is no interaction between the psychological, socio-demographic and physical variables at baseline and type of treatment received with regard to outcome at six months.

H^1 - the alternative hypothesis

a. Psychological, socio-demographic, physical and treatment variables at baseline are predictive of outcome at six months for neck pain patients receiving physiotherapy interventions.
b. There is an interaction between the psychological, socio-demographic, and physical variables at baseline and type of treatment received with regard to outcome at six months.

7.2 METHODS

7.2.1 Summary of the study design

This study utilised data collected from 151 neck pain patients recruited to the randomised controlled trial outlined in Chapter Six. These patients were randomised to either 1) a neck and upper limb exercise class (GET) or 2) usual physiotherapy (UP). The measure used to assess outcome was the Northwick Park Neck Pain Questionnaire (NPQ) score. NPQ scores were collected at baseline and six months. In addition a range of patient orientated predictive variables were collected at baseline only. These included psychological, socio-demographic and physical variables. These baseline variables were investigated to determine their ability to predict treatment outcome at six months for patients randomised to GET and those randomised to UP.

7.2.2 The study sample

Participants in this study were 151 neck pain patients recruited to the randomised controlled trial in Chapter Six. The sample including inclusion and exclusion criterion is described in detail in Chapter Six, section 6.2.3 to 6.2.5

7.2.3 Data collection – baseline and follow-up

The data were collected using self-administered questionnaires at two time-points: at baseline and six month follow-up. These questionnaires are shown at Appendices 15 and 24.

7.2.3.1 Dependent variable

The dependent variable for this study was neck pain and disability score at six months as measured by the Northwick Park Neck Pain Questionnaire (NPQ)(Leak et al., 1994). Further detail is presented in Chapter Four, section 4.2.1. NPQ score was selected as the dependant variable because it was the primary measure of treatment outcome in the GET UP neck pain trial. Baseline NPQ scores were assessed by questionnaires completed during the interview phase of the recruitment process for the trial. Outcome of physiotherapy intervention at six months follow-up was assessed by postal questionnaire (see Chapter Six, section 6.2.12). With the exception of patients who withdrew, this questionnaire was sent to all patients randomised to the trial.

7.2.3.2 *Covariates*

All patients randomised to the trial completed a baseline questionnaire (see Appendix 15) that measured psychological, sociodemographic and physical variables. A range of these variables were identified in Chapter Five as being potentially predictive of outcome for physiotherapy. The following baseline variables were utilised in this study as potential predictors:

- Intervention Received which was recorded dichotomously as either GET or UP. These interventions are described in detail in Chapter Six, section 6.2.9.
- Neck Pain and Disability at baseline was measured by the Northwick Park Neck Pain Questionnaire (NPQ) and is described in detail in Chapter Four, section 4.2.1.
- Age, which was recorded in years at the time of baseline data collection. Age is discussed in detail in Chapter Five, section 5.2.
- Gender, which was recorded dichotomously as male or female gender. Gender is discussed in greater detail in Chapter Five, section 5.3.

- Upper Limb Disability at baseline was measured by the Disabilities of Arm, Shoulder and Hand (DASH) and is described in detail in Chapter Four, section 4.3.1.
- Pain Self Efficacy at baseline was measured by the Pain Self Efficacy Questionnaire (PSEQ) and is described in detail in Chapter Five, section 5.5.
- Fear Avoidance Beliefs: Fear of movement, re-injury and increased pain was measured by the Tampa Scale for Kinesiophobia (TSK) and is described in detail in Chapter Five, section 5.4.
- Catastrophising was measured using section three of the Coping Strategies Questionnaire (CSQ). This is described in detail in Chapter Five, section 5.6.
- Anxiety and Depression were measured using the Hospital Anxiety and Depression Scale (HADS). This is described in detail in Chapter Five, section 5.7.
- Current Smoking Status, which was recorded dichotomously as smoker or non-smoker. Smoking is discussed in detail in Chapter Five, section 5.9.
- Material and Social Deprivation. Trial participants were allocated a Townsend material deprivation score by converting their postcodes to ward codes and then from ward codes to Townsend scores. Material and social deprivation is discussed in detail in Chapter Five, section 5.10.
- Activity Level. Patients were asked how frequently they exercised in the past three months, where the exercise caused the patient's heart rate to increase or caused them to breathe slightly harder than normal. This was recorded as, never, less than once per month, once or twice per month, once or twice per week, three or four times per week or more than four times per week. This was dichotomised as non exercisers and exercisers. Non exercisers were those that reported doing no exercise at all. Exercisers reported that they did some form of exercise that caused them to get slightly out of breath or caused their heart rate to increase at least once per month. Physical Activity is discussed in detail in Chapter Five, section 5.11.

7.2.4 Data analysis

The influence of each of the baseline variables on neck pain and disability at six month follow-up was investigated with ANCOVA using the general linear model procedure on SPSS. General linear modelling was used which allows flexible entering of categorical and continuous predictive variables and interaction terms. Initially the relationship between NPQ six month follow-up scores and each of the continuous baseline covariates was investigated using scatter plots, in order to scan for outliers / extreme

values and to assess for approximate linearity of relationship. Pearson correlations were calculated to ensure that none of the covariates were strongly correlated with one another. If any covariates were strongly correlated ($r > 0.7$) then one of the two covariates was removed from the analysis to avoid problems of multicollinearity. After adjusting for baseline NPQ score and intervention type, NPQ score at six month follow-up was adjusted for each baseline covariate in turn. Interactions between intervention group and these baseline covariates were also assessed. In this process, parameter estimates, confidence intervals and p values were used to establish whether any of the baseline covariates or interaction terms were additionally predictive of outcome, after adjusting for NPQ score at baseline and intervention type. A value of $p<0.05$ was considered to be statistically significant. Model selection started by including all the covariates and interaction terms that were found to be significantly predictive in the process outlined above. Backward removal of the non significant variables was done one by one, removing the least significant variable first, until all variables remaining in the model contributed with a $p<0.05$ to the fitting of the model using type III sum of squares (Tabachnik and Fidell, 2001). However, covariates were not removed whilst their interaction with treatment group was kept in the model. Allowing for a total of 24 individual and interactive predictive variables, it is suggested that a sample size of 104 + 24 = 128 cases is a sufficient sample size for testing the multiple correlations (Tabachnik and Fidell, 2001). All data was analysed using SPSS 14.0 for Windows.

7.3 RESULTS

7.3.1 Study population

One hundred and fifty one patients were recruited into the trial and completed the baseline questionnaire. One hundred and seventeen patients completed the NPQ at six month follow-up. This represented a follow-up response rate of 77.5%. Previous analysis in Chapter Six, section 6.3.1.2 revealed significant differences between responders and non-responders in this trial. Non-responders were significantly more likely to come from the GET group, have lower pain self efficacy and higher catastrophising scores. This may have implications regarding whether the results of this study are generalisable to the wider neck pain population.

7.3.2 Baseline data

Table 6.2 of Chapter Six shows the baseline clinical and demographic characteristics of the patients allocated to each intervention group. This indicates that were no differences

between the patients in each intervention groups for any of the measured baseline characteristics.

7.3.3 Results - analysis of covariance

Table 7.1 Mean NPQ scores (and standard deviations) at baseline and six months

	Frequency	Mean % NPQ score (SD)
NPQ score at baseline	151	38.7 (15.0)
NPQ score at 6 month follow-up	117	32.2 (20.2)

Table 7.1 shows that the mean NPQ score and standard deviations at baseline and six months for the whole group. At baseline the mean NPQ score was 38.7 (15.0). At six month follow-up this had reduced to 32.2 (20.2). This represents a mean group improvement of 6.5 percent over 6 months.

Initial examination of the data using scatter plot analysis and Pearson correlation revealed that none of the variables were strongly correlated with any other (see Appendices 29 and 30). Therefore the assumptions for ANCOVA were met. An ANCOVA was performed, adjusting for baseline NPQ scores and intervention group, for each baseline covariate and for each interaction between intervention group and baseline covariate in turn. The results of this analysis are shown in Table 7.2 below. After adjusting for baseline NPQ scores and intervention, six month NPQ scores were significantly predicted by pain self efficacy ($p=0.023$), DASH score ($p=0.04$), catastrophising ($p=0.025$) and Townsend scores ($p=0.005$) at baseline. In addition, intervention type (GET or UP) interacted significantly with baseline TSK score ($p=0.017$) to predict six month NPQ score.

All covariates and interactions found to be statistically significant were entered into an ANCOVA. During backward elimination of non significant covariates, PSE score, DASH score and catastrophising no longer predicted NPQ score at six months and were therefore removed from the regression model. Table 7.3 below shows the final model

Table 7.2 Results of ANCOVA for individual baseline covariates and interactions between covariates and interventions (after adjusting for intervention type and baseline NPQ score)

Effect	Estimate	±Standard error	F	dF	p value	95% confidence interval	
						Lower bound	Upper bound
Age	0.020	0.120	0.027	1	0.869	-0.219	0.258
Gender	0.596	3.536	0.028	1	0.867	-6.410	7.601
PSE	-0.343	0.148	5.359	1	0.023	-0.637	-0.049
DASH	0.307	0.148	4.320	1	0.040	0.014	0.600
Catastrophising	0.596	0.262	5.185	1	0.025	0.077	1.115
Anxiety	-0.641	0.940	0.465	1	0.497	-2.503	1.221
Depression	1.184	0.706	2.810	1	0.096	0.215	2.584
Townsend	1.550	0.423	13.431	1	<0.001	0.712	2.389
Smoking	6.720	3.906	2.960	1	0.088	-1.018	14.459
Activity level	2.331	3.683	0.401	1	0.528	-4.970	9.632
Intervention*Age	-0.235	0.248	0.900	1	0.345	-0.725	0.256
Intervention*Gender	-4.419	7.167	0.380	1	0.539	-18.618	9.781
Intervention*PSE	0.184	0.228	0.651	1	0.422	-0.268	0.635
Intervention*TSK	-1.128	0.465	5.898	1	0.017	-2.050	-0.207
Intervention*DASH	-0.287	0.178	2.615	1	0.109	-0.640	0.065
Intervention*catastrophising	-0.057	0.506	0.013	1	0.911	-1.059	-.946
Intervention*anxiety	-0.626	1.907	0.108	1	0.743	-4.404	3.152
Intervention*depression	-2.448	1.387	3.114	1	0.080	-5.197	0.301
Intervention*Townsend	-1.186	0.838	2.000	1	0.160	-2.847	0.475
Intervention*smoking	-1.329	7.783	0.029	1	0.865	-16.750	14.091
Intervention*activity level	-2.673	7.306	0,134	1	0.715	-17.158	11.812

*** indicates the interaction between the intervention allocated and the variable under consideration**

Note: Intervention*TSK is statistically significant therefore results for TSK is not reported here.

that significantly predicts NPQ score at six month follow-up. After adjusting for baseline NPQ score and intervention type, NPQ score at six months was found to be independently predicted by Townsend score (p=0.002). There was also an interaction between intervention type and TSK score (p=0.024) which predicted NPQ score at six months. Analysis of residuals for the ANCOVA was normally distributed and the assumptions for ANCOVA were therefore met (see Appendix 31). These two variables together predicted approximately 30% of the variance in outcome at six months (R^2). The process of backward elimination and the final general linear model is shown in Appendix 31.

Table 7.3 General linear model fitted to %NPQ score at six month follow-up

Effect	Estimate	±Standard error	F	dF	p level	95% confidence interval	
						Lower bound	Upper bound
Intercept	-14.542	12.122	0.877	1	p=0.351	-38.586	9.503
Intervention type • GET • UP	45.198 0[a]	16.167	7.817	1	p=0.006	13.132	77.265
Baseline NPQ score	0.389	0.105	13.800	1	p<0.001	0.181	0.597
Townsend score	1.375	0.428	10.307	1	p=0.002	0.525	2.224
Baseline TSK score	0.781	0.340	0.714	1	p=0.024	0.106	1.456
Intervention type*baseline TSK score • GET*TSK • UP*TSK	-1.158 0[a]	0.446	-2.594	1	p=0.011	-2.044	-0.273

Backward model. Variables with $p<0.05$ are interpreted as contributing significantly to the model. $R^2=0.299$)
a. This parameter is set to zero because it is redundant

The model gives rise to two equations for patients in each intervention as follows:

For those receiving GET intervention:

NPQ 6 months (GET) = -14.542 + 45.198 + 0.389*NPQ score + 1.375*Townsend score + 0.781*TSK score -1.158*TSK score

= 30.656 + 0.389*NPQ score + 1.375*Townsend score - 0.377*TSK score

For those receiving UP intervention:

NPQ 6 months (UP) = -14.542 + 0.389*NPQ score at baseline + 1.375*Townsend score + 0.781*TSK score

This model predicted that regardless of intervention Townsend score predicted NPQ score at six month. Increased positive Townsend score (indicating increasing levels of material deprivation) predicted increased NPQ score at six months. Conversely negative Townsend scores (indicating increasing levels of affluence) predicted decreased NPQ score at six months. This suggested that patients from more affluent areas were more likely to achieve better six month treatment outcomes. In addition TSK interacted with intervention type to predict NPQ score at six months. The

equations above if considered independently suggest that in the GET group increasing TSK score (indicating higher levels of fear avoidance beliefs) predicted decreasing NPQ scores at six months. In the UP group higher TSK scores predicted higher NPQ scores at six months. Taken together the equations suggest that there is a transition point on the TSK scale when one intervention is considered more beneficial than the other. This transition point can be calculated by resolving these two equations as follows:

$$30.656 - (-14.542) = 0.781 * \text{TSK score} + 0.377 * \text{TSK score}$$

$$\longrightarrow \text{TSK} = \frac{30.656 + 14.542}{1.158}$$

$$\longrightarrow \text{TSK} = 39.03$$

In this model patients with TSK scores greater than 40 are predicted to obtain better NPQ scores in GET than in UP, whilst patients with TSK scores less than 39 are predicted to obtain better NPQ scores in UP than in GET. Those with TSK scores around 40 are predicted to achieve similar outcomes regardless of intervention. This suggested that patients with high levels of fear avoidance beliefs were likely to benefit more from GET, whilst patients with low levels of fear avoidance beliefs were likely to benefit more from UP. Those with moderate levels of fear avoidance beliefs were likely to fare similarly well regardless of intervention.

7.4 DISCUSSION.

7.4.1 Summary of findings

After adjusting for baseline NPQ score, intervention type and baseline TSK scores, there were two independent significant predictors of treatment outcome for patients with neck pain namely; Townsend scores and TSK. Higher Townsend score predicted poorer outcome compared with lower Townsend score regardless of intervention type. This means that those from more materially deprived areas were more likely to have poorer outcome than those from more affluent areas. In addition, TSK and intervention allocated interacted to predict six month outcome. Those neck pain patients with greater fear avoidance beliefs were predicted to have better six month outcome with GET. Those with lower fear avoidance beliefs were predicted to have better six month outcome with UP.

7.4.2 Deprivation as a predictor of outcome

This study is the first to link deprivation to poor treatment outcome for patients with neck pain. This finding is not unexpected, considering the growing evidence reported in Chapter Five, section 5.10 suggesting that deprivation influences outcome in a wide range of other musculoskeletal (McEntegart et al., 1997; Carr et al., 2005; Carr and Klaber Moffett, 2005) and health disorders (Marmot and McDowell, 1986; Watt, 1996). The findings in the GET UP neck pain trial are consistent with the findings of a randomised controlled trial comparing a group exercise programme with usual physiotherapy for back pain patients in a severely deprived area (Carr et al., 2005). They found that patients from the most severely deprived areas were slightly worse at three months follow-up whereas those from more affluent areas tended to improve. Section 6.3.4.3 of Chapter Six reported that trial responders at six months were significantly less materially deprived than the population referred from participating physiotherapy departments. Consequently the deprivation data in this study is somewhat truncated. Nevertheless, after adjusting for baseline NPQ score and intervention type, deprivation status significantly predicted of outcome of physiotherapy treatment, regardless of intervention type.

7.4.3 Fear avoidance beliefs as a predictor of outcome

Chapter 5.4 reported that fear avoidance beliefs may predict outcome in neck pain although the impact may be less profound in neck pain than LBP. In this study fear avoidance beliefs interacted with intervention to predict outcome six months following physiotherapy intervention. This suggested that patients with high levels of fear avoidance beliefs i.e. TSK scores above 40 were likely to benefit more from GET, whilst patients with low levels of fear avoidance beliefs i.e. TSK scores below 40 were likely to benefit more from UP. This appears to be the first study investigating the predictive validity of fear avoidance beliefs for outcome following intervention for neck pain. Although no similar neck pain studies were identified, these results are consistent with findings of other studies which suggest that high levels of fear avoidance beliefs predicts poor outcome following physiotherapy treatment of LBP (Fritz and George, 2002; Burton et al., 2004; Al-Obaidi et al., 2005). One further study conducted a subgroup analysis of patients (n=187) from a randomised controlled trial comparing a Back to Fitness exercise programme with usual general practitioner care (Klaber Moffett et al., 2004). They found that high fear avoiders in the exercise programme were three times more likely to report reduced disability at one year than those in usual

GP care. The fear avoidance model proposes that fear of pain or re-injury leads to the avoidance of particular movements or activities (Vlaeyen and Linton 2000). The avoidance of normal activities may exacerbate the fear and result in development of poor behavioural performance, physical disuse, deconditioning, continued disability, and adverse psychological consequences (Lethem et al., 1983; Slade et al., 1983; Vlaeyen and Linton, 2000). Participating in an exercise programme may help to reverse some of these factors and help patients confront their worries about physical activity and reduce fear avoidance beliefs (Dolce et al., 1986; Mannion et al., 1999; Brox et al., 2003; George et al., 2004). The findings of the GET UP neck pain trial suggest that exercise programmes may not suit all patients but that there may be particular benefits for patients who present with high levels of fear avoidance beliefs. In addition patients with high fear avoidance beliefs may not be suited to usual physiotherapy. The evidence from this study and previous LBP research suggests that physiotherapists should encourage patients with high levels of fear avoidance beliefs to participate in exercise rehabilitation rather than usual physiotherapy.

7.4.4 Limitations of the study

At six months follow-up the sample of respondents (n=117) was smaller than the target figure (n=128) based on power calculations. In addition missing data from baseline covariates potentially made the available data set even smaller. Initial univariate modelling as per protocol with each variable entered individually meant that cases with data on each variable resulted in a usable data set of 108. Five variables or interactions were entered into the final general linear model. Based on estimates in section 7.2.4, 108 cases may be a borderline sample size to test for the multiple correlations based on five predictive variables (Tabachnick and Fidell, 2001). Other suitable options were to enter all variables en bloc into the modelling process to take into consideration the other potential covariates but this would have resulted in an even smaller sample (n=93) for statistical analysis. However, using these two different options did not result in a different set of predictor variables. The results of en bloc entry are shown at Appendix 32 for comparison. This suggested that the model presented in this chapter may be relatively stable. However further research would be required with a larger population in order to confirm the findings of our study.

In the modelling process, after adjusting for baseline NPQ and intervention type, pain self efficacy (p=0.023) and catastrophising (p=0.025) significantly predicted six month

treatment outcome (see table 7.2). Both of these variables and intervention were entered into the linear model. In the final model PSE and catastrophising were no longer significant and were removed from the model. The non-responders in this study were significantly different from responders in three key areas (see section 7.3.1 above). Responders were more likely to have higher pain self efficacy, lower catastrophising scores and to have been randomised to the UP intervention. Consequently, it is possible that pain self efficacy and catastrophising may have had a more important role than the model suggested.

7.4.5 Implications for clinical practice

These predictors may assist physiotherapists and neck pain patients in their decision making processes about treatment choices, what advice to give and what the likely prognosis for treatment might be.

Those living in areas of social deprivation appear less likely to access health care (Kim et al., 2004) and more likely to discharge themselves from treatment (Watt, 1996). This study showed that neck pain patients from socially deprived areas were also less likely to benefit from physiotherapy intervention than those from more affluent areas (see section 7.4.2). Physiotherapy departments serving deprived populations are likely to have high attrition rates and poor outcome if they use traditional methods of delivering physiotherapy (see Chapter Six, section 6.3.4.3). They need to consider innovative and tageted strategies for improving access and utilisation of physiotherapy resources in order to maximise health outcomes and reduce health care waste. As previously discussed in Chapter Six, section 6.4.3, triage services focussing on a brief intervention of early advice and self management options may result in a decreased attrition rate (personal communication, Tomlinson et al., 2006).

This study indicated that fear avoidance beliefs and treatment type interacted to predict treatment outcome at six months. Neck pain sufferers with higher TSK scores tended to do better in GET, whilst those with lower scores tended to do better in UP. The transition point on the TSK score is about 39 points. As discussed in section 7.4.3, exercise may help patients confront their fears about physical activity and reverse poor behavioural performance, physical disuse, deconditioning, disability and adverse psychological. This suggests that clinicians should listen carefully for the presence of fear avoidance beliefs in patients with neck pain. The TSK could be used as a screening

tool to identify patients with high fear avoidance levels and quantify the level of fear. Those with high levels of fear avoidance beliefs need simple messages to meet their individual needs, to reinforce that hurt is not necessarily the same as harm, to encourage them to return to normal movement, activities and lifestyle as soon as possible (Waddell et al., 2004). In addition, these patients should be encouraged to participate in active rehabilitation such as GET which may help to reduce fear levels, reduce neck pain and return them to normal levels of activity and function.

7.4.6 Implications for research

This study supported the view that some groups of neck pain patients benefit from physiotherapy more than others. It also supports the view that some groups of patients benefit more from one type of intervention than another. However the baseline measures used in this study identified 30% of the variance in outcome. Therefore, further research is required to evaluate alternative variables which may also predict response to treatment.

This study demonstrates a need for more research into the influence of deprivation and fear avoidance beliefs on treatment outcome. In particular there is a need to develop and evaluate conservative management approaches which are suitable and effective for patients from deprived neighbourhoods e.g. triage services.

In this study PSE and catastrophising were not included in the final linear regression model and were therefore not reported here as predictors of six month treatment outcome. However, responders in this study were more likely to have higher pain self efficacy and lower catastrophising scores, so these variables may have had a more important role to play than our model suggests (see section 7.4.4 above). Chapter Five, section 5.5 and 5.6 also identified the growing body of evidence which suggests that PSE and catastrophising predict pain intensity, disability and outcome in a variety of a range of musculoskeletal conditions. Therefore their role as potential predictors of treatment outcome in non-specific neck pain should be investigated further.

7.5 CONCLUSIONS

This study identified several variables that predicted the outcome of physiotherapy intervention at six month follow-up. Social deprivation predicted poorer outcome compared with more affluent status. Additionally neck pain patients with low fear

avoidance beliefs were predicted to have better outcome with UP intervention. Neck pain patients with high fear avoidance beliefs were predicted to have better outcome with GET intervention. Physiotherapists managing patients with neck pain should routinely elicit negative or maladaptive beliefs and attitudes, provide relevant advice about returning to normal movements, activities and function and provide a graded exercise programme for patients identified as having above average levels of fear avoidance beliefs.

The next chapter will investigate the relationship between neck pain and upper limb disability.

CHAPTER 8

AN INVESTIGATION TO DETERMINE THE ASSOCIATION BETWEEN NECK PAIN AND UPPER LIMB DISABILITY FOR PARTICIPANTS IN THE GET UP NECK PAIN TRIAL: A SECONDARY ANALYSIS

8.1 INTRODUCTION

It is recognised that neck pain can result in symptoms being referred into the upper limbs. For example, in the presence of radiculopathy dermatomal loss and myotomal weakness in the upper limbs may occur and clinical neurological examination of the upper limb may identify specific impairments to the neurological system. Non-specific neck pain may also be associated with referral of symptoms into the upper limbs but this is often a diffuse pattern (Greening and Lynn 1998). A survey of UK patients with mechanical neck pain found that 67% presented with associated upper limb symptoms without neurological deficit (Frank et al., 2005). Referred symptoms to the arms or hands may be functionally limiting e.g. dropping things, weakness etc (Frank et al., 2005). Clinically it is common that patients with non-specific neck pain report problems with upper limb function. However it is not known what proportion of these patients report such problems. There appears to be a lack of research investigating the impact of neck pain on upper limb function. This chapter describes a secondary analysis which investigates the relationship between neck pain and upper limb disability in neck pain patients participating in the GET UP neck pain trial.

8.1.1 Aim

The aim of this study was to investigate the relationship between neck pain/ disability and upper limb disability.

8.1.2 Hypothesis

H^0 - the null hypothesis - There is no association between neck pain/disability and upper limb disability.

H^1 - the alternative hypothesis

a) There is an association between neck pain/disability and upper limb disability.

b) There is an independent association between neck pain/disability and upper limb disability, after adjusting for other potentially confounding variables.

8.2 METHODS

8.2.1 Summary of the study design

This study investigated associations between neck pain/disability and upper limb disability. Relevant data was extracted from baseline data of 151 neck pain patients who participated in the RCT reported in Chapter Six. Measures used to assess baseline neck pain/disability were the Northwick Park Neck Pain Questionnaire (NPQ) and the Quadruple Visual Analogue Scale (QVAS). The measure of baseline upper limb disability was the Disabilities of Arm, Shoulder, Hand (DASH). A range of psychological, sociodemographic and physical variables were also measured at baseline as potential confounding variables.

8.2.2 The study sample

Participants in this study were 151 neck pain patients recruited to the randomised controlled trial in Chapter Six. The sample and inclusion and exclusion criterion is described in detail in Chapter Six, section 6.2.3 to 6.2.5. The main criterion for inclusion in the study was the presence of mechanical neck pain. Patients were excluded if they had any previous traumatic injury to the affected upper limbs or shoulder girdles resulting in current or prolonged disability. They were also excluded in the case of deteriorating or serious neurology such as clear radicular signs and symptoms which required urgent intervention (see Chapter Six, section 6.2.5). It is therefore likely that the vast majority of patients in this study had simple mechanical neck pain with no clear neurological impairment. A few patients may have had relatively minor peripheral nerve injuries where there is no obvious changes of nerve function (Greening and Lynn 1998).

8.2.3 Measures

8.2.3.1 Neck pain and disability measures

Neck pain and disability was measured in two ways using The Northwick Park Neck Pain Questionnaire (NPQ)(Leak et al., 1994) and the Quadruple Visual Analogue Scale (QVAS)(Von Korff et al., 1993). Baseline scores were assessed by questionnaire during the interview phase of the recruitment process for the trial.

The NPQ (Leak et al., 1994) is a reliable and valid measure of neck pain and disability. See Chapter Four section 4.2.1 for further details.

Neck related pain status was assessed using the QVAS (Von Korff et al., 1993). The QVAS was included in the baseline assessment. Patients were asked to mark the level of pain on a scale of 0 to 10 (0= no pain; 10= worst possible pain) in four situations: 1) pain at the time of interview, 2) typical or average level pain, 3) pain at its best, and 4) pain at its worst. A QVAS score is calculated by summing the scores of (1)+(2)+(4), giving a score out of 30 and then converting to a percentage. A score of 50-100 is considered to be a high intensity, whilst <50 constitutes a low intensity score (Von Korff et al., 1993). The reliability and validity of the VAS as a pain measure was established in different populations with acute, chronic or experimentally induced pain (Seymour, 1982; Price et al., 1983; McGrath et al., 1996; Ogon et al., 1996). The QVAS has been used in several musculoskeletal related research studies (Eldridge and Russell, 2005; Krishnan et al., 2005)

8.2.3.2 Upper limb disability measure

Upper limb disability was measured by the Disabilites of Arm, Shoulder, Hand (DASH) and is described in Chapter Four, section 4.3.1.

8.2.3.3 Psychological confounding variables

Five potentially confounding psychological variables were assessed during the interview phase of the recruitment process for the trial.

- Pain Self Efficacy was assessed using the Pain Self Efficacy Questionnaire (PSEQ) and is described in detail in Chapter Five, section 5.5.
- Anxiety and Depression were measured using the Hospital Anxiety and Depression Scale (HADS). This is described in Chapter Five, section 5.7.
- Fear Avoidance Beliefs: Fear of movement, re-injury and increased pain was measured by the Tampa Scale of Kinesiophobia (TSK) and is described in detail in Chapter Five, section 5.4.
- Coping Strategies were measured using the Coping Strategies Questionairre (CSQ). This is described in detail in Chapter Five, section 5.6

8.2.3.4 Socio-demographic variables

A range of demographic information was collected including:

- Age, which was recorded in years and is discussed in Chapter Five, section 5.2.
- Gender, which was recorded dichotomously as male or female gender. Gender is discussed in greater detail in Chapter Five, section 5.3.
- Current smoking status, which was recorded dichotomously as smoker or non-smoker. Smoking is discussed in detail in Chapter Five, section 5.9.
- Material and Social Deprivation. Trial participants were allocated a Townsend material deprivation score by converting their postcodes to ward codes and then from ward codes to Townsend scores. The tables which support this process are based on data collected from Census 2001 and are available through Manchester University (http://www.mimas.ac.uk). Material and social deprivation is discussed in detail in Chapter Five, section 5.10.
- Activity Level. Patients were asked how frequently they exercised in the past three months, where the exercise caused the patient's heart rate to increase or caused them to breathe slightly harder than normal. This was recorded as, never, less than once per month, once or twice per month, once or twice per week, three or four times per week or more than four times per week. This was dichotomised as non exercisers and exercisers. Non exercisers were those that reported doing no exercise at all. Exercisers reported that they did some form of exercise that caused them to get slightly out of breath or caused their heart rate to increase at least once per month. Physical activity is discussed in detail in Chapter Five, section 5.11.

8.2.3.5 Clinical/physical variables

Clinical variables included length of current episode of neck pain (weeks), length of history of neck pain in total (weeks), sites of pain (recorded on a body chart and the total number of pain sites reported was summed for each participant).

8.2.4 Data analysis

In this study the primary data was checked for normality and linearity to test for suitability for analysis using parametric statistics. The Shapiro-Wilk test was used to test for normality and checks for linearity of association used scatterplots of the NPQ, DASH and QVAS data fitted with a smoothed curve. Where assumptions of normality and linearity were met, the hypotheses for this study were investigated using Pearson correlations for the following two comparisons: NPQ scores v DASH scores, QVAS v DASH scores. A two-tailed p value of less than 0.05 was considered statistically significant. Stepwise linear regression was used to determine the independent

association between functional neck pain and disability scores and upper limb disability (Altman, 1991). Pairwise associations between continuous baseline covariates were examined to check if any covariates were strongly correlated ($r>0.7$). If this occurred then one of the two covariates was removed from the analysis to avoid problems of multicollinearity (Tabachnick and Fidell, 2001). Predictor variables were included in the linear model if they were associated with the DASH at the $p<0.05$ level, or if they were considered to be clinically important. All significant variables were entered into the regression model at once and a stepwise regression analysis performed. Statistical tests were two-tailed and p values less than 0.05 were considered statistically significant in the final regression model.

8.3 RESULTS

8.3.1 Study population and baseline characteristics

One hundred and fifty one patients completed all three questionnaires at baseline. The average age of the participants was 53.9 (14.45) years and 60% were female. The NPQ was completed satisfactorily by all respondents and the mean NPQ score was 38.7 (15.0). The QVAS was completed correctly for all bar one patient and mean QVAS score was 60.9 (16.6). This mean pain score lies in the high intensity bracket and more than 70% of patients scored more than 50 points. The DASH was completed satisfactorily by 94% of patients (9 patients did not answer enough questions in order to calculate a valid DASH score). The mean DASH score was 31.0 (19.1). See Table 8.1 below for the baseline characteristics of the patients who entered this study.

8.3.2 Baseline data

Appendix 33 provides a breakdown of the functional upper limb tasks from the DASH and reports the breakdown of scores for each question. The functional element of the DASH consisted of 21 questions ranging from light precision tasks such as writing to heavy endurance tasks such as gardening. Generally patients found greatest difficulty with doing heavy household chores, gardening, carrying heavy objects, and recreational tasks which involved impact through the hand, or free movement of the arm such as badminton. The hardest tasks were gardening work and carrying heavy objects over 10 pounds. More than 60% of the group indicated at least moderate difficulty undertaking

Table 8.1: Baseline characteristics of the study population

	frequency	Mean (standard deviation)	Range
Age	151	53.9(14.4)	20 to 88
Gender[1] • Male • Female	 61 (40.4%) 90 (59.6%)		
Smoker[1] • Yes • No	 43 (28.7%) 107 (71.3%		
Townsend scores	150	1.5364 (4.1617)	-3.7925 to 12.5230
NPQ score	151	38.7 (15.0)	5.6 to 80.6
QVAS score	150	60.9 (16.6)	0 to 96.7
DASH score	142	31.0 (19.1)	0 to 74.2
TSK score	139	35.6 (7.4)	19 to 56
PSE score	145	37.1 (15.3)	0 to 60
Diverting attention	143	14.1 (8.6)	0 to 36
Reinterpreting pain sensation	142	9.7 (7.9)	0 to 36
Catastrophising	141	10.5 (7.3)	0 to 36
Ignoring sensations	148	16.9 (8.1)	2 to 36
Praying and hoping	141	16.8 (9.1)	0 to 36
Coping self statements	143	24.0 (6.4)	7 to 36
Increased behaviour	143	17.4 (7.4)	0 to 36
Depression	149	9.9 (2.6)	3 to 16
Anxiety	151	9.2 (1.8)	0 to 14
Length of current episode[2] (weeks, median, upper and lower quartiles)	151	32 (12,78)	1 to 1872
Total length of neck pain[2] (weeks, median, upper and lower quartiles)	150	204 (52,520)	3 to 1872
Previous history of neck pain[1] • Yes • No	 92 (61.3%) 58 (38.7%)		
Number of sites of symptoms • One • Two • Three • Four • Five	 12 (8.0%) 53 (35.3%) 34 (22.7%) 21 (14.0%) 30 (20.0%)		
Participation in exercise[1] • None • < once per month • 1-3 times per month • 1-2 times per week • 3-4 times per week • > 4 times per week	 84 (55.6%) 2 (1.3%) 5 (3.3%) 31 (20.5%) 13 (8.6%) 16 (10.6%)		

1 Categorical data is presented as frequency and percentages

2 This variable had a skewed distribution therefore the data is presented as medians and interquartile ranges

Figure 8.1 Scatterplot showing the relation between baseline NPQ scores and baseline DASH scores (r=0.799, p<0.001)

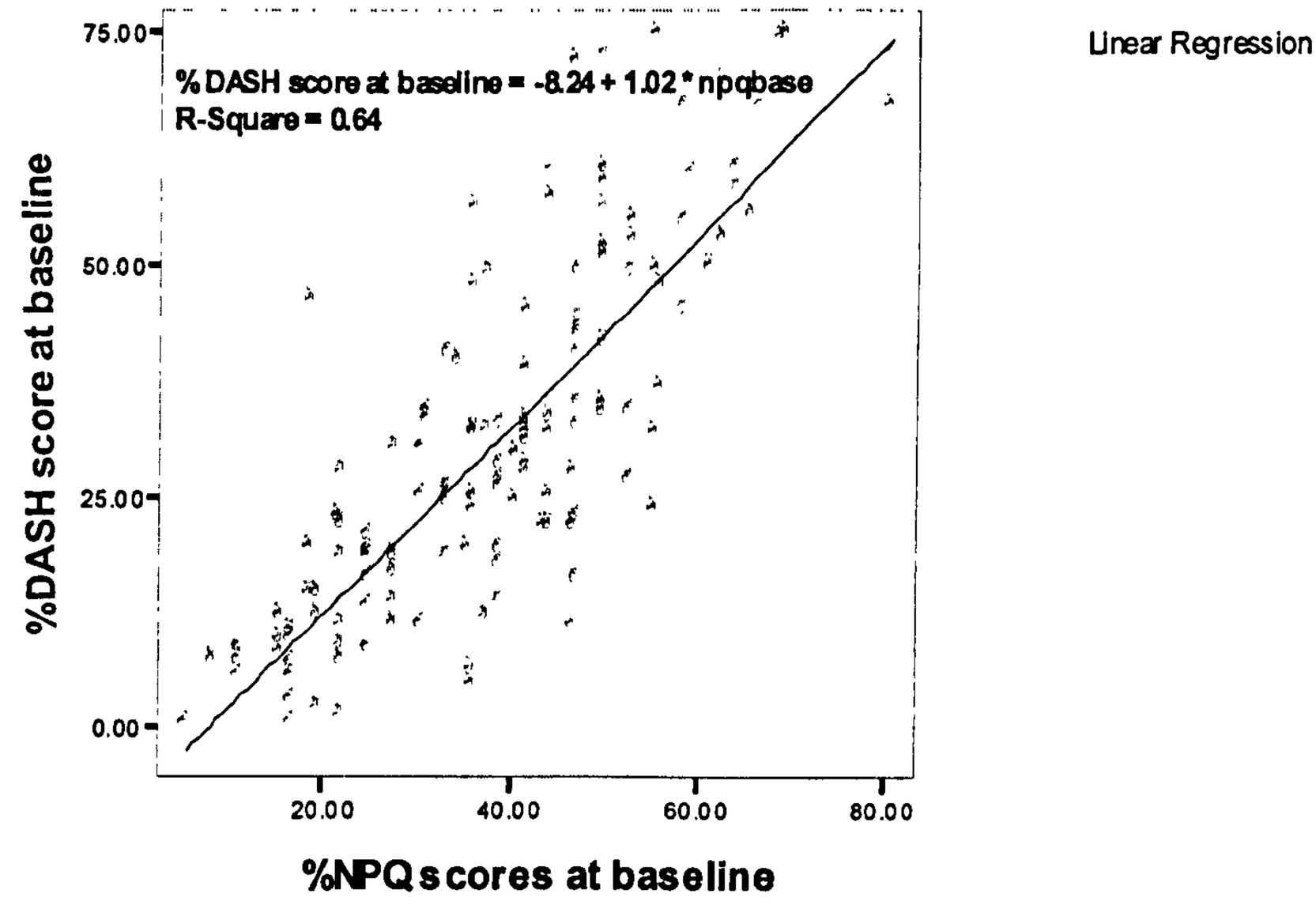


Figure 8.2 Scatterplot showing the relation between baseline QVAS scores and baseline DASH scores (r=0.481, p<0.001)

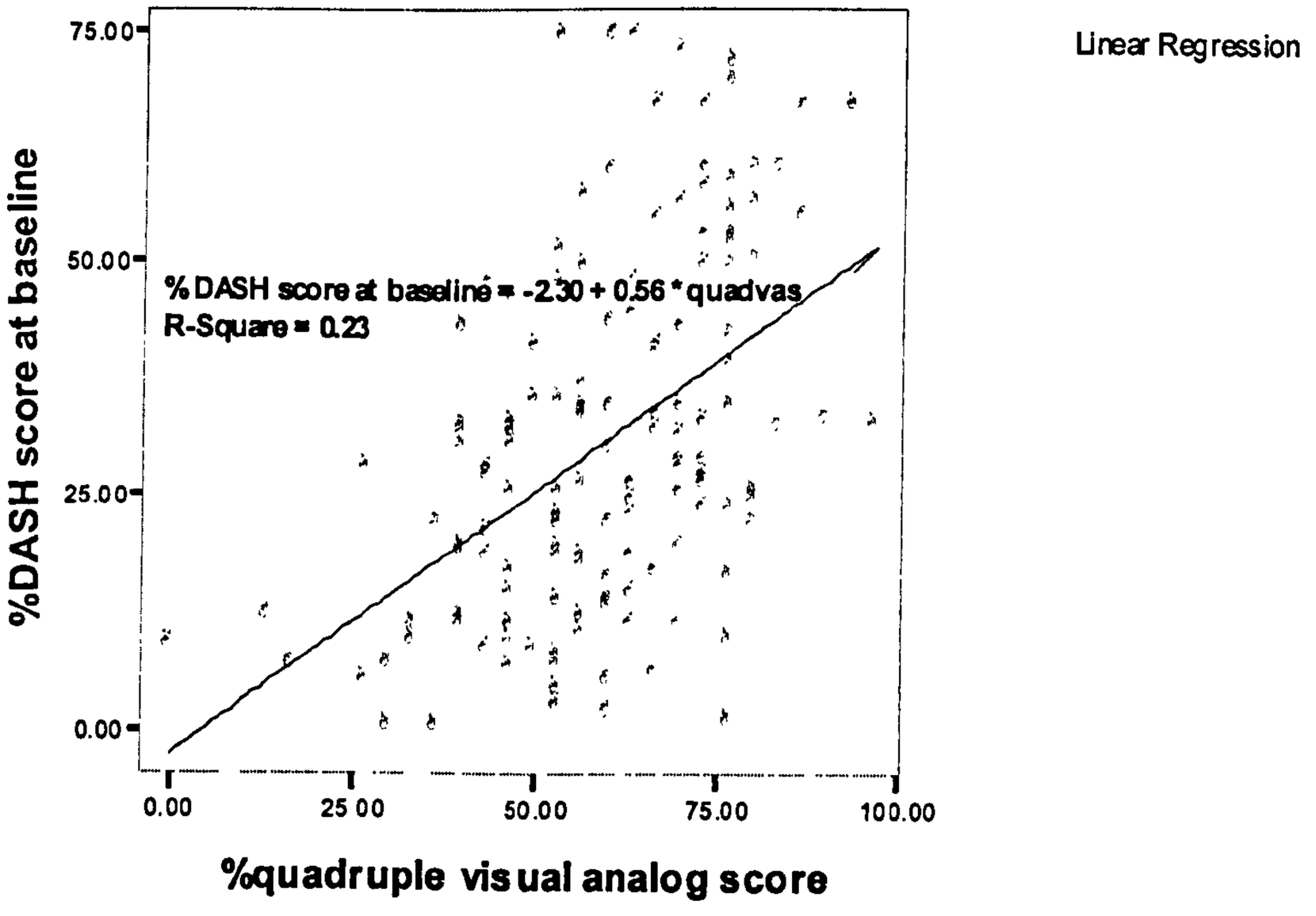


Table 8.2: Pairwise associations of predictor variables compared with the DASH

not adjusted for other variables.

Variables	Frequency[1]	DASH scores	
		Correlation coefficient	Significance level (2 tailed)
Age	142	0.117	0.167
TSK	131	0.204	0.020*
PSE	137	-0.666	<0.001*
Diverting attention	136	0.408	<0.001*
Reinterpreting pain sensation	135	0.233	0.007*
Catastrophising	135	0.367	<0.001*
Ignoring sensations	140	0.025	0.769
Praying and hoping	134	0.278	0.001*
Coping self statements	137	-0.053	0.535
Increased behaviour	136	0.222	0.009*
Depression	140	0.245	0.004*
Anxiety	142	0.104	0.220
NPQ score	142	0.799	<0.001*
QVAS score	141	0.481	<0.001*
Townsend score	141	0.089	0.293
Gender (male v female)[3]	142	t= -2.815 df=137.423	0.006*
Longer or shorter current episode[3] (<13 weeks or ≥ 13 weeks)	142	t= -2.184 df=140	0.031*
Number of sites of symptoms[3] (neck shoulder v neck shoulder arm)	141	t= -3.209 df=139	0.002*
Participation in exercise [3] (never v >1 per week)	136	t= 2.030 df=133	0.044*
Smoking[3]	141	t= 2.387 df=139	0.018*

1. no of patients who provided satisfactory variable data for comparison with DASH scores
2. Correlation coefficients are calculated using Pearsons's r for the continuous predictive variables
3. t values are calculated using independent samples t test for dichotomous categorical variables
4. * significant at p<0.05

these tasks because of their neck pain. Generally patients had least difficulty with writing, turning a key, preparing a meal and using a knife to cut food.

8.3.3 Results

Tests for normality and linearity revealed that the NPQ, DASH and QVAS data were normally distributed and pairwise associations appeared linear. Tests of associations were conducted and the results of scatterplot analysis and Pearson correlations are shown at figures 8.1 and 8.2 above. Figure 8.1 shows that baseline NPQ scores and baseline DASH scores were significantly and highly correlated with one another

(Pearsons' r=0.799, p<0.001 (2 tailed), n=142). Figure 8.2 shows that baseline QVAS scores and baseline DASH scores were significantly and moderately correlated with one another (Pearsons' r=0.481, p<0.001 (2 tailed), n=141).

Table 8.2 above shows the results of pairwise associations of the predictor variables compared with DASH scores and identifies those which are significantly correlated with the DASH. There were no other strong correlations between the other covariates. See Appendix 34 for the pairwise associations between covariates.

Table 8.3 General linear model fitted to baseline DASH score

	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	20.502	6.080		3.372	p=0.001
NPQ scores at baseline	0.743	0.088	0.571	8.471	p<0.001
PSEQ score at baseline	-0.489	0.089	-0.368	-5.468	p<0.001

a. Dependent Variable: %DASH score at baseline
(R^2=0.713; $F_{(2,98)}$=121.970, p<0.001, stepwise regression)

The variables which were significantly associated with DASH were entered into the regression model. These were TSK, PSE, diverting attention, reinterpreting pain sensation, catastrophising, praying and hoping, increased behaviour, depression, NPQ, QVAS, gender, longer or shorter current episode, number of sites of symptoms, participation in exercise and smoking. The following variables demonstrated no significant predictive ability in this regression model: TSK, diverting attention, reinterpreting pain sensation, catastrophising, praying and hoping, increased behaviour, depression, QVAS, gender, length of current episode, number of sites of symptoms, participation in exercise and smoking. The final regression model is shown at Table 8.3. This shows that NPQ score and PSE scores independently and significantly contributed to the prediction of DASH scores {R^2=0.713; $F_{(2,98)}$=121.970, p<0.001, stepwise regression}. DASH score was predicted by the following equation:

DASH score = 20.502 + 0.743*Baseline NPQ - 0.489*PSEQ

This model indicated that higher DASH scores were predicted by higher NPQ scores such that increasing neck pain and disability predicted increasing upper limb disability. Those patients with lower PSEQ scores were predicted to have higher DASH scores than those with higher PSEQ scores. Lower PSEQ scores equate to lower levels of pain self efficacy or reduced belief in ones ability to cope in spite of pain. Together these predictor variables combined to account for approximately 70% of the variance of baseline DASH scores (R^2). The scatterplot of standardised residuals against standardised predicted scores shows no obvious pattern. An analysis of residuals is shown at Appendix 35. The cumulative normal probability plot shows that the points lie along a straight line. This confirms that the assumptions of linearity and homogeneity of variance have been met. The full stepwise regression analysis is shown at Appendix 35.

8.4 DISCUSSION

This study demonstrated a strong positive pairwise correlation between baseline NPQ scores and baseline DASH scores. In addition, linear regression suggested that the severity of upper limb disability was predicted by two main factors; higher NPQ scores and lower PSEQ scores. Higher NPQ scores indicated increasing levels of neck pain and disability. Lower PSEQ scores indicated that a patient had low belief in their ability to accomplish a range of activities despite their pain. These two factors predicted more than two thirds of the variance of upper limb disability experienced by neck pain sufferers.

8.4.1 Neck pain and upper limb disability

No previous research has been found supporting the presence of upper limb disability in neck pain patients, although clinically this phenomenon is common. The findings from this study confirmed that patients reporting severe neck pain were likely to have high levels of upper limb disability. Whilst this analysis does not support conclusions about causality, it is clear that there is a strong relationship between the presence of neck pain and the presence of upper limb disability. The main criterion for inclusion in the study was the presence of mechanical neck pain. Patients were excluded if they had any previous traumatic injury to the affected upper limbs or shoulder girdles resulting in current or prolonged disability. They were also excluded in the case of deteriorating or serious neurology such as clear radicular signs which required urgent intervention (see Chapter Six, section 6.2.5). It is possible that the findings of upper limb disability in

this group were a consequence of neck pain. The mechanisms that bring these two variables together are not understood, but three hypotheses are discussed. These mechanisms are related to mechanical loading, minor peripheral nerve damage and deconditioning.

Firstly, the upper limb is mechanically connected to the neck and shoulder girdle via skeletal and muscular structures. Mechanical loading of the upper limbs may cause neck pain as a direct consequence of increasing the mechanical loading to the articular and ligamentous structures of the neck or by creating protective muscle spasm (Gorski and Schwarz, 2003). This may inhibit patients from using their upper limbs.

Secondly, the upper limb is further mechanically attached to the neck via the brachial plexus which extends from the neck into the upper limb. Chronic upper limb problems following obvious nerve injury e.g. cervical radiculopathy, present few diagnostic difficulties, however recent studies suggest that diffuse painful symptoms in the limbs may result from relatively minor nerve injuries where there is no obvious changes of nerve function (Greening and Lynn 1998). Neurogenic neck pain may result in the presence of inflammation and increased neural mechanosensitivity within and around the connective tissue structure of the cervical nerve roots (Greening et al., 2005). Upper limb function results in sliding or elongation of neural structures throughout the brachial plexus including the neck (Butler, 2000; Dilley et al., 2003). Elongation of inflamed and sensitive neural structures at the neck may to lead to a neck pain response (Hall and Quintner, 1996; Butler, 2000) possibly resulting in reluctance of these patients to use their upper limbs.

Finally, if patients feel discouraged from using their upper limbs because of a direct mechanical pain response this may result in physical deconditioning which may lead to loss of cardiovascular capacity and strength and endurance of muscles (Smeets et al; 2006). In the GET UP neck pain trial the main tasks that patients reported problems with were heavy household chores, gardening, carrying heavy objects, and recreational tasks which involved impact through the hand such as hammering, or free movement of the arm such as badminton, tasks which require strength and endurance. There is evidence that neck pain leads to decreased neck muscle stabilising, strength and endurance capacity (Jull, 2000; Ylinen et al., 2004; Lee et al., 2005). There is little

evidence to support the view that neck pain leads to reduced cardiovascular function or upper limb strength/ endurance. This study did not seek to quantify these factors.

8.4.2 Pain self-efficacy and upper limb disability

Until now no research has been found investigating the mediating effect of PSE in the relationship between neck pain and upper limb disability. Generally there is little evidence investigating the effect of self-efficacy in a neck pain population. In a range of other chronic musculoskeletal conditions PSE has been shown to be an important predictor of pain behaviours and disability (Buescher et al., 1991; Buckelew et al., 1994; Estlander et al., 1994; Lacker et al., 1996; Levin et al., 1996; Arnstein et al., 1999; Strahl et al., 2000; Ayre and Tyson, 2001; Denison et al., 2004). In the PSE model, a person who believes that they can cope with pain is more likely to engage in painful activities, work harder and persevere with tasks in the presence of pain (Levin et al., 1996; Ayre and Tyson 2001). Conversely those with low levels of PSE are more likely to avoid painful tasks or to give up on tasks when faced with the possibility of pain. It follows that people with lower levels of PSE, who avoid potentially painful functional activities, may be more likely to report higher levels of upper limb disability than those with higher levels of PSE.

8.4.3 Limitations of this research

Patients with potentially serious or urgent neck pain were not included in this trial. They were seen as urgent cases in the physiotherapy departments or referred to other health professionals. Patients referred to neurosurgical, orthopaedic or chronic pain management clinics were not included. These patients would be expected to have more severe and disabling neck pain and upper limb disability e.g. cervical radiculopathy, intransigent longstanding disabling neck pain. This study would have benefited from the inclusion of these patients.

This study utilised 16 baseline predictor variables and found two which independently and significantly predicted baseline upper limb dysfunction in patient with neck pain. Although these variables explained more than two thirds of the variance of upper limb disability, there were a range of other potential psychological, clinical, sociodemographic and physical factors which were not utilised which may have provided an improved model.

8.4.4 Implications for clinical practice

The patients in this group reported high intensity levels of neck pain as measured by the QVAS (see Table 8.1). Those patients with high severity of neck pain should be tested for the presence of upper limb disability. Early encouragement of pain relieving measures such as medication, heat or ice may be a simple way to control pain and encourage people to return to normal activities as soon as possible. This is in line with the messages from the Neck Book (Waddell et al., 2004) which provides evidence based recommendations for dealing with neck pain.

This research demonstrated that higher levels of baseline NPQ and lower levels of PSE predicted higher levels of upper limb disability. Clinically, the presence of these predictor variables should direct clinicians towards a careful examination of upper limb function in patients presenting with neck pain. Simple questions such as "How confident are you that can cope with your pain in most situations" or "How confident are you that you can gradually become more active, despite the pain?" may be a way to elicit tendencies towards low self efficacy. The PSEQ could be used as a screening tool to identify patients with low levels of self efficacy. Those patients with low pain self efficacy should be tested for the presence of upper limb disability.

In patients who indicate that there may be potential upper limb disability the DASH should be used to quantify upper limb disability. There is no known clinical objective measure of upper limb disability validated for use in this population of patients. Simple screening of shoulder range of motion may not be sufficient to rule out upper limb disability, since range of motion is often not conclusively correlated with disability (Olson et al., 2000; Poitras et al., 2000; Kwak et al., 2005). A more robust measure of upper limb function is required. For example a single arm military press with a 3kg weight repeated over 30 seconds can be used clinically to differentiate problems with overhead activities. Although this test has not yet been validated, it does seem to be useful in a clinical setting. Further research in this area would be useful.

The most effective strategy for managing upper limb disability associated with neck pain is not clear, since Chapter Six showed that neither GET nor UP was effective at reducing upper limb disability. However managing upper limb disability in this group of patients may be important since the presence of shoulder problems has been identified as a strong prognostic factor for the progression of non specific neck pain (see

Chapter Two, section 2.3.5). It is possible that identifying and managing upper limb disability may be an important strategy for preventing neck pain in the first place and for minimising the impact of neck pain over the longer term. An extended period of upper limb rehabilitation may be effective however this hypothesis would require further validation.

8.4.5 Implications for research

This study represents a preliminary investigation into the relationship between neck pain and upper limb disability and further research in this area is warranted. Research that encompasses a wide spectrum of neck pain patients attending orthopaedic, neurosurgical or pain management clinics would be useful to gain an appreciation of the impact of neck pain on upper limb function in the widest range of neck pain patients. Chapter Six suggested that neither GET nor UP was effective at reducing upper limb disability, so further research looking at effective conservative interventions for reducing upper limb disability in this group of patients is required. Validation studies of the single arm military press could produce a useful, practical assessment tool and clinical outcome measure for neck pain patients.

8.5 CONCLUSIONS

The results of this study demonstrated that for neck pain patients the severity of upper limb disability was independently predicted by two main factors: higher NPQ score and lower PSE score. These factors predicted more than two thirds of the variance of upper limb disability experienced by neck pain sufferers. Clinically the presence of one of these predictors variables should direct clinicians towards a careful examination of upper limb function in patients presenting with neck pain. Neck dysfunction and associated upper limb disability is an area that is poorly understood and warrants further much needed research.

The next chapter will summarise this thesis, discuss the main findings and draw overall conclusions and implications regarding those findings.

CHAPTER 9

DISCUSSION & CONCLUSIONS

9.1 INTRODUCTION

This thesis was concerned with evaluating physiotherapy management for patients with non-specific neck pain and a range of psychological, sociodemographic and clinical variables. Two approaches to physiotherapy, namely a group based graded exercise treatment (GET) and one-to-one usual physiotherapy (UP) were compared for effectiveness. Very little research has been conducted on either approach in relation to the conservative management of neck pain. Neck pain is highly prevalent and will affect more than two thirds of the population at some point in their lives (Makela et al., 1991; Cote et al., 1998). Approximately 5% of a general population reported severely disabling neck pain (Cote et al., 1998). In the UK the cost of neck pain has not been calculated but, based on findings in other European countries, the socioeconomic cost is assumed to be high for individuals, industry and society. Given the potential impact and the relative lack of information regarding non-specific neck pain, research in this field has become more highly prioritised (Chartered Society of Physiotherapy, 2002). The GET UP neck pain trial was conducted to meet this challenge, to increase the understanding of neck pain and to facilitate improvement in conservative management of neck pain.

9.2 SUMMARY OF THE THESIS METHODOLOGY

The findings and conclusions reached in this thesis were reported through four critical reviews and three scientific studies. In addition to one systematic review, three further comprehensive reviews of the literature were undertaken. This evidence from reviews was used to inform the development and conduct of the three scientific studies comprising the primary research component of this thesis. The first study was an RCT comparing GET with UP for patients with neck pain (GET UP neck pain trial). The second study investigated a range of patient psychological, socio-demographic and physical variables to establish whether any of the variables predicted outcome following treatment in the GET UP neck trial. The final study investigated the relationship between neck pain and upper limb disability for the participants in the GET UP neck pain trial.

9.3 FINDINGS OF THIS THESIS

9.3.1 Findings from the literature reviews.

Four separate areas of evidence were reviewed and presented in Chapters Two to Five. These investigated firstly, prognostic factors for the progression of non-specific neck pain in general populations; secondly, the conservative management of non-specific neck pain; thirdly, outcome measures for the assessment of neck pain/disability and upper limb disability and; finally, patient variables that potentially predicted outcome following treatment of neck pain.

Chapter Two reported the findings of a systematic review of prognostic factors for the progression of non-specific neck pain to chronic, persistent or recurrent neck pain in general populations. The overall findings revealed that research had identified very few clinically relevant prognostic factors. This was mainly due to a lack of high quality research investigating the predictive nature of potentially relevant variables. Strong evidence was found to link older age, longer duration of the current episode of neck pain, history of neck, shoulder or other musculoskeletal disorders to unfavourable outcome (see section 2.3.5). There was strong evidence that participating in physical exercise was protective and this may be important information in the clinical setting (see section 2.3.5). Thus encouraging patients with neck pain to remain as physically active as possible may improve or mitigate the progression of their neck pain. These findings were used to inform the choice of potentially predictive variables reviewed in Chapter Five and utilised in the study in Chapter Seven.

Chapter Three reviewed the conservative management of non-specific neck pain. Again, little good quality research was found. The provision of advice and education is central to the role of the physiotherapist and other health professionals and yet there is little evidence investigating this role (see section 3.3). The majority of passive interventions e.g. massage, physical modalities, acupuncture and traction had little support from research. At best these modalities may be most effectively employed either in combination with each other, or in combination with other forms of treatment such as exercise as part of a multimodal package of treatment. Given the possibility that passive treatments may lead to patient passivity, inactivity and disability behaviour these modalities are not recommended as the sole means of treating patients with neck pain (see section 3.4). Of all the conservative management options, active interventions based on exercise appeared to have the strongest evidence base for the treatment of

chronic neck pain. However, this evidence was not completely consistent and active interventions were not necessarily superior to other conservative treatments. General neck and upper limb endurance training or dynamic strengthening programmes, cervical stabilisation exercises and proprioceptive exercise approaches appeared to be the most favourable exercise options. Multimodal treatment that incorporated exercise in combination with other forms of treatment such as manipulation or mobilisation was also effective. There was a lack of research into the effectiveness of usual multimodal physiotherapy compared with a comprehensive exercise based approach for the treatment of neck pain (see section 3.5). The findings from this review were used to develop and inform the protocol for the RCT described in Chapter Six.

Chapter Four reviewed outcome measures for neck pain disability and upper limb disability. The primary outcome measure selected for neck pain and disability was the Northwick Park Neck Pain Questionnaire (NPQ)(see section 4.2.1). The secondary outcome measure for upper limb disability was the Disabilities of Arm, Shoulder, Hand (DASH) (see section 4.3.1). These were used in the RCT described in Chapter Six. Upper limb disability was used as a predictor variable for the study in Chapter Seven.

Chapter Five reviewed variables that potentially predicted outcome following treatment of neck pain. The variables reviewed were: age, gender, fear avoidance beliefs, pain self efficacy, coping strategies, anxiety, depression, upper limb disability, current smoking status, deprivation and physical activity. All the variables selected predicted outcome for a range of musculoskeletal conditions. None had evidence of being predictive of outcome following conservative treatment for neck pain.

9.3.2 Research findings

This thesis assessed the effectiveness of two different physiotherapy approaches to treatment of neck pain; namely GET and UP.

In Chapter Six, the GET UP neck pain trial demonstrated that UP and GET both reduced neck related pain and disability at six months follow-up (see section 6.3.3). There was no significant difference in pain and function at six weeks or six months between patients receiving GET and those receiving UP. Both intervention reduced NPQ scores by a clinically important amount i.e 5%; UP reduced NPQ scores by 7% and GET by 5%. GET had a higher attrition rate than UP, but those who completed

treatment as per protocol derived reduction in neck pain and disability comparable with those receiving UP. Neither intervention improved upper limb disability. Both approaches are appropriate for the management of neck pain. GET should not be considered a straightforward rehabilitation strategy for neck pain, since there are many organisational, physiotherapist and patient variables which may influence the effectiveness of the approach. Adherence issues, particularly for GET, must be addressed since evidence suggests that adhering to an exercise programme improves pain and function in many musculoskeletal conditions. Clinicians need to consider how best to employ exercise rehabilitation for the maximum benefit of their patients.

In Chapter Seven, secondary analysis of the GET UP neck pain trial tested whether baseline psychological, socio-demographic or physical variables predicted outcome at six months for patients receiving one or other of the interventions. After adjusting for baseline NPQ score and intervention type, general linear modelling identified two significant predictors of outcome for patients with neck pain (see section 7.3.3). Regardless of intervention type, increasing social and material deprivation predicted poorer six month outcome. In addition TSK score and intervention received interacted to predict six month outcome. Those neck pain patients with high fear avoidance beliefs were predicted to have better six month outcome with GET. Those with low fear avoidance beliefs were predicted to have better six month outcome with UP. These two variables explained approximately 30% of the variance in outcome at six months.

Chapter Eight explored the relationship between neck pain and upper limb disability. Pairwise analysis revealed a strong, positive correlation between NPQ scores and DASH scores. Linear regression showed that the severity of upper limb disability was predicted by two baseline variables: higher NPQ scores and lower PSE scores (see section 8.3.3). Higher NPQ scores indicated increased levels of neck pain disability. Lower PSE scores indicated that patients had low belief in their ability to accomplish a range of activities despite their pain. These two factors predicted 70% of the variance of baseline DASH scores.

9.4 STRENGTHS OF THE STUDY

The GET UP neck pain trial was designed, conducted, analysed and interpreted according to the recommendations of the CONSORT statement (Moher et al., 2001). The GET UP neck pain trial achieved its recruitment target of 150 patients and had a

reasonably good follow-up rate (77.5% at six months). Outcomes were self assessed validated questionnaires collected by post, eliminating the possibility of therapist or assessor bias. Statistical analysis was by intention to treat, although imputation of missing data was not undertaken. The use of broad inclusion criteria were used to try to ensure that trial participants were representative of the non-specific neck pain patients referred to the physiotherapy departments involved with this trial. It could also be considered strength that the study sample was drawn from more deprived areas than the average population in the UK. The findings of the GET UP neck pain trial are an important contribution to the evidence regarding the effect of deprivation on health outcome, since findings of health based RCTs are least likely to emerge from or apply to areas of socioeconomic deprivation (Watts, 1996).

9.5 LIMITATIONS OF THE STUDY

A large number of patients in the GET UP neck pain trial did not complete treatment as per protocol. They either failed to attend for treatment or failed to complete treatment. Further analysis suggested that these patients were significantly younger and came from significantly more deprived neighbourhoods than those who completed treatment. Younger age may indicate that family, work or lifestyle commitments do not fit with the conventional appointment times within physiotherapy departments or an exercise class. In deprived populations, use of health resources, adherence to treatment and non-response in trials are acknowledged problems (Urwin et al., 1998; Kim et al., 2004; Self et al., 2005). These are issues which affect all health professionals and researchers.

The drop-out rate from the GET group was greater than that for UP. This is a recognised problem for exercise groups (Crook et al., 1998; Campbell et al., 2001). The GET UP neck pain trial demonstrated that the majority of patients did not participate in any form of exercise (see Table 6.1). This may simply reflect national statistics which show that the majority of the UK population do not engage in exercise (Department of Health, 1998). Alternatively, it may reflect the fact that the patients in the GET UP neck pain trial were drawn from a number of areas where material and social deprivation is high. Motivation to exercise and adherence to exercise treatments in this generally deprived population may have been low. In addition, many barriers for this patient group may have existed such as poor education, poor history of exercise, perceived poor health, social support, transport issues, work issues (see Chapter 6.4.2). This may explain, at least in part, the rather modest changes seen in the NPQ scores,

especially for GET patients. Future studies which hope to conduct further research in socially deprived populations may need to consider how best to enhance treatment adherence and minimise drop-out rates. In addition, physiotherapists involved in exercise based rehabilitation need to be trained to deal with a range of issues such as adherence, motivation, fear of exercising, patients beliefs and attitudes about exercise and their neck pain in order to achieve optimal outcomes for their patients.

The participants in GET were asked to attend between six and 12 sessions of treatment. This may not have been sufficient in order to obtain an optimal change in pain or function for the patients participating in GET. It is possible that a three month programme of exercise may have been more effective (see Chapter Six, section 6.4.2). However, adherence to treatment in a longer programme might also have been worse, especially since the patients in the trial were generally drawn from a socially deprived population.

Every attempt was made to ensure that the patient sample was representative of the population, however this may not be the case. Firstly, patients on the waiting list of participating physiotherapy departments who required urgent treatment were not included in the trial. Secondly, patients referred to orthopaedic, neurosurgical or pain management clinics were not included. Potentially this group of patients may have higher than average levels of pain and disability. Thirdly, the average Townsend score of 1.5364 (4.1617) indicated that the study population was drawn from mainly deprived areas. In this study deprivation has been shown to predict treatment outcome (see Chapter Seven, section 7.4.2). Therefore the findings from this study may not be generalisable to affluent regions of the country or specific groups of patients.

This research has looked at the predictive role of a limited number of variables. The variables were selected because, in the absence of neck pain research, evidence suggested they may predict outcome in a range of other musculoskeletal conditions. Many other potentially predictive variables were not used and warrant further investigation.

9.6 IMPLICATIONS OF THE STUDY FOR CLINICAL PRACTICE

This thesis provided evidence that UP was effective for the management of neck pain (see Chapter Six). GET was effective for patients who completed treatment. However, this should be qualified by the fact that neck pain patients from more socially deprived areas were likely to have poorer outcome at six month follow-up, regardless of treatment allocation. In addition patients with high levels of fear avoidance beliefs experienced greater benefits from participating in GET. Those with low levels of fear avoidance beliefs gained greater benefits from participating in UP (see Chapter Seven). This reinforces the need for neck and upper limb rehabilitation in particular groups of patients and should be available in physiotherapy departments. Exercise based approaches such as GET should be promoted and encouraged for neck patients who display high levels of fear avoidance beliefs. However, the role of exercise programmes should be carefully explained to patients and gently integrated into the management plan since adherence to exercise regimes appears to be low. This was the case in the GET UP neck pain trial and is true for the national population as a whole, particularly in the older and female populations. Neck and upper limb exercise strategies should take into account each individuals barriers to exercising and their lifestyle commitments. Some patients may wish to attend the physiotherapy department (for class or individual sessions) and have regular support and encouragement. Some may be happy to undertake a programme of rehabilitation in a gym setting, some may prefer to do a few selected exercises at home or in the work place, others may not be prepared to do exercise at all. It seems likely that discussing the different options with the patient and agreeing the choice of rehabilitation approach is best done through a usual physiotherapy setting. Exercise rehabilitation is complex and physiotherapists involved in exercise based rehabilitation need to be trained to deal with a range of psychosocial issues in order to achieve optimal outcomes for their patients.

Chapter Eight provided evidence that those reporting higher levels of neck pain disability and lower levels of pain self efficacy were more likely to report higher levels of upper limb disability. The presence of these predictor variables should direct clinicians to a careful examination of upper limb function. Methods of clinically quantifying upper limb disability are limited. The DASH is a suitable patient completed questionnaire which should be used for patients with suspected upper limb disability. There are no known clinical objective measures of upper limb disability which are validated for use in the neck pain population. The single arm military press described in

Chapter Eight, section 8.4.4 may be a useful clinical test. Validation of this test is required.

Overall, this research has shown that management of neck pain is a complex process which requires commitment from the patient. It also demonstrated that physiotherapists need to be aware of a range of psychosocial variables which may influence patients ability to engage with treatment. Physiotherapists should be able to identify potential barriers to good treatment outcome, discuss these barriers with the patient and encourage and help patients to overcome them.

9.7 SUGGESTIONS FOR FUTURE RESEARCH

More research into prognostic factors for the progression of neck pain is required since relatively few clinically relevant variables have been investigated for their predictive ability. The identification of factors that predispose individuals to develop progressive neck problems may suggest strategies for secondary prevention. Clinicians treating patients with neck pain might be able to address or reduce the impact of those factors that increase the risk of developing recurrent, persistent or disabling problems. In addition further research is required in relation to factors which predict outcome following treatment. This could help clinicians guide their treatment of patients in a particular direction or avoid treatments that may be detrimental to a certain individuals.

There is little research investigating methods of improving adherence with physiotherapy interventions and this is an important avenue for research since participating in physical activity (see Chapter Two, section 2.3.5) and adherence with treatment (see Chapter Six, section 6.4.2) is linked to outcome. In particular the identification of innovative and targeted strategies which increase treatment adherence in socially deprived populations is an important area for research, especially in light of the Government's current agenda to decrease health inequalities (Department of Health 2006).

The relationship between neck dysfunction and upper limb disability is largely intuitive. However, secondary analysis of the GET UP neck pain trial provided preliminary evidence that high baseline neck pain and low PSE predicted upper limb disability in patients with neck pain. The physiological, mechanical and psychological mechanisms

which mediate this relationship are generally very poorly understood. Further research in these areas are warranted.

Further research is required to validate an appropriate clinical test for assessing upper limb function e.g. a single arm military press. This could provide a useful tool to help clinicians identify neck pain patients with upper limb disability.

9.8 CONCLUSIONS

The GET UP neck pain trial investigated the effectiveness of two physiotherapy approaches to the management of neck pain. UP was effective at reducing neck pain and disability at six month follow-up. GET was effective for a subgroup of patients. Several patient baseline variables predicted outcome six months after intervention. Regardless of intervention and after adjusting for baseline neck pain and disability, high levels of deprivation predicted poor outcome at six month follow-up. In addition there was an interaction between fear avoidance beliefs and intervention type. Consequently, neck pain patients with high fear avoidance beliefs were predicted to benefit from GET and those with lower fear avoidance beliefs were predicted to benefit from UP. Finally a strong relationship existed between neck dysfunction and upper limb disability. This relationship was mediated by PSE. Consequently higher levels of upper limb disability were associated with higher severity of baseline neck dysfunction and lower levels of PSE.

This research identified the existence of relatively little high quality evidence relating to the development, progression and management of non-specific neck pain. This thesis provided evidence of the usefulness of both UP and GET in physiotherapy practice, of factors that predicted outcome following treatment and of the relationship between neck pain and upper limb disability. It is clear that much research in these areas is still required.

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Quality assessment tool for studies on prognostic factors in patients with non-specific neck pain. (adapted from Scholten-Peeters et al, 2003)

Quality Criteria		Score
Study population		
A	Inception cohort	+/ - / ?
B1	Description of source population	+/ - / ?
B2	Size of the cohort	+/ - / ?
C	Description of relevant inclusion and exclusion criteria	+/ - / ?
Follow-up		
D	Follow-up at least 12 months	+/ - / ?
E	Drop-outs/loss to follow-up < 20%	+/ - / ?
F	Information completers versus loss to follow-up/drop-outs	+/ - / ?
G	Prospective data collection	+/ - / ?
Treatment		
H	Treatment in cohort is fully described/standardized	+/ - / ?
Prognostic factors		
I	Clinically relevant potential prognostic factors	+/ - / ?
J	Standardized or valid measurements	+/ - / ?
K	Data presentation of most important prognostic factors	+/ - / ?
Outcome		
L	Clinically relevant outcome measures	+/ - / ?
M	Standardized or valid measurements	+/ - / ?
N	Data presentation of most important outcome measures	+/ - / ?
Analysis		
O	Appropriate univariate crude estimates	+/ - / ?
P	Appropriate multivariate analysis techniques	+/ - / ?

[+ = positive (design or conduct adequate); - = negative (design or conduct inadequate); ? = unclear (item insufficiently described)]

Assessment standards for the quality of studies investigating prognostic factors for non-specific neck pain

Criteria

Study population

A A reliable prognostic study requires a well defined inception cohort at the same stage of the disease

- Positive if patients were identified at an early (3 weeks) uniform point (inception cohort) in the course of their neck complaints (e.g. first point at which symptoms were first noticed after trauma or first consultation at general practice or emergency room or first presentation of a claim). Also positive in case of a heterogeneous population (survival cohort) for which sub-groups of neck pain patients were identified and analysed - examples of sub-groups include: neck pain / no neck pain; chronic neck pain / acute neck pain etc. In studies in which more than 60% of the sample was interviewed within 3 weeks of onset, this criterion was deemed fulfilled (Pincus et al, 2002).
- Also positive if the inception cohort is a group of asymptomatic population or has been pain-free for at least 1 year (Pincus et al (2002).
- Negative if the inception cohort is not well defined as above
- Don't know' if it is not clear if an inception cohort was used.

B1
- Positive if the source population was described in terms of place of recruitment (e.g. Amsterdam, The Netherlands etc), time-period of recruitment and sampling frame of source population (e.g. primary care, secondary care departments, insurance companies, occupational groups, general population, etc).
- Negative if ≤ 2 features of the source population are given.

B2
- Positive if sample size is ≥ 300.
- Negative if sample size is < 300

C Inclusion and exclusion criterion for the inception cohort should be well described for subjects in the inception cohort.

- Positive if at least 3 inclusion and exclusion criteria were formulated, examples below:

1) Sociodemographic status (eg age/adult , gender, occupation etc)
2) Non-specific neck complaints which may include upper limb symptoms or neck pain free (fractures, dislocation, disc herniation, previous neck surgery or whiplash are excluded).
3) Exclusion of well defined relevant co morbidity (e.g. systemic diseases, osteoporosis, inflammatory disorders history of psychiatric disorders, etc)
4) Duration of complaint or time since accident or asymptomatic
5) Type of complaints after trauma (headache, neck pain or disabilities in daily life activities).

---

	6) Other practical exclusion criteria (e.g. illiteracy, transport problems etc) • Negative if ≤ 2 criteria were formulated.
Follow-up	
D	• Positive if the follow-up period was at least 12 months and data was provided for this moment in time.
E	• Positive if total number of drop-outs/loss to follow-up ≤ 20% at 12 months. • A drop-out rate of 20% is particularly difficult to achieve. Positive for studies with higher drop-out rates if comparisons of baseline variables did not reveal statistically significant (or substantial) differences between those subjects who completed the study and those who did not. (Pincus et al, 2002) • Negative if this figure is greater than 20% unless comparative data suggests that reponders and non-responders are similar. (see above) • Don't know if it is not possible to calculate this figure.
F	• Positive if sociodemographic/clinical information (e.g. age, sex, type of complaints/ disabilities/ participation problems or prognostic factors) was presented for completers and those loss to follow-up/drop-outs at baseline, or no drop-outs/loss to follow-up.
G	• Positive if a prospective design was used. • Also positive in case of a historical cohort when the determinants (prognostic factors) are measured before the outcome was determined. • 'Don't know' if a historical cohort is used, considering prognostic factors at time zero which are not related to the primary research question for which the cohort is created
Treatment	
H	• Positive if in case of treatment subsequent to inclusion into cohort, treatment is fully described and standardised. Also positive in case of no treatment given or if multi-variate correction for treatment is performed in analysis. • Negative if different treatment regimens are used or it is not clear how outcome is influenced by it. • Don't know if it is not clear whether any treatment is given or if it is not clear that the cohort has been treated in a standardised way.
Prognostic factors	
I	• Positive if the report describes beside the socio-demographic factors (age and gender) at least one other factor of the following at baseline: 1) Neck factors (e.g. severity of pain, cervical range of motion, duration of

	complaints, localization of complaints, concentration problems, dizziness) 2) Physical factors (e.g. exercise, work postures and activities, vibration etc) 3) Psychological factors (e.g. anxiety, depression, fear avoidance beliefs, self efficacy) 4) Pre-existing factors (e.g. cervical degeneration, pre-existing headache of neck pain) 5) Insurance system related factors (e.g. financial compensation, litigation) 6) Sociodemographic factors (e.g. employment status, occupation, co-morbidity, work satisfaction, life events)
J	• Positive if at least one of the factors of I above, excluding age and gender, are reported in a well used standardized or valid way (for example by means of a questionnaire, a diary, an objective measurement [e.g. CROM, police report or patient-status]). The instruments used in these studies should have been developed or re-validated for use in the neck pain population, or in patients with physical illness in general (Pincus et al, 2002)
K	• Positive if frequencies, or percentages or mean (and standard deviation/CI), or median (and Inter Quartile Range/ CI) are reported for the three most important prognostic factors of i) namely age, gender and at least one other factor, for the most important follow-up measurements. • Negative, unless there is sufficient raw data to calculate these figures
Outcome	
L	• Positive if besides 'complaints' in terms of symptoms (e.g. pain) at least one other outcome criteria for 'recovery' is considered (e.g. disabilities in daily life activities, lost days of work, return to work, health care usage, medication usage)
M	• Positive if one or more of the main outcome measures of L (symptoms and disabilities/ lost days of work) are reported in a standardized or valid way (for example by means of a questionnaire, a diary or an objective outcome measure such as registration of lost days of work at work or medication use in the patient- status of general practitioners). The measures used in these studies should have been developed or re-validated for use in the neck pain population, or in patients with physical illness in general (Pincus et al, 2002).
N	• Positive if frequencies, or percentages or mean (and standard deviation/CI), or median (and Inter Quartile Range) are reported for one or more of the main outcome measures for the most important follow-up measurements. • Negative, unless there is sufficient raw data to calculate these figures.

Analysis	
O	• Positive if univariate crude estimates (RR, OR, HRR) between prognostic factors separately and outcome are provided. • Negative if only p-values or wrong association values (Spearman, Pearson, sensitivity) are given, or if no tests are performed at all.
P	Appropriate statistical methodology should be conducted to derive results for individual risks factors adjusted for other factors. • Positive if appropriate multivariate techniques are used, such as logistic regression analysis or survival analysis for dichotomous outcomes, or linear regression analysis for continuous outcomes. • Negative if no multivariate techniques are performed at all.

Data extraction form – Neck Pain

(Use one form per title)

Administration Details

Study Reference No of article_____

Journal name:_____Publication year:_____

First author name:_____

Title:_____

Extractor name:_____

Other references to which this cohort study may link with:

_____

_____

_____

_____

(Please circle relevant letter in the following questions)

Is this prospective study looking at :	
a	risk factors for the development of neck pain
b	prognostic factors for the progression of neck pain
c	Both (if both then complete 2 seperate forms. One for development factors and another for progression factors)
Is the population (cohort at baseline):	
a	adult (≥ 18 years old)
b	child (< 18 years old)

Scoring: (*Please enter scores once you finished extracting the data):*

Criteria	A	B1	B2	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Total Score
0 or 1																		(Max 17)

(For + give a score of 1; for - or ? give a 0 score)

Quality Assessment

Please complete the following information for each section The quality score should be registered as one of + , - or ? where + = positive (design or conduct adequate); - = negative (design or conduct inadequate); ? = unclear (item insufficiently described).

A Study Population

a.1 Type of cohort: *(Select by circling the right source population of the study)*

1. Asymptomatic inception cohort
2. Symptomatic inception cohort
3. Survival cohort
4. Other

Quality score: + / - / ?

Additional

notes:_____

_____

B1 Description of Source population

b1.1 Sampling frame *(Select by circling the right source population of the study)*

1 Patient seeking treatment at primary care practices (physiotherapy, chiropractic, general practice)

2 Patients seeking care in secondary care departments

3 General population (the sampling frame covers the general population or the whole population of patients who report neck pain)

4 Occupational

(which groups) _____

5. Other

b1.2 Time period of recruitment (in months or years):

_____

b1.3 Place of recruitment (eg country, city)

_____

Quality score: + / - / ?

Additional

notes:_____

B2 Size of Population

b2.1 Size of cohort n=_____

Quality score: + / - / ?

Additional

notes:_____

_____

C In- and exclusion criteria

Please list the inclusion and exclusion criteria provided in the study

c.1 Inclusion criteria

_____

_____

_____

c.2 Exclusion criteria

_____

_____

_____

Quality score: + / - / ?

Additional

notes:_____

_____

D Follow-up period

d.1 Description of follow-up period (in months or

years):_____

Quality score: + / - / ?

Additional

notes:_____

E Drop outs/ lost to follow up

e.1 Total eligible for inclusion into cohort

(n=):_____

Total number enrolled into cohort

(n1=):_____

Number of dropouts or lost to follow up in cohort (n2=): _____

Number completing cohort (n=): _____

% of dropouts (n2/n1 x 100) =_____(Should be <20%)

e.2 For studies with >20% drop-outs. Does comparison of baseline variables suggest that there is no significant difference between completers and non-completers. **Y/ N/ Don't know**

Quality score: + / - / ?

Additional

notes:_____

_____

F. Information completers versus loss to follow-up / drop-outs

Is sociodemographic / clinical information compared for completers and dropouts **Y / N**

Quality score: + / - / ?

Additional

notes:_____

_____

G Prospective Data Collection

Select by circling the right design

1) Prospective cohort

2) Retrospective cohort

3) Other:_____

Quality score: + / - / ?

Additional

notes:_____

_____

H. Treatment

Quality score: + / - / ?

Additional

notes:_____

_____

I Clinically relevant prognostic factors

Select by circling the chosen group of prognostic factors and fill in the specific factor(s) that is(are) mentioned in the study

1. Neck factors (eg. severity of pain, cervical range of motion, duration of complaints since the accident, localization of complaints, concentration problems, dizziness)

_____

2. Physical factors (e.g. exercise, work postures and activities, vibration etc)

_____

3. Psychological factors (eg. anxiety, depression, FAB, self efficacy etc)

_____

4. Pre-existing factors (eg. cervical degeneration, pre-existing headache)

_____

5. Insurance system related factors (eg. financial compensation, litigation)

_____

6 Sociodemographic factors (eg. age, sex, employment status, occupation, co-morbidity, work satisfaction, life events)

_____

7 Other factors:

_____

_____

Quality score: + / - / ?

Additional

notes:_____

J. Standardized / valid measures of prognostic factors

Factor:_____ Measure / Tool:_____ Valid Y/ N

Factor:_____ Measure/ Tool:_____ Valid Y/ N

Factor:_____ Measure/ Tool:_____Valid Y/ N

Quality score: + / - / ?

Additional

notes:_____

K Data Presentation of 3 important prognostic factors

Factor:_____ Data:_____

Factor:_____ Data:_____

Quality score: + / - / ?

Additional

notes:_____

L Clinically relevant outcome measure

Select by circling the outcome measure used in the study

1) Complaints in terms of symptoms (eg. pain)

2) Disabilities in daily life activities

3) Lost days of work

4) A recognised and validated outcome questionnaire (NPQ, SF 36 etc)

5) Well being

6) Return to work

7) Health care usage

8) Medication usage

9)

Others:_____

_____

Quality score: + / - / ?

Additional

notes:_____

_____

M. Standardized / valid measures of outcome

Outcome:_____ Measure/ Tool:_____ Valid Y/ N

Outcome:_____ Measure/ Tool:_____ Valid Y/ N

Quality score: + / - / ?

Additional

notes:_____

_____

N Data presentation of important outcome measures

Measure:_____

Data:_____

Measure:_____

Data:_____

Quality score: + / - / ?

Additional

notes:_____

_____

O Univariate Associations

Please fill in the table using the prognostic factors and outcome measured as used in the study:

Type of prognostic factor	***Outcome measure***	***Type and value of univariate association as stated by the author***

Quality score: + / - / ?

Additional notes:_____

_____

P Association values (multivariate analysis, adjusted estimates and 95% CI)

Please fill in the table using the prognostic factors and outcome measured as used in the study:

Type of prognostic factor	***Outcome measure***	***Type and value of multivariate association as stated by the author***

Quality score: + / - / ?

Additional notes:_____

_____

References	Reason for exclusion
Abenhaim et al. (1988). "Risk of recurrence of occupational back pain over three year follow up." British Journal of Industrial Medicine **45**(12): 829-33	Neck pain not separately analysed
Andersen et al. (2003). "Risk factors in the onset of neck/shoulder pain in a prospective study of workers in industrial and service companies." Occupational and Environmental Medicine, **60**(9): 649-54.	Not related to prognostic factors
Ariëns et al (2002) "High physical and psychological load at work and sickness absence due to neck pain." Scandinavian Journal of Work, Environment and Health **28**(4): 222-231.	Not related to prognostic factors
Ariens et al. (2001). "Are neck flexion, neck rotation, and sitting at work risk factors for neck pain? Results of a prospective cohort study." Occupational and Environmental Medicine **58**(3): 200-7	Not related to prognostic factors
Ariens et al. (2001). "High quantitative job demands and low coworker support as risk factors for neck pain: results of a prospective cohort study." Spine **26**(17): 1896-901	Not related to prognostic factors
Barnekow-Bergkvist et al. (1998). "Determinants of self-reported neck-shoulder and low back symptoms in a general population." Spine **23**(2): 235-43.	Not related to prognostic factors
Berg et al. (1988). "Persistence of musculoskeletal symptoms: a longitudinal study." Ergonomics **31**(9): 1281-5	Not related to prognostic factors
Burdorf, A., B. Naaktgeboren, et al. (1998). "Prognostic factors for musculoskeletal sickness absence and return to work among welders and metal workers." Occupational and Environmental Medicine **55**(7): 490-495.	Not related to prognostic factors
Carroll et al. (2004). "Depression as a risk factor for onset of an episode of troublesome neck and low back pain." Pain **107**(1-2): 134-139	Neck pain not separately analysed
Croft et al. (2001). "Risk factors for neck pain: a longitudinal study in the general population." Pain **93**(3): 317-25	Not related to prognostic factors
Ehrmann Feldman et al. (2002). "Risk factors for the development of neck and upper limb pain in adolescents." Spine **27**(5): 523-8	Neck pain not separately analysed
el Metwally et al. (2004). "Prognosis of non-specific musculoskeletal pain in preadolescents: A prospective 4-year follow-up study till adolescence." Pain **110**(3): 550-559.	Neck pain not separately analysed
Enthoven et al. (2004). "Clinical course in patients seeking primary care for back or neck pain: a prospective 5-year follow-up of outcome and health care consumption with subgroup analysis." Spine **29**(21): 2458-65	Neck pain not separately analysed
Gerr et al. (2002). "A prospective study of computer users: I. Study design and incidence of musculoskeletal	Not related to prognostic

symptoms and disorders." Am J Ind Med **41**(4): 221-35.	factors
Grooten et al. (2004). "Seeking care for neck/shoulder pain: a prospective study of work-related risk factors in a healthy population." Journal of Occupational & Environmental Medicine. 46(2):138-46	Not related to prognostic factors
Hellsing & Bryngelsson (2000). "Predictors of musculoskeletal pain in men: A twenty-year follow-up from." Spine **25**(23): 3080-6	Neck pain not separately analysed
Hellsing et al. (1994). "A prospective study of patients with acute back and neck pain in Sweden." Physical Therapy **74**(2): 116-28	Neck pain not separately analysed
Hertzberg, A. (1985). "Prediction of cervical and low-back pain based on routine school health examinations. A nine- to twelve-year follow-up study." Scand J Prim Health Care **3**(4): 247-53.	Not related to prognostic factors
Holmstrom et al. (1992). "Low back and neck/shoulder pain in construction workers: Occupational workload and psychosocial risk factors. Part 2: Relationship to neck and shoulder pain." Spine **17**(6): 672-677	Not prospective
Jonsson et al. (1988). "Disorders of the cervicobrachial region among female workers in the electronics industry: A two year follow-up." International Journal of Industrial Ergonomics **3**: 1-12	Not related to prognostic factors
Kaergaard & Andersen (2000). "Musculoskeletal disorders of the neck and shoulders in female sewing machine operators: Prevalence, incidence, and prognosis." Occupational and Environmental Medicine **57**(8): 528-534	Neck pain not separately analysed
Kjellman et al. (2001). "A 12-year follow-up of subjects initially sicklisted with neck/shoulder or." Physiotherapy Research International **6**(1): 52-63.	Not related to prognostic factors
Kjellman et al. (2002). "Prognostic factors for perceived pain and function at one-year follow-up in primary care patients with neck pain." Disability & Rehabilitation. **24**(7): 364-70.	Intervention study
Korhonen, T., R. Ketola, et al. (2003). "Work related and individual predictors for incident neck pain among office employees working with video display units." Occupational and Environmental Medicine **60**(7): 475-82.	Not related to prognostic factors
Lauren et al. (1997). "Arm motion speed and risk of neck pain. A preliminary communication." Spine **22**(18): 2094-9.	Not related to prognostic factors
Leclerc, A., I. Niedhammer, et al. (1999). "One-year predictive factors for various aspects of neck disorders." Spine **24**(14): 1455-62.	
Leino & Hanninen (1995). "Psychosocial factors at work in relation to back and limb disorders." Scandinavian Journal of Work, Environment and Health **21**(2): 134-142.	Not related to prognostic factors
Leino & Magni (1993). "Depressive and distress symptoms as predictors of low back pain, neck-shoulder pain, and other musculoskeletal morbidity: a 10-year follow-up of metal industry employees." Pain **53**(1): 89-94.	Not related to prognostic factors

Magnusson et al. (1996). "Are occupational drivers at an increased risk for developing musculoskeletal." Spine **21**(6): 710-7	Not prospective
Manninen et al (1995) "Incidence and risk factors of neck pain in middle-aged farmers." Journal of Musculoskeletal Pain **3**(3): 75-87.	Not related to prognostic factors
Mercado et al. (2005). "Passive coping is a risk factor for disabling neck or low back pain." Pain **unpublished.**	Neck pain not separately analysed
Mikkelsson et al. (1997). "Non-specific musculoskeletal pain in preadolescents. Prevalence and 1- year persistence." Pain **73**(1): 29-35.	Not related to prognostic factors
Niedhammer et al. (1994). "Back pain and associated factors in French nurses." Int Arch Occup Environ Health **66**(5): 349-57. Environmental Health. 66(5):349-57, 1994.	Not related to prognostic factors
Öberg et al. (2003). "Back pain in primary care: a prospective cohort study of clinical outcome and healthcare consumption." Advances in Physiotherapy **5**(3): 98-108	Not related to prognostic factors
Pietri-Taleb et al. (1994). "Longitudinal study on the role of personality characteristics and psychological distress in neck trouble among working men." Pain **58**(2): 261-7.	Not related to prognostic factors
Rundcrantz et al. (1991). "Pain and discomfort in the musculoskeletal system among dentists. A prospective study." Swedish Dental Journal **15**(5): 219-28	Not related to prognostic factors
Schofferman, J. (2000). "Low back and neck pain: psychological predictors of chronicity: Waddell." Journal of Musculoskeletal Medicine **17**(12): 724-6.	Review
Siivola, S. M., S. Levoska, et al. (2004). "Predictive factors for neck and shoulder pain: A longitudinal study in young adults." Spine **29**(15): 1662-1669.	Not related to prognostic factors
Skargren & Oberg (1998) "Predictive factors for 1-year outcome of low-back and neck pain in patients treated in primary care: comparison between the treatment strategies chiropractic and physiotherapy." Pain **77**(2): 201-7.	Neck pain not separately analysed
Smedley, J., H. Inskip, et al. (2003). "Risk factors for incident neck and shoulder pain in hospital nurses." Occupational and environmental medicine, **60**(11): 864-9.	Not related to prognostic factors
Takala et al. (1992). "Seasonal variation in neck and shoulder symptoms." Scandinavian Journal of Work, Environment and Health **18**(4): 257-261.	Follow up < 1 year
Tornqvist et al. (2001). "The influence on seeking care because of neck and shoulder disorders from work-related exposures." Epidemiology **12**(5): 537-545.	Not prospective

Torp et al. (2001). The impact of psychosocial work factors on musculoskeletal pain: a prospective study. Journal of Occupational & Environmental Medicine. 43(2):120-6.	Not related to prognostic factors
van den Heuvel et al. (2005). "Psychosocial work characteristics in relation to neck and upper limb symptoms." Pain **114**(1-2): 47-53	Not related to prognostic factors
Veiersted & Westgaard (1993). "Development of trapezius myalgia among female workers performing light manual work." Scand J Work Environ Health **19**(4): 277-83	Not related to prognostic factors
Veiersted et al. (1993). "Electromyographic evaluation of muscular work pattern as a predictor of trapezius myalgia." Scandinavian Journal of Work, Environment and Health **19**(4): 284-290.	Follow up < 1 year
Viikari-Juntura et al. (1991). "A life-long prospective study on the role of psychosocial factors in neck-shoulder and low-back pain." Spine. **16**(9): 1056-61	Not related to prognostic factors
Viikari-Juntura et al. (2001). "Longitudinal study on work related and individual risk factors affecting radiating neck pain." Occupational and Environmental Medicine **58**(5): 345-52	Not related to prognostic factors
Westerling & Jonsson (1980). "Pain from the neck-shoulder region and sick leave." Scandinavian Journal of Social Medicine. **8**(3): 131-6.	Not prospective

Cohort		
Bot et al. (2005)	Quality Score	17
	Recruitment	The Netherlands, June 2001 to June 2002
	Population	Symptomatic cohort of subjects who visited their GP with a new episode of neck pain (e.g. they had not visited a GP for the same problem during the preceding 3 months). Patients excluded if they had any potentially severe pathology or were pregnant. (n=443)
	Follow-up period	1 year
	% lost to follow up	17.8%
	Outcome	1) Perceived recovery 2) Change in pain intensity 3) Functional disability at 3 and 12 months
	Prognostic Factor	Sociodemographic Psychological Physical Clinical
	Univariate Results (crude estimates and 95% CI, significant differences and association)	All prognostic factors significantly predict outcome (p<0.2) **Recovery** (HRs<1.00 indicate a lower likelihood of recovery compared with the reference group): employed (HR=1.32; 0.91 to 1.93),tertiary level education (HR=1.55; 0.94 to 2.54), intense baseline pain (HR=0.91; 0.84 to 0.98), more baseline disability (HR=0.99; 0.98 to1.00, current episode of neck pain >6 months (HR=0.24; 0.12 to 0.48), previous history of neck pain (HR=0.36; 0.24 to 0.54), localised symptoms (HR= 1.89; 1.32 to 2.71), both shoulders involved (HR=0.28; 0.14 to 0.58), headaches (HR=0.68; 0.41 to1.13), loss of concentration (HR=0.56; 0.34 to 0.95), tingling in hands/fingers (HR=0.62; 0.42 to 0.93), numbness in hands/fingers (HR=0.39; 0.2 to 0.78), loss of strength (HR=0.61; 0.39 to 0.96), overload by ADL (HR=0.69; 0.47 to 1.01), accident during sport (HR=1.96; 0.96 to 4.02), anxiety stress (HR=0.56; 0.31 to 0.99), no co-morbidity (HR=1.56; 1.09 to 2.23), symptoms hip/knee (HR=0.69; 0.43 to 1.12), symptoms ankle/ft (HR=0.42; 0.1 to 0.96),

		symptoms back (HR=0.65; 0.43 to 0.97), multiple MSK symptoms (HR=0.22; 0.07 to 0.68), psychological problems (HR=0.63; 0.37 to 1.09), high pain transformation (HR=0.74; 0.47 to 1.17), high retreating (HR=0.74; 0.48 to 1.14), high worrying (HR=0.41; 0.25 to 0.68), high resting (HR=0.62; 0.4 to 0.97), distress (HR=0.92; 0.87 to 0.98), high fear and avoidance (HR=0.74; 0.49 to 1.11), high score on social support (HR=0.45; 0.24 to 0.84), better perceived health (HR=1.46; 1.21 to 1.78), poorer QoL (HR=0.19; 0.06 to 0.61), more vital (HR=1.02; 1.01 to 1.03) **Pain intensity** Variables which were significantly ($p<0.2$) associated were given as regression coefficients: being married/living together (0.5; -0.2 to1.21), more intense baseline pain (0.55; 0.44 to 0.67), more disability at baseline (0.03; 0.02 to 0.05), longer duration of current symptoms e.g. 6m (-1.54; -2.72 to -0.36), history of neck problems (-1.14; -1.7 to -0.57), localisation of symptoms (0.74; 0.12 to 1.36), involvement of both shoulders (-1.56; -2.3 to -0.82), headaches (-0.60; -1.39 to 0.19, tingling in hands/fingers (-0.65; -1.24 to -0.06), numbness in hands/ fingers (-0.72; -1.48 to 0.04), loss of hand co-ordination (-0.87; -1.89 to 0.16), tendency to massage hands (-0.60; -1.21 to 0.02), overload by ADL (-0.74; -1.37 to -0.11), anxiety/stress (-0.66; -1.49 to 0.17), chronic disease (-1.4; -2.87 to 0.06), no co-morbidities (0.59; 0.01 to 1.16), symptoms in hip/knee (-0.94; -1.62 to -0.26), symptoms in ankle/ft (-1.07; -1.98 to -0.16), multiple MSK symptoms (-0.88; -1.83 to 0.07), psychological problems (-0.63; -1.37 to 0.12), medium pain transformation (0.65; -0.06 to 1.36), high social support scores (-0.63 -1.44 to 0.17), better perceived health (0.55; 0.23 to 0.88), poorer QoL (-1.39; -2.28 to -0.5), more vital (0.02; 0.01 to 0.04). **Functional disability** Variables which were significantly ($p<0.2$) associated were given as regression coefficients: female gender (3.02; -0.33 to 6.37), older age (-0.12; -0.24 to 0.0), having no children (2.49; -0.74 to 5.73), more intense baseline pain (1.78; 1.08 to 2.48), more disability at baseline (0.54; 0.45 to 0.62), longer duration of current symptoms e.g. 6m (-10.87; -17.51 to -4.24), history of neck problems (-5.61; -8.78 to -2.43), localisation of symptoms (3.53; 0.06 to 7.01), involvement of both shoulders (-7.11; -11.3 to -2.85), symptoms in dominant shoulder (3.79; 0.16 to 7.43), no use of medication (-

		2.63; -6.06 to 0.80), tingling in hands/fingers (-2.33; -5.64 to 0.98), numbness in hands/ fingers (-3.24; -7.51 to 1.04), loss of strength (4.07; 0.55 to 7.58), loss of hand co-ordination (-4.07; -9.83 to 1.69), tendency to massage hands (3.89; 0.47 to 7.32), overload by ADL (-5.11; -8.73 to -1.49), accidents (4.99; -2.41 to 12.4), chronic disease (-6.98; -15.18 to 1.23), no co-morbidities (2.21; -1.04 to 5.46), symptoms in hip/knee (-3.45; -7.3 to 0.39), symptoms in ankle/ft (-4.77; -9.9 to 0.37), multiple MSK symptoms (-3.9; -9.29 to 1.49), cardiovascular disease (-3.29; -7.71 to 1.13), cancer (10.08; -2.54 to 22.7), medium distraction (4.31; 0.44 to 8.18), high retreating (3.47; -0.5 to 7.44), high fear and avoidance (6.17; 2.54 to 9.79), high importance of exercise (4.59; 0.69 to 8.48), high social support scores (-3.8; -8.3 to 0.69), better perceived health (1.93; 0.1 to 3.77), poorer quality of life (-8.66; -13.61 to -3.7), more vital (0.06; 0.02 to 0.15).
	Multivariate results (adjusted estimates and 95% confidence intervals and significance levels)	Cox regression, adjusted for significant variables ($p<0.2$) during univariate analysis e.g. baseline pain, duration of symptoms, history of neck problems, frequent discomfort, more resting, being less vital etc. All prognostic factors significantly predict outcome $p<0.05$ **Recovery** (HRs<1.00 indicate a lower likelihood of recovery compared with the reference group) • Current episode of neck pain lasting more than 6 months (HR=0.46; 0.21 to 0.99) • History of neck symptoms (HR=0.58; 0.36 to 0.93) • Both shoulders affected (HR=0.39; 0.18 to 0.85) • Multiple MSK symptoms (HR=0.31; 0.1 to 1.0) **Pain intensity** [1] Variables which were significantly ($p<0.05$) associated were: • Baseline intensity of pain (b=0.73; 0.62 to 0.84) • Current episode of neck pain lasting more than 6 months (b= -1.2; -2.2 to -0.18) • A history of neck problems (b=-0.56; -1.1 to 0.02) • Both shoulders being affected (b= -0.88; -1.49 to -0.27) • Numbness in the hands/fingers (b=-0.77; -1.4 to -0.14) • High levels of worrying (b=-0.96; -1.59 to -0.34)

		• Better perceived health (b=0.51; 0.22 to 0.8) • Poorer QoL scores (b=-0.99; -1.77 to -0.2). **Functional disability** [1] Variables which were significantly (p<0.05) associated were: • Older age (b=-0.09; -0.18 to 0.0) • Greater disability at baseline (b=0.58; 0.52 to 0.65) • Current episode of neck pain lasting more than 6 months (b= -10.6; -15.45 to -5.77) • Numbness in the hands/fingers (b=-3.97; -7.04 to -0.9) • Tendency to massage hands (b=2.68; 0.2 to 5.15) • Hip/knee symptoms (b=-5.72; -8.51 to -2.93) • Multiple MSK symptoms (b=-5.12; -9.16 to -1.07) • Poorer QoL scores (b=-7.59; -11.68 to -3.5) • More vitality (b=0.77; 0.03 to 1.5)
Hill et al. (2004)	Quality Score	16
	Recruitment	South Manchester, UK, 1992
	Population	General population, symptomatic subjects, >18 years of age, with at least 1 month period prevalence of neck pain. (n=1359)
	Follow-up period	1 year
	% lost to follow up	42%
	Outcome	Persisting neck symptom in past month
	Prognostic Factor	Sociodemographic Psychological Physical Clinical
	Univariate Results (crude estimates and 95% CI, significant	Variables which were significantly (p<0.05) associated with outcome were: older age 45-59y (OR=3.4; 2.0 to 5.7), alcohol intake on 3 or more days of the week (OR=0.7; 0.5 to 0.9), poor general health (OR=1.9; 1.0 to 3.7), psychological distress (OR=2.2; 1.3 to 3.6), low back

	differences and association)	pain (OR=1.7; 1.3 to 2.3), previous neck injury (OR=1.5; 1.1 to 2.2), not employed (OR=1.8; 1.3 to 2.5), less than average physical activity (OR=1.4; 1.0 to 1.9), cycling (OR=2.0; 1.3 to 3.2)
	Multivariate results (adjusted estimates and 95% confidence intervals and significance levels)	Linear Regression ($p<0.05$) • Older age 45-49y (OR=3.9; 2.2 to 6.7) • Low back pain (OR=1.6; 1.1 to 2.2) • Not employed (OR=1.6; 1.1 to 2.3) • Cycling (OR=2.4; 1.5 to 4.0)
Hoving et al. (2004)	Quality Score	15
	Recruitment	Zoetermeer and Gouda, The Netherlands, February 1997 to November 1998
	Population	A symptomatic inception cohort of consecutive patients who consulted their GPs because of neck pain. Included if between 18-70 years of age, pain or stiffness in the neck for at least 2 weeks, neck complaints reproducible during the physical examination. Excluded if they received physiotherapy in the 6 months prior to baseline examination or had undergone surgery to the neck. (n=183)
	Follow-up period	1 year
	% lost to follow up	2.7%
	Outcome	1) Perceived recovery 2) Pain intensity 3) Neck dysfunction
	Prognostic Factor	Sociodemographic Clinical
	Univariate Results (crude estimates and 95% CI, significant differences and association)	Variables which were significantly ($p<0.1$) associated with outcome were: **Predictors of perceived recovery** age ≥40y (OR=0.34; 0.17 to 0.69), headache (OR=0.73; 0.37 to 1.44), low back pain (OR=0.46; 0.23 to 0.94), no change in neck pain for previous 2 weeks (OR=0.38; 0.21 to 0.72) **Predictors of pain intensity**[2] Variables which were statistically significantly associated were given as regression coefficients: age ≥ 40 years (1.04; 0.27 to 1.80), pain intensity at baseline (0.26; 0.07 to 0.45), concomitant low

		back pain (1.13; 0.29 to 1.97), duration of neck pain ≥ 13 weeks (1.03; 0.19 to 1.86), a history of neck pain (0.83; 0.06 to 1.59), no change in neck symptoms for 2 weeks (0.66; -0.08 to 1.39). **Predictors for neck dysfunction[2]** Variables which were statistically significantly associated were given as regression coefficients: neck function at baseline (0.36; 0.22 to 0.49), age over 40y (2.42; 0.42 to 4.42), concomitant low back pain (3.11; 0.94 to 5.82), duration of neck pain ≥ 13 weeks (2.03; -0.04 to 4.19), a history of neck pain (2.2; 0.24 to 4.17), no change in neck symptoms for 2 weeks (2.49; 0.6 to 4.38)
	Multivariate results (adjusted estimates and 95% confidence intervals and significance levels)	Multiple regression adjusted for all significant variables ($p<0.1$). Variables which were associated[3] with outcome were: **Perceived recovery** • Age ≥40y (OR=0.26; 0.11 to 0.61) • Previous trauma (OR=0.4; 0.15 to 1.05) • Low back pain (OR=0.37; 0.17 to 0.80) • No change in neck pain for previous 2 weeks (OR=0.33; 0.17 to 0.66) • High baseline severity of physical dysfunction (OR=0.54; 0.27 to 1.11) **Predictors of pain intensity [2]** • Older age ≥40y (B=0.26; 0.07 to 0.45) • Higher pain intensity at baseline (B=1.11; 0.38 to 1.84) • Concomitant low back pain (B=0.8; -0.02 to 1.61) • Duration of neck pain ≥ 13 weeks (B=1.35; 0.34 to 1.93) • A history of neck pain.(B=1.35; 0.13 to 1.58) **Predictors for neck dysfunction [2]** • Neck function scores at baseline (B=0.41; 0.28 to 0.54) • Older age ≥40y (B=2.13; 0.22 to 4.05)

		• Duration of neck pain ≥ 13 weeks (B=1.89;-0.22 to 4.00) • Neck trauma (B= 2.75; 0.27 to 5.32) • Concomitant low back pain (B=2.97; 0.87 to 5.07) • No change in neck symptoms for 2 weeks (B=2.07; 0.22 to 4.91)
Eriksen et al. (1999)	Quality Score	13
	Recruitment	Ullensaker, Norway, 1990
	Population	2 cohorts of a general occupational subjects; 1 symptomatic cohort (n=696) and 1 asymptomatic cohort (n=618) who had experienced no neck pain in the twelve months prior to baseline assessment.
	Follow-up period	4 years
	% lost to follow up	20.2%
	Outcome	Neck pain in previous 12 months Neck pain during previous week
	Prognostic Factor	Sociodemographic Physical Clinical
	Univariate Results (crude estimates and 95% CI, significant differences and association)	Significant factors ($p<0.05$) for persistence of neck pain were: female gender, sleeping problems, headaches , shoulder pain, low back pain, little influence on work situation, sustained work postures, repetitive stereotypical movements at work.
	Multivariate results (adjusted estimates and 95% confidence intervals and significance levels)	Logistic regression, adjusted for multiple baseline co-variates. Variables significantly associated ($p<0.05$) were: • Little influence on own work situation (OR=2.54; 1.17 to 5.5) • Female gender (OR=1.99; 1.3 to 3.02) • Headaches in previous year (OR=2.89; 1.69 to 4.95) • Shoulder pain in previous year (OR=2.56; 1.44 to 4.55)
Pernold et al. (2005)	Quality Score	13
	Recruitment	Norrtälje, Sweden, 1993
	Population	General adult working population between ages of 20-59 who sought care for neck pain at baseline.

		Subjects who had sought care for neck pain in the 6 months prior to baseline were excluded. (n=439)
	Follow-up period	5 years
	% lost to follow up	49.8%
	Outcome	Pain intensity Functional disability
	Prognostic Factor	Physical
	Univariate Results (crude estimates and 95% CI, significant differences and association)	Prognostic Factors Tests of association show that improvements in pain intensity and disability over 5 years are significantly ($p<0.05$) associated with high intensity levels of exercise. Non exercisers show no significant changes in their baseline intensity scores or their disability scores after 5 years.
	Multivariate results (adjusted estimates and 95% confidence intervals and significance levels)	No data provided
Viikari-Juntura et al. (1994)	Quality Score	13
	Recruitment	?Finland, March 1984
	Population	Male machine operators, carpenters and office workers. At baseline the cohort contained subjects with no, moderate and severe neck trouble. (n=2222)
	Follow-up period	3 years
	% lost to follow up	17.6%
	Outcome	Number of days of neck trouble in preceding 12 months
	Prognostic Factor	Sociodemographic Physical
	Univariate Results (crude estimates and 95% CI, significant differences and association)	No significance levels stated: carpentry v office work (OR=2.5; 1.2 to 5.2), machine operator v office work (OR=3.5;1.8 to 7.1), duration of current occupation > 15 years (OR=1.5; 0.7 to 3.1), current smoker (OR=1.9; 1.0 to 3.5), physical exercise≥2 times per week (OR=0.5; 0.3 to 0.8), a lot of twisting/bending of trunk at work

		(OR=1.6; 0.7 to 3.6)
	Multivariate results (adjusted estimates and 95% confidence intervals and significance levels)	Logistic regression adjusted for age, occupation, smoking, physical exercise, duration of occupation. No significance levels stated: • Machine operator v office work (OR=4.2; 2.0 to 9.0) • Carpentry v office work (OR=3.0; 1.4 to 6.4) • Current smoker (OR=1.4; 0.7 to 2.8) • Physical exercise >2 times per week (OR=0.5; 0.2 to 0.9)
Mikkelsen et al. (1999)	Quality Score	11
	Recruitment	Lahti, Finland , 1995
	Population	Primary school children with neck pain at baseline (n=108)
	Follow-up period	1 year
	% lost to follow up	13.8%
	Outcome	Development of widespread pain
	Prognostic Factor	Physical Sociodemographic Psychological Clinical
	Univariate Results (crude estimates and 95% CI, significant differences and association)	In schoolchildren with neck pain, development of widespread pain was significantly associated ($P<0.05$) with: score ≥ 3 on the Children's Depression Inventory, sleep score, Yunus criteria ≥ 3
	Multivariate results (adjusted estimates and 95% confidence intervals and significance levels)	In the logistic regression model none of the factors independently predicted the change of neck pain to widespread pain

Cassou et al. (2002)	Quality Score	11
	Recruitment	France, 1990
	Population	A group of symptomatic and asymptomatic subjects (n=21378) divided into 2 cohort; an asymptomatic cohort and a symptomatic cohort (numbers in each cohort at baseline is not clear)
	Follow-up period	5 years
	% lost to follow up	12.5%
	Outcome	Presence of neck pain > 6 months, with functional limitation
	Prognostic Factor	Sociodemographic Psychological Other
	Univariate Results (crude estimates and 95% CI, significant differences and association)	In men disappearance of chronic neck and shoulder pain was significantly ($p<0.05$) associated with: • Low job demands In women disappearance of chronic neck and shoulder pain was significantly associated with: • Not doing repetitive work • Low job demands
	Multivariate results (adjusted estimates and 95% confidence intervals and significance levels)	Logistic regression adjusted for variables which were significant ($p<0.1$) such as age, social class, repetitive work, awkward work, precise movement, job demand, job control, shift work, depressive symptoms, previous MSK disorders and smoking. Variables which were associated[3] with outcome were (OR <1.0 indicates worse disappearance rate of neck pain compared with ref group): • Older age >45y (female OR≈0.6; 0.4 to 0.9) • Repetitive work prior to baseline (female OR=0.5; 0.3 to 0.7) • MSK disorders in the past (male OR=0.4; 0.3 to 0.6) (female OR=0.6; 0.5 to 0.8) • Undertaking sporting activities (male OR=1.5; 1.1 to 2.1) • High job demands (male OR=0.7; 0.5 to 0.9) (female OR=0.7; 0.6 to 0.9)

Gore et al. (1987)	Quality Score	6
	Recruitment	?USA
	Population	Historical symptomatic cohort of patients attending a consultation with an orthopaedic surgeon who had previously a similar consultation >10 years earlier for their neck problem. None had undergone neck surgery. (n=205)
	Follow-up period	>10 years
	% lost to follow up	Don't know
	Outcome	Symptoms
	Prognostic Factor	Physical Other
	Univariate Results (crude estimates and 95% CI, significant differences and association)	Moderate or severe pain at follow-up was significantly associated ($p<0.05$) with: severe pain at baseline examination
	Multivariate results (adjusted estimates and 95% confidence intervals and significance levels)	No data provided

1. Where risk estimates are not given, the regression coefficients (b) and 95% CI have been included. A positive b value represents a favourable change of the outcome measure per unit of the independent predictor; b negative represents an unfavourable change in the outcome measure per unit of the independent predictor.
2. Where risk estimates are not given, the regression coefficients (B) and 95% CI have been included. A positive B value represents worse prognosis of the outcome measure in the presence of the predictor; a negative B value represents a better prognosis in the in the presence of the predictor.
3. Hoving et al (2004) and Cassou et al (2002) do not explicitly state that the final outcomes of multiple regression are statistically significant at $p<0.05$). However statistical methods and analysis are well described and the results of both studies have been retained in support of final levels of evidence.
4. The following abbreviations are used in this table:

CI = confidence interval; HR = hazard ratio; ADL = activities of daily living; MSK = musculoskeletal symptoms; QoL = quality of life; OR = odds ratio; GP = general practitioner

HULL AND EAST RIDING LOCAL RESEARCH ETHICS COMMITTEE

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Ms S McLean
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13 January 2004

Dear Ms McLean,

LREC/ 11/03/235
Protocol number: 1/11/03 A Comparison of "Physiotherapy as usual" & Exercise Therapy in Patients with Neck Pain

The Chair of the Hull and East Riding REC has considered the amendments submitted in response to the Committee's earlier review of your application on 17th November 2003 as set out in our letter dated 21st November 2003. The documents considered were as follows:

- Your letter dated 18th December 2003 addressing the concerns of the committee
- A Copy of "The Neck Book" (McKabi)
- Reference document – Active Neck Muscle Training in the Treatment of Chronic Neck Pain in Women
- Reference document – Comparison of Two Physical Exercise Programs for the Early Intervention of Pain in the Neck, Shoulders and Lower Back in Female Hospital Staff
- Reference document – Intensive Dynamic Training for Females with Chronic Neck/Shoulder Pain. A Randomised Controlled Trial
- Reference document – A Randomised Controlled Trial of Exercise and Manipulative Therapy for Cervicogenic Headache

The Chair, acting under delegated authority, is satisfied that these accord with the decision of the Committee and has agreed that there is no objection on ethical grounds to the proposed study. I am, therefore, happy to give you the favourable opinion of the committee on the understanding that you will follow the conditions set out below.

Conditions

- You do not undertake this research in an NHS organisation until the relevant NHS management approval has been gained as set out in the Framework *for Research Governance in Health and Social Care.*

- You do not deviate from, or make changes to, the protocol without prior written approval of the REC, except where this is necessary to eliminate immediate hazards to research participants or

when the change involves only logistical or administrative aspects of the research. In such cases the REC should be informed within seven days of the implementation of the change.

- You complete and return the standard progress report form to the REC one-year from the date on this letter and thereafter on an annual basis. This form should also be used to notify the REC when your research is completed and in this case should be sent to this REC within three months of completion.

- If you decided to terminate this research prematurely you send a report to this REC within 15 days, indicating the reason for the early termination.

- You advise the REC of any unusual or unexpected results that raise questions about the safety of the research.

Yours sincerely

Mr G S Duthie
Chair of the Hull and East Riding REC

LREC/ 11/03/235 Please quote this number on all correspondence

Mid & South Buckinghamshire Local Research Ethics Committee
Wycombe Hospital
c\o Clinical Effectiveness Dept.
Chiltern Medical Education Centre
Queen Alexandra Road
High Wycombe
Buckinghamshire
HP11 2TT

Tel/Fax: (01494) 42 6370

17 March 2004

Miss Sionnadh McLean
Superintendent II Physiotherapist
Hull & East Yorkshire Hospitals Trust
Institute of Rehabilitation
215 Anlaby Road
Hull HU3 2PG

Dear Miss McLean,

Ref: REC(F)/01-04/057: A randomised controlled trial comparing graded exercise treatment and usual physiotherapy for patients with neck pain

Thank you for your letter of 5 March 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 application form, protocol and supporting documentation as revised.

The favourable opinion applies to the following research site:

Site: Wycombe NHS Primary Care Trust

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 23/01/04
Research Protocol
Questionnaire
Research participants information sheet – version 2, 24 February 2004
Research participants consent from – version 1, 01 November 2003
GP letter - version 1, 01 November 2003
Letter of invitation to research participants

CV for the chief investigator
CV for the supervisor

Management approval

The study may not commence until final management approval has been confirmed by the organisation hosting the research.

Notification of other bodies

We shall notify the research sponsor the host organisation 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.

REC reference number: REC(F)/01-04/057 Please quote this number on all correspondence

Yours sincerely,

Dr Susan Kelly, D Phil FRCP FRCPath
Consultant Haematologist
Chairman, LREC

Cc. Wycombe Primary Care Trust
Ms Sara Watkinson, Arthritis Research Campaign
Enclosures Standard approval conditions SL-AC2

Hull & East Riding Local Research
Ethics Committee
Room C24
College House
Willerby Hill Business Park
Willerby
HULL
HU10 6NS

27 July 2004

Ms Sionnadh McLean
215 Anlaby Road
Hull
HU3 2PG
England

Dear Ms McLean,

Full title of study: A Comparison of "Physiotherapy as usual" & Exercise Therapy in Patients with Neck Pain
REC reference number: 11/03/235
Protocol number: 1.0

The Research Ethics Committee reviewed the above application at the meeting held on 13th January 2004.

Ethical opinion

The Hull and East Riding Local Research Ethics Committee are the Lead LREC for this study acting as MREC, Dr Janet Wisley has granted us permission for this to happen

The members of the Committee present gave a favourable ethical opinion to the above research on the basis described in the application form, protocol and supporting documentation.

The favourable opinion applies to the research sites listed on the attached sheet. Confirmation of approval for other sites listed in the application will be issued as soon as local assessors have confirmed that they have no objection.

Management approval

If you are 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 other site until the local Principal Investigator has obtained final management approval from the relevant host organisation.

All researchers and research collaborators who will be participating in the research must obtain management approval from the relevant host organisation before commencing any research procedures. Where a substantive contract is not held with the host organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Statement of compliance *(from 1 May 2004)*

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.

REC reference number: 11/03/235 Please quote this number on all correspondence

Yours sincerely,

Mr G S Duthie
Chairman

Enclosures *List of approved sites*

List of Approved Sites

Host Organisation:
Northern Lincolnshire &Goole NHS Trust
Decision by: South Humber Local Research Ethics Committee
SSA Reference: 04/Q1105/30

Host Organisation:
Nottingham City Hospital
Department of Haematology
Decision by: Nottingham Research Ethics Committee 2
SSA Reference: 04/Q2404/71

Hull and East Yorkshire Hospitals NHS

NHS Trust

Castle Hill Hospital
Castle Road
Cottingham
East Yorkshire
HU16 5JQ

Research & Development Department
Clinical Governance Directorate
Admin Porta Cabin
01482 875875 Ext 3137/3936

Our Ref: SB/EL

16 January 2004

Ms S McLean
Institute of Rehabilitation
215 Anlaby Road
Hull
HU3 2PG

Dear Ms McLean

Re: A comparison of "physiotherapy as usual" and exercise therapy in patients with neck pain. ELSY NO: 2943

I am pleased to notify you formally that this study has been approved by the Trust and may now proceed.

The Trust is required to return information on the progress of studies to the National Research Register, and to report research findings. We will, therefore, ask you every quarter for such updates, and would be very grateful if you would provide this information. I would like to wish you every success with this project.

Yours sincerely

P.p. S Richardson

Dr Sally Brown
Research & Development Facilitator

Hull and East Yorkshire Hospitals NHS
NHS Trust

Castle Hill Hospital
Castle Road
Cottingham
East Yorkshire
HU16 5JQ

Research & Development Department
Clinical Governance Directorate
Admin Porta Cabin
01482 875875 Ext 3137/3936

Our Ref: SB/EL

16 January 2004

Ms S McLean
Institute of Rehabilitation
215 Anlaby Road
Hull
HU3 2PG

Dear Ms McLean

Re: A comparison of "physiotherapy as usual" and exercise therapy in patients with neck pain. ELSY NO: 2943

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Yours sincerely

P.P. S Richardson

Dr Sally Brown
Research & Development Facilitator

Wycombe NHS
Primary Care Trust

Buckinghamshire & Milton Keynes
PCT Research Office
Verney House
Gatehouse Road
Aylesbury
Bucks
HP19 8ET

Tel: 01296 508703
Fax: 01296 310104

Miss Sionnadh McLean
Superintendent II Physiotherapist
Hull & East Yorkshire Hospitals Trust
Institute of Rehabilitation
215 Analby Rd
Hull
HU3 2PG

29/04/2004

Dear Miss McLean

R&D Steering Group
Research Project Approval Process

Final Approval Letter

Project Title	A randomised controlled trial comparing graded neck exercise treatment and usual physiotherapy for patients with neck pain
Lead Researcher	Miss Sionnadh McLean

Thank you for submitting a copy of the LREC approval letter, showing LREC Number and Date of Approval.

This now completes the PCT R&D Approval Process and you may now proceed with the above research project in the PCT.

Can I remind you of your signed agreement to submit regular progress reports and a final report on completion, as well as to disseminate the findings appropriately.

Good luck with your project.

Yours sincerely

Diana Moule, Research Management and Governance Administrator
Diana.moule@voa-pct.nhs.uk
Cc Morag Thomson

Nottingham City Hospital NHS
NHS Trust

Please ask for: Graeme Docherty

Ref: GD/04PT16

27 September, 2004

Miss SM McLean
Trial Manager
The Institute of Rehabilitation
215 Anlaby Road
Hull HU3 2PG

Research and Development
Hucknall Road
Nottingham
NG5 1PB

Direct Dial: 0115 9627913
Tel: 0115 969 1169 ext 45356
Fax: 0115 9627639
e-mail: gdochert@ncht.trent.nhs.uk
Minicom: 0115 962 7749
www.ncht.org.uk

Dear Miss McLean

A randomised controlled trial comparing graded Exercise Treatment and Usual Physiotherapy for patients with neck pain
Project Registration Number: 04PT16 Ethics Committee Number:

The above project has been approved by the Director of Research and Development, subject to the conditions listed below and Ethical Committee approval when required.

YOUR PROJECT CANNOT START AND DOES NOT HAVE INDEMNITY UNTIL YOU HAVE AGREED THE CONDITIONS OF APPROVAL. PLEASE COMPLETE AND RETURN THE FORM ATTACHED TO THIS LETTER CONFIRMING YOUR COMPLIANCE WITH THE CONDITIONS OF APPROVAL.

Conditions of Approval

That you have read and agree to abide with the Research Governance Framework for Health and Social Care, and comply with all reporting requirements, systems and duties of action put in place to deliver Research Governance including:

- All projects are liable to be monitored by the Trust.
- That a system for recording, reporting and reviewing all adverse events and adverse drug reactions in research is in place. This is in addition to the reporting to the approved Research Ethics Committee and the agreed sponsor.
- Honorary contracts for all non Nottingham City Hospital NHS Trust employees, involved in the project are obtained from Human Resources.
- That R&D are notified of the Research Ethics Committee 'favourable opinion' (approval) and that a copy of the letter and all approved documents (if different from those originally submitted) are forwarded to R&D with the attached Registration Details.
- All research which is discontinued temporarily or permanently should be reported to R&D.
- All changes to the project protocol including amendments, changes in study personnel and change in duration/timescale of the project should be referred to R&D as well as the appropriate ethics committee.
- That R&D are notified when project findings are published or disseminated in any way.
- To complete yearly/final reports as requested.

Northern Lincolnshire and Goole Hospitals NHS
NHS Trust

[illegible]/SCC/R&D/1903
[illegible]search & Development
[illegible]rthern Lincolnshire & Goole
[illegible]pitals Trust
Tel 01724 – 290410
[illegible]sclark@nlg.nhs.uk

[illegible] 23 August 2004

[illegible] Mr Airey

[illegible] **A Randomised Controlled Trial Comparing Graded Exercise Treatment and Usual [illegible]physiotherapy for Patients With Neck Pain (Get Up Neck Trial)**

[illegible] study has been processed by the Trust R&D department and submitted to the North & East [illegible]shire & Northern Lincolnshire Strategic Health Authority (South Humber LREC) on your behalf.

[illegible] inform you that in addition to the LREC approval, of which, the Trust has been informed, the Trust [illegible] grant approval for the study to commence.

[illegible]owever, you are required to inform the Trust R&D department in advance of any significant proposed [illegible]nges to the original protocol, adverse events or issues of safety. Your project will be subject to [illegible]nitoring in line with the requirements for Research Governance.

[illegible]uld you require any further assistance regarding this study, please do not hesitate to contact me.

[illegible]ring you every success with your study.

[illegible]d regards

[illegible]

[illegible]. C. Clark
[illegible]D Manager
[illegible]rthern Lincolnshire & Goole
[illegible]pitals NHS Trust

Nottingham City Hospital NHS
NHS Trust

Physiotherapy Department
Hucknall Road
Nottingham
NG5 1PB

Direct Dial: 0115 9627699
Tel: 0115 969 1169 ext 46699
Fax: 0115 9628002
e-mail: abeswick@ncht.org.uk
Minicom: 0115 962 7749
www.ncht.org.uk

Please ask for: Anne Beswick

Ref: ds/jh/ab

16th June 2004

Sionaddh McLean
Trial Manager
Institute of Rehabilitation
215 Anlaby Road
HULL
HU3 2PG

Dear Sionaddah

Re: GETUP neck trial

I would like to confirm that I am very happy to support the use of the Physiotherapy Department here at the Nottingham City Hospital, as a trial centre for the GETUP neck trial being led by you at the Institute of Rehabilitation in Hull.

The lead person here will be Mrs Claire Diver, Lecturer Practitioner in Physiotherapy.

Yours sincerely

Anne Beswick

Mrs Anne Beswick
Physiotherapy Services Manager

Professor J Klaber Moffet
Deputy Director
Institute of Rehabilitation
215 Analby Road
Hull
HU3 2PG

Wycombe NHS
Primary Care Trust

Physiotherapy Department
Wycombe Hospital
Queen Alexandra Road
High Wycombe
Buckinghamshire
HP11 2TT

Tel: (01494) 425431
Fax: (01494) 425429

24.10.03

Dear Professor Moffet,

A Randomised Controlled Trial Comparing Graded Exercise Treatment and usual physiotherapy for patients with Neck Pain

I have recently met with Siomadh McLean to discuss the involvement of the Wycombe NHS Primary Care Trust Physiotherapy service in this randomised controlled trial. I would like to confirm that we are aware of the trial procedures and the commitment that would be required from the physiotherapy service in order to undertake the above research. Having discussed this with the physiotherapy staff we agree that this research would provide extremely useful information both at this trust and nationally, which may inform our treatment provision and management of resources to the neck pain patients that are referred to this service.

I therefore can confirm that I am happy to commit the physiotherapy out patient service of this trust to undertake the above research study.

We look forward to the opportunity to work with you.

Yours sincerely

Morag Thomson

Morag Thomson MCSP SRP
District Physiotherapist

Northern Lincolnshire and Goole Hospitals NHS

NHS Trust

Diana Princess of Wales Hospital
Scartho Road
Grimsby
North East Lincolnshire
DN33 2BA

Tel: 01472 874111
www.nlg.nhs.uk

9th June 04

Professor J. Klaber Moffet
Deputy Director
Institute of Rehabilitation
215 Anlaby Road
Hull
HU3 2PG

Dear Jennifer,

A Randomised Controlled Trial Comparing Graded Exercise Treatment and Usual Physiotherapy for Patients with Neck Pain

I am writing to confirm my support for the above clinical trial and that the physiotherapy departments in the North Lincolnshire & Goole Hospitals NHS Trust will be available to take part in the study.

Yours sincerely

Glenna Briggs
Trust Lead for Physiotherapy

Headed Paper

A Randomised Controlled Study of Graded Exercise Therapy and "Usual Physiotherapy" for Patients with Mechanical Neck Pain

The physiotherapy department informed me that you have been referred by your GP for physiotherapy for your neck pain. The Institute of Rehabilitation, which is part of the Postgraduate Medical Institute at the University of Hull, is currently collaborating with the physiotherapy department in a study to compare two forms of physiotherapy for neck pain. This is described in the attached patient information sheet.

The aim of the scientific study is to find out which is best at improving patients' ability to cope with their condition and reduce disability in the long term.

Patients taking part in the study will be randomly allocated to receive one or the other treatment for their neck pain. We are hoping to recruit at least 150 patients for the study from Hull, Grimsby and High Wycombe. This is an important piece of research and the outcome will help provide information as to how services and treatment can be improved both locally and nationally. The study has been approved by the Research Ethics Committee.

If you do not want to be contacted about this study please fill in the attached slip and return it in the FREEPOST envelope provided. If you do not return the reply slip you will be contacted by telephone in 5-10 days time to find out if you are interested and eligible to take part in the study. If you are willing to take part you will be invited to attend your local physiotherapy department for an initial interview to see if you are suitable for inclusion. While you are there, you will be asked to fill in a number of questionnaires. You will be followed up by a postal questionnaire at six weeks, six months and one year after your discharge by the physiotherapist. Your GP knows about this study.

If you would like more information about this study please contact the Trial Manager, Sionnadh McLean, on 01482-675643 or Trial Co-ordinator, Mike Mooney , on 01482 675641. Additional information about the study and the Institute is enclosed.

I do hope that you will agree to take part, but if you decide not to this will not affect any treatment you receive from your physiotherapy department.

Yours faithfully

Professor Jennifer Klaber Moffett, PhD MSc MCSP
Deputy Director, Institute of Rehabilitation

Headed Paper

Patient Information Sheet

A Randomised Controlled Study of Graded Exercise Therapy and "Physiotherapy as Usual" for Patients with Mechanical Neck Pain

We wish to invite you to take part in a research study. Before you decide whether to do so, please read the following information carefully and discuss it with friends, relatives and your GP if you wish. Please ask if there is anything that it not clear or if you would like more information. You will be given as much time as you want to make a decision.

What is the purpose of this study?

Neck pain is a very common, painful and sometimes disabling complaint. Physiotherapy and exercise are both common ways of treating patients with neck pain. However the extent to which these treatments help patients with their pain and quality of life is not well understood. In recent years there has been increasing national and international interest in assessing the effectiveness of conservative (non-surgical) neck treatment and finding out who benefits. Both the Chartered Society of Physiotherapy and the Institute of Rehabilitation have identified research into neck pain as one of their research priorities.

The aim of this study is to evaluate the long term (ie 12 months) effectiveness of physiotherapy and graded exercise programmes on 150 patients with neck pain.

Why have I been invited?

We are inviting patients, aged 18 years or over, with neck pain, to become involved in this study. This neck problem may or may not be accompanied by headaches or arm symptoms. The patients we are looking for should be able to travel to the physiotherapy department where you have been referred and be able to get on and off a bed without help.

You have been invited to take part in this research project because you have been referred by your doctor for physiotherapy, because of your neck pain. If you are not currently having treatment or have not had treatment for you neck in the past 3 months then you may be eligible for this study.

What will happen if I decide to take part?

If you are interested in being involved in the study, our research trial co-ordinator will initially contact you by telephone. This will provide you with the opportunity to ask questions about the trial. She will also ask you about your neck problem and general health and let you know whether you would be potentially suitable for the trial.

If you decide to enter the trial, you will be given a mutually convenient appointment to meet the trial co-ordinator at the physiotherapy department where you have been referred. You will have the opportunity to ask further questions if you need to and you will be asked to sign a consent form to say that you agree to be involved with the trial. You will then be asked to complete some questionnaires which will give us information about your neck and arms and your general physical and

psychological well being. It will take you between 20 and 30 minutes to complete these questionnaires. The researcher will help you complete the questionnaires if you need help. After this you will be randomly allocated to either physiotherapy treatment or graded exercise treatment. You will then be offered an appointment to see the physiotherapist who will be responsible for your treatment. If you are in the exercise group you will asked to attend between 9 to 12 sessions over a 6 week period. If you are in the physiotherapy group you may need to see your physiotherapist on average 4 to 6 times.

Once you have started treatment you will be seen at the physiotherapy department at regular intervals until your treatment is completed. Treatment will usually last 4-6 weeks . This is about normal for treatment in a physiotherapy department. Once treatment is finished you will be asked to complete questionnaires on three more occasions; immediately after treatment has finished, again after 6 months and finally 12 months after your treatment has finished. These questionnaires will be posted to you.

What do I have to do?

You will attend your physiotherapy treatment or graded exercise sessions in the same way as all other patients attending the physiotherapy department. The only addition will be your meeting with the trial co-ordinator before treatment begins and completing questionnaires at the beginning and end of treatment.

Do I have to take part?

Only if you want to.

Participation is voluntary, you may refuse to participate or withdraw from the study at any time. But please let us know if you are unable fully to take part, as doing only parts of the study, rather than all of it, will affect the value of the research. You do not need to tell us why you do not want to take part. If you choose to withdraw or not to participate, your decision will in no way affect your future treatment. It may be that the investigator or sponsor of the study consider that it is in your interests to withdraw you or stop the study altogether.

Are there any risks involved?

There are no known risks. This is not a drug trial and simply compares two methods of physiotherapy treatment.

Are there any costs involved?

There will be no costs involved for you, other than the usual cost of getting to the physiotherapy department. The only extra time costs will be incurred at the first session when you meet with the research trial co-ordinator at the physiotherapy department. This will involve about 45 minutes of discussion and assessment.

Confidentiality

In order to meet legal obligations, a member of the Institute of Rehabilitation may inspect your hospital records. Details of your treatment and your past relevant medical history as required for the study, will be recorded on a Case Record Form

(CRF) the information from which will be entered onto computer at the Institute of Rehabilitation A CRF includes all information collected in the course of the research study. This information will be retained by the Institute of Rehabilitation and will only be made available to the members of the research team at the Institute of Rehabilitation. The records will identify you only by a number (not your hospital number) and your initials. All information in your notes and CRF will be treated in strict confidence.

The information from this study will be retained at the Institute of Rehabilitation until the data is analysed.
In order to ensure that physiotherapy staff not involved with the study are aware of your participation in it, an alert notice will be attached to the cover of your physiotherapy notes.
By signing the consent form, when you meet the trial co-ordinator, you will be giving permission for the above to occur. A copy of the informed consent form will be kept with the CRF and you will be given a copy.

If you agree to participate in this study, your General Practitioner will be informed, unless you state otherwise.

Your rights

Your participation in this study is entirely voluntary and refusal will not affect any other medical treatment. You may, without giving reason, refuse to take part in the trial, and this will not in any way affect your continuing treatment by your physiotherapist. Your physiotherapist will give you any relevant updated information about procedures that may occur during the study.

Who is organising and funding the research?

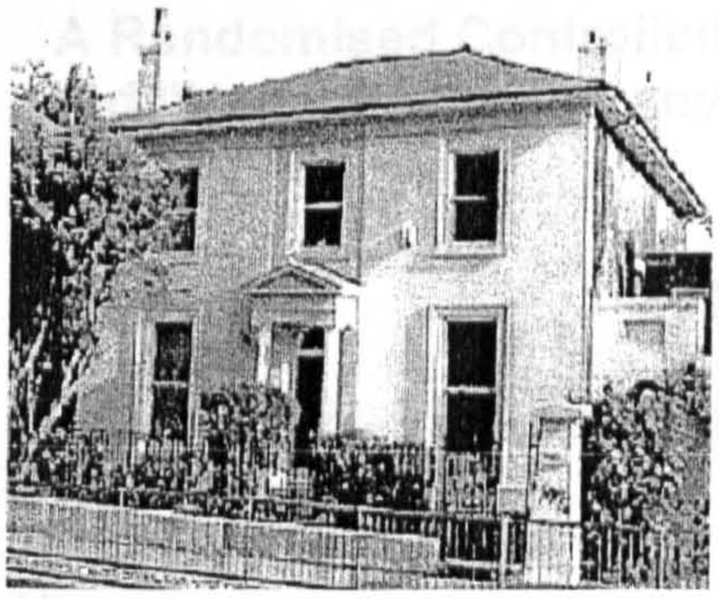
The study has been sponsored by the Institute of Rehabilitation, which is part of the University of Hull. It is being supported by the physiotherapy departments at Hull & East Yorkshire Hospitals NHS Trust and Wycombe NHS Primary Care Trust.

Trial-related injury

If you suffer from illness or injury during the study, or have any questions about the research study, please contact Sionnadh McLean at the Institute of Rehabilitation on 01482-675643 or Caroline Pickering, Trial Co-ordinator, on 01482 675644.

Thank you.

Professor Jennifer Klaber Moffett, PhD, MSc, MCSP
Deputy Director
Institute of Rehabilitation



The Institute of Rehabilitation
215 Anlaby Road, Hull, HU3 2PG
Tel 01482 675046 Fax 01482 675636

BACKGROUND INFORMATION

Opened in April 1997, the Institute of Rehabilitation is a joint University and National Health Service venture. The Director is Professor Leslie G Walker and the Deputy Director is Professor Jennifer Klaber Moffett.

AIMS

The aims of the Institute are to:

1. secure blue-chip funding for nationally and internationally significant research,
2. provide local and national educational programmes,
3. enhance the professional standing of the Therapies,
4. facilitate evidence-based practice locally, and
5. provide a research resource for clinicians in Hull and the East Riding of Yorkshire.

PRINCIPLES OF THE INSTITUTE

The principles on which the Institute are based are that it be multidisciplinary, multi-agency
(acute and community services) and integrated with local service provision.

RESEARCH THEMES

Currently, there are five research themes:

1. Pain
2. The Therapies
3. Cancer
4. Fatigue
5. Cardiac Rehabilitation

PAIN AND THE THERAPIES

These two themes are directed by Professor J Klaber Moffett. Disability from musculo-skeletal disorders is a major socio-economic burden. Back and neck pain are very common and there is a need to develop and to evaluate cost-effective interventions to reduce chronic disability and distress. Four major studies are currently in progress to investigate back and neck pain.

A Randomised Controlled Study of Graded Exercise Therapy and "Usual Physiotherapy" for Patients with Mechanical Neck Pain

Freepost Reply Slip

I have read the information about this clinical study and I **do not** wish to take part.

Name: _____

Address: _____

_____

_____

Postcode: _____

Signature: _____

Date: _____

You have declined to take part in the study. But since you are within the population that interests us for research purposes, it would be helpful if we could retain some of your details for comparative purposes. These would only be your date of birth, gender and postcode.

These details will be treated confidentially and we will not disclose these to any other persons.

Please tick (√) one of the following:

- I am happy for you to retain this information for research purposes ☐

- Please do not retain this information for research purposes ☐

Please return this form in the FREEPOST envelope provided.
Thank you.

Get up Neck Trial
Telephone Checklist

Name:	
Address: Postcode:	
Date of Birth:	
Telephone (H) (W) (M)	
GP Name: GP Surgery:	

(To be completed by a member of the trial team)

Contact attempted:

Eligible for trial:
Yes ☐ No ☐

Does not want to be seen

To be seen at:

Appt made for:

Confirmation letter sent:

Introduction

Hello, my name is Sionnadh McLean / Caroline Pickering. I am phoning from the Institute of Rehabilitation at the University of Hull. I was wondering if you have received a letter from the physiotherapy department at Nottingham City Hospital about our Neck Pain study?

We are working with the physiotherapy departments in Hull, High Wycombe, Nottingham and Grimsby to try to compare two types of physiotherapy treatment for patients with neck pain.

Would you like to hear more about it?

The Trial

We want to find out if one approach to treatment is better than another in terms of making people feel better and helping them to cope better with normal daily activities.

So we are recruiting people with neck pain and then dividing them into two groups. One group has one treatment approach and the other group has the other approach.

If you are interested in being involved in our study, then you will be met by a member of our team at your local physiotherapy department. She will tell you more about the study and ask you to fill in some questionnaires. After you have had treatment we will contact you again after 6 weeks, 6 months and 12 months. This is so that we can compare how you are before and after you have had your treatment, and how you are managing in the long term. We will send you the questionnaires in the post, so you will not have to come back to the department.

If you decide to take part in the study we will have no control over which treatment group you would be allocated to. So you need to be sure that if you take part in the study, that you would be happy to go into either group.

This is what the two treatment groups are:

- Treatment 1: This consists of being seen by a physiotherapist who will examine and assess you. They will advise you on treatment options that are suitable for you and follow these through with you. This may mean that you receive a "hands on" approach and the use of specific exercises.
- Treatment 2: You will be entered into a neck and upper limb exercise programme. This programme is carried out under the supervision of a physiotherapist who has received specific training in this area. The programme consists of postural re-education, strengthening of postural muscles of the trunk and upper limbs and some additional strengthening and fitness work. The programme is done at your pace and progressed at a pace that is suitable for you.

Would you be happy to go into either group? Yes ☐ No ☐

Do you think that you might be interested in taking part in the study?
Yes ☐ No ☐

May I first ask you a few questions about your neck? This will help me to determine whether this trial is suitable for you. Any information that you give me will be kept confidential.

Have you had your neck symptoms for longer than 2 weeks?
Yes ☐ No ☐

Have you had any treatment to your neck in the last 3 months?
Yes ☐ No ☐

Are planning to see anyone else for treatment? Yes ☐ No ☐

Are you generally well? Yes ☐ No ☐

Are you able to get on/off a bed without help? Yes ☐ No ☐

Do you think that you would be able to take part in a (gentle) exercise class
Yes ☐ No ☐

Will you be using your own transport to the physiotherapy department?
Yes ☐ No ☐

Thankyou for taking the time to answer those questions. I can tell you that at this stage it would seem that

- either of the trial treatments would be suitable for you (make appt)
- the trial is not suitable for you. **(end)**

Making Appointment

Can I make an appointment to meet up with you at your local physiotherapy department. Would you like me to send you a confirmation letter with a map. **(end)**

Get Up Neck Trial – Patient Initial Assessment/Checklist

Assessment date	__/__/__ (dd/mm/yy)
Patient ID number	__/_____
Name:	
Address: Postcode:	
Date of Birth:	__/__/__ (dd/mm/yy)
Gender	Male ☐ Female ☐
Telephone Home: Work: Mobile:	
GP Name: GP Surgery:	

Routine Questions

Where are your symptoms now? (complete body chart)
Over the past 2 weeks are your pain/symptoms: getting better ☐ getting worse ☐ same ☐ If worsening, in what way: (exclude deteriorating neurological conditions eg cord signs, radiculopathy)
Complete the Quadruple Visual Analogue Scale attached
Were you involved in an accident which caused your pain?: Yes ☐ No ☐ If so, specify what type of accident? (exclude recent major trauma)
How long have you had neck/arm symptoms on this occasion? (in weeks)
How long ago did you first experience neck pain?
Have you had any physio for your neck problem in the past 3 months Yes ☐ No ☐
Have you ever injured your shoulder, arm or hand substantially Yes ☐ No ☐ If yes, please specify (exclude injuries which has resulted in current or prolonged disability)
Is your weight steady? Yes ☐ No ☐ (exclude unintentional weight loss)
Is your appetite OK? Yes ☐ No ☐
Are you sleeping OK at night? Yes ☐ No ☐ (exclude very severe night pain problems)
Are you having any problems with dizziness, double vision, speech, swallowing, LOC? Yes ☐ No ☐ If so, specify what type of problems. (exclude vertebral artery problems)
Do you have any general medical problems? Yes ☐ No ☐

If so, specify what.
(Exclude – severe rheumatoid arthritis, severe multiple sclerosis, cancer, osteoporosis, cardiac conditions, severe SOBOE, uncontrolled hypertension, postural hypotension, balance problems)

Do you smoke? Yes ☐ No ☐

What is your usual work?

At present are you
(cross all relevant boxes)

- In employment ☐
- Unemployed ☐
- On sick leave ☐
- Other (specify) ☐

How old were you when you left school?

How many working days have you had off work,
due to your neck and/or arm pain in the last 6 months?

If you are not in paid employment, how many days in the last 6 months have you been unable to carry out your normal activities (eg gardening, socialising, sport) because of your neck

In the last 3 months, how often do you usually exercise?
(exercise which raises your heart rate or makes you breathe slightly harder)

- None ☐
- Less than once a month ☐
- 1-2 times per month ☐
- 1-2 times per week ☐
- 3-4 times per week ☐
- More than 4 times per week ☐

What sort of exercise do you do?

I would like to ask you about your preference for treatment, even though I have no control over which treatment you will receive

Do you have a preference over which treatment you would like? Yes ☐ No ☐
If yes, which type of physiotherapy intervention would you prefer?
• Graded group exercise programme in physiotherapy department ☐
• Home exercise programme ☐
• Individual treatment with a physiotherapist ☐
• BI – Assessment and advice only by a physiotherapist ☐

Objective Examination (if required

QUADRUPLE VISUAL ANALOGUE SCALE

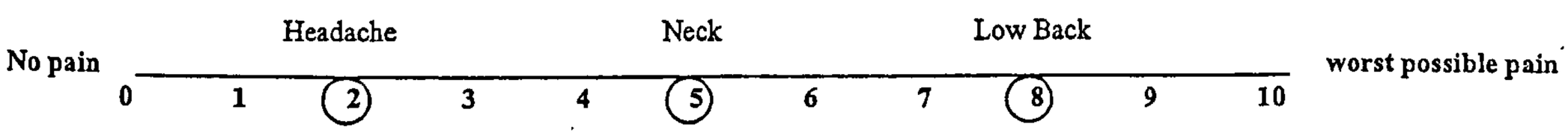
Patient Name _____ Date _____

Please read carefully:

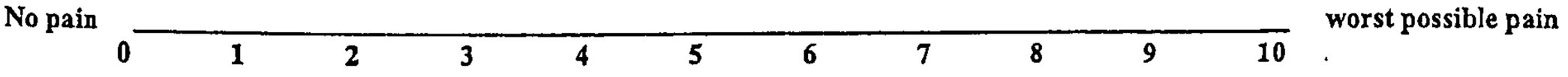
Instructions: Please circle the number that best describes the question being asked.

Note: If you have more than one complaint, please answer each question for each individual complaint and indicate the score for each complaint. Please indicate your pain level right now, average pain, and pain at its best and worst.

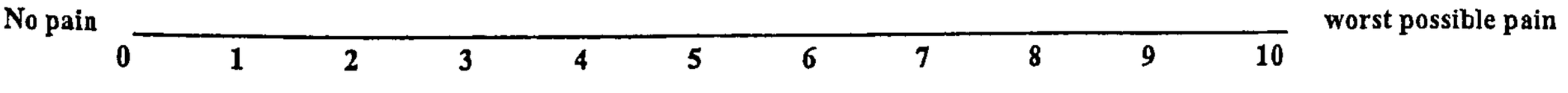
Example:



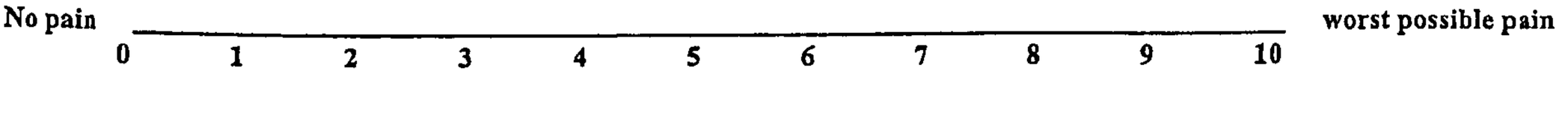
1 – What is your pain RIGHT NOW?



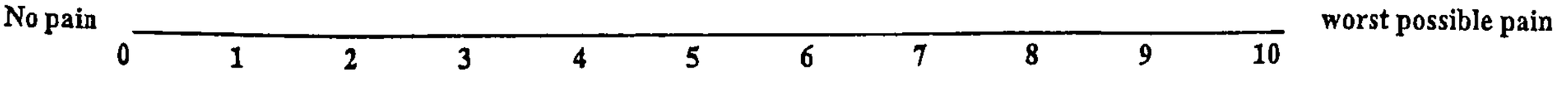
2 – What is your TYPICAL or AVERAGE pain?



3 – What is your pain level AT ITS BEST (How close to "0" does your pain get at its best)?



4 – What is your pain level AT ITS WORST (How close to "10" does your pain get at its worst)?

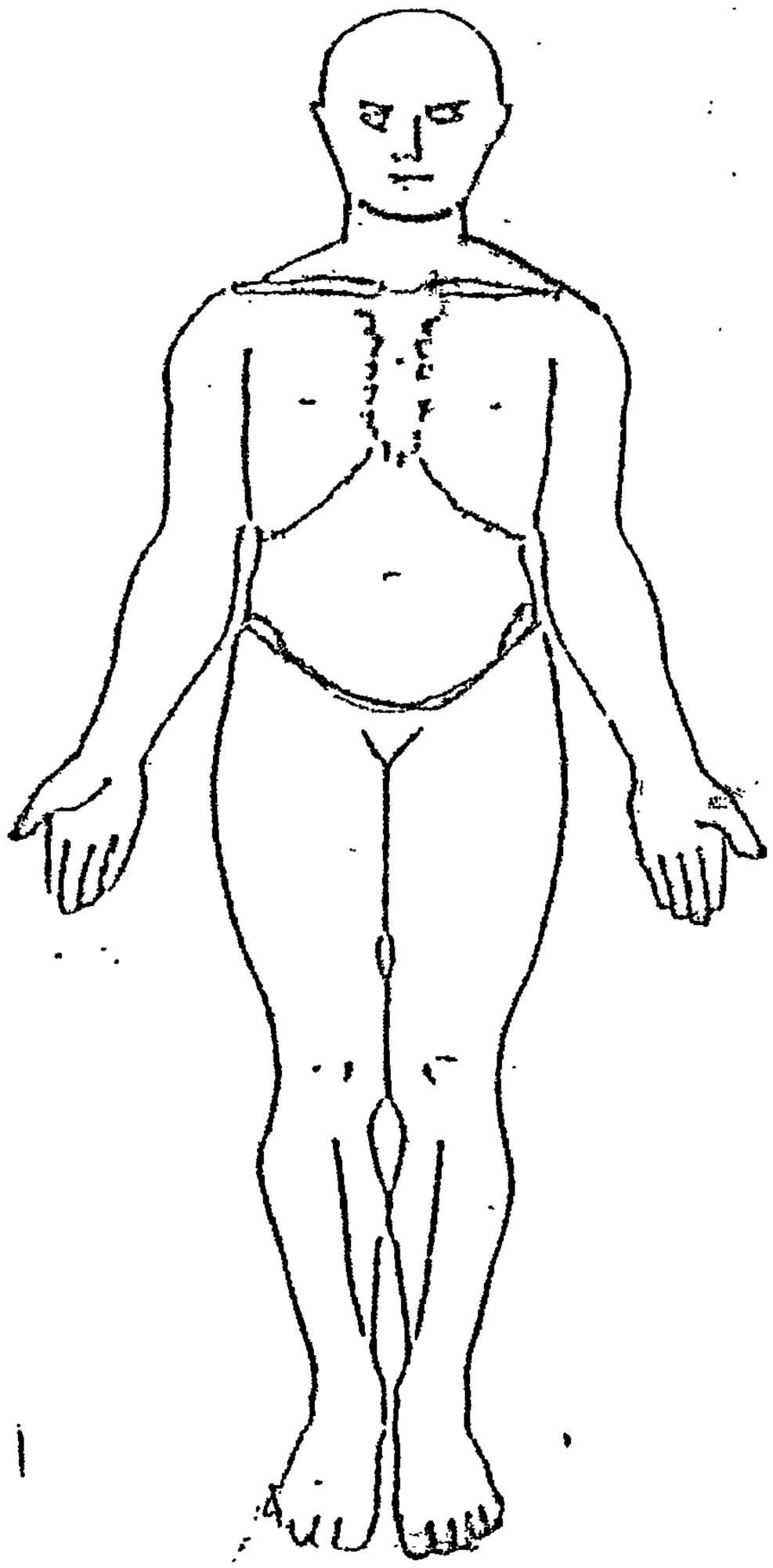


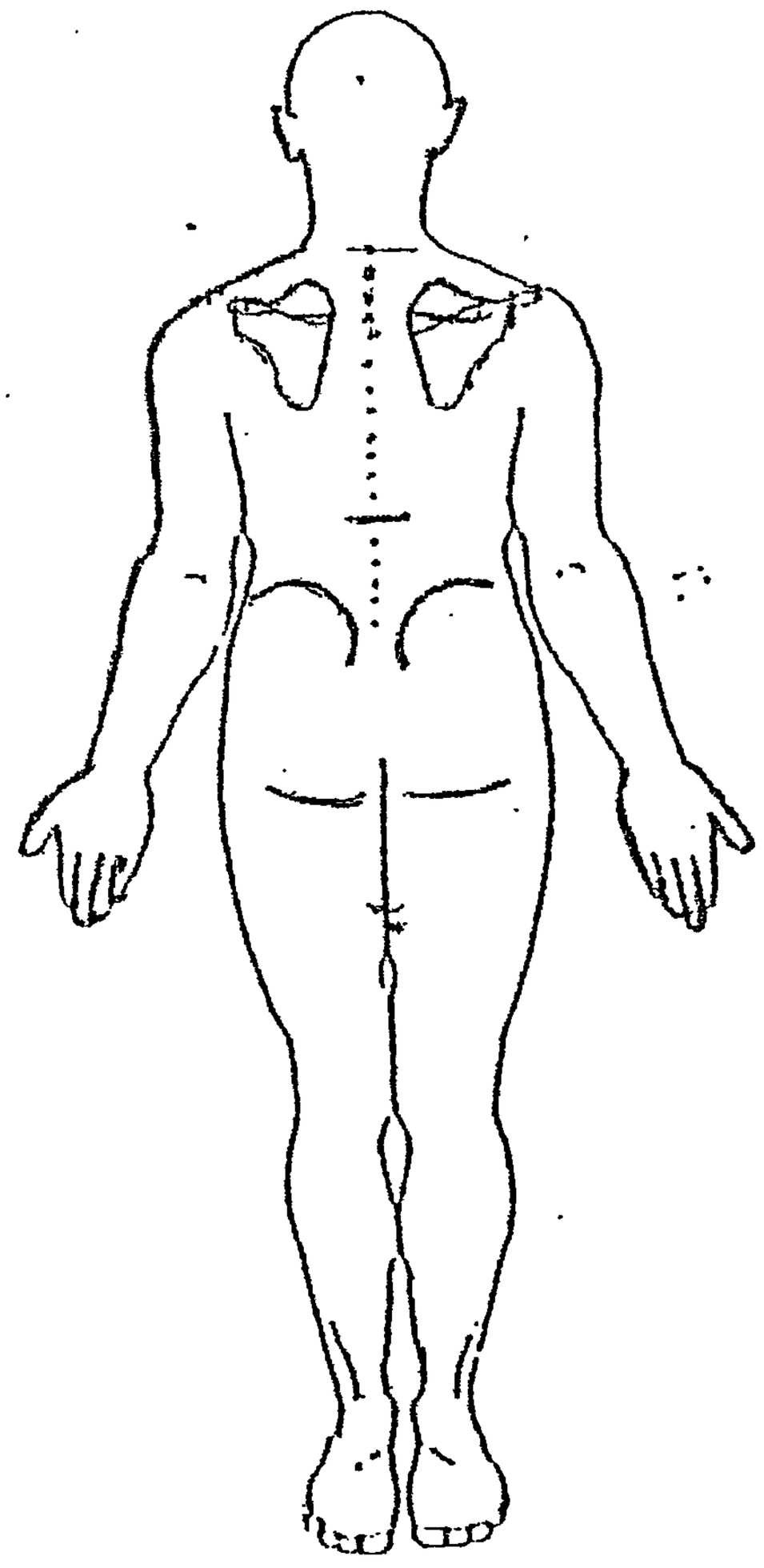
OTHER COMMENTS:

_____

_____

_____
Examiner






Get up
Baseline Questionnaire
In confidence

Get up Neck Trial

Baseline Questionnaire

Please carefully read all the instructions in each section before completing the questionnaire.

Please answer **all** the questions by placing a cross (☒) in the relevant box. Although it may seem that questions are asked more than once, it is still important that you answer everyone.

In each section it is your first response that we are interested in, so please do not think about your answer for too long.

In confidence

THE UNIVERSITY OF HULL

The Institute of Rehabilitation
215 Anlaby Road, Hull HU3 2PG

Wycombe NHS
Primary Care Trust

Northern Lincolnshire and Goole Hospitals NHS
NHS Trust

Hull and East Yorkshire Hospitals NHS
Anlaby Road, Hull HU3 2JZ
NHS Trust

Nottingham City Hospital NHS
NHS Trust

Get up Neck Pain Trial – Patient Initial Assessment

This section will be filled in for you. Please go to the next page.

1. Postcode ☐☐☐☐ ☐☐☐☐

2. Gender ☐ Male ☐ Female

3. What is your age? ☐☐ years

4. Body chart score ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

5. Quadruple Visual Analogue Score ☐☐ Part 1 ☐☐ Part 2 ☐☐ Part 3 ☐☐ Part 4

6. How many weeks have you been having neck/arm symptoms on this occasion? ☐☐☐ weeks

7. Length of neck pain overall? ☐☐☐ weeks

8. Do you smoke? ☐ Yes ☐ No

9. What is your usual work?

10. At present are you: ☐ In employment ☐ Unemployed ☐ On sick leave
☐ Other *(please specify)*

11. Your age on leaving school? ☐☐

12. Lost working days due to neck last 6 months? ☐☐☐

13. Lost days of normal activity due to neck last 6 months? ☐☐☐

14. How often do you usually exercise?

☐ None ☐ 1-3 times per month ☐ 3-4 times per week
☐ Less than once a month ☐ 1-2 times per week ☐ More than 4 times per week

15. What sort of exercise do you do?

☐ High ☐ Low intensity ☐ LL
☐ Moderate ☐ UL

16. Which type of physiotherapy intervention would you prefer?

☐ GET ☐ IT ☐ No preference
☐ HEP ☐ BI

OFFICE USE ONLY I.D. Number ☐☐–☐☐☐ Date ☐☐/☐☐/☐☐☐☐

☐ Section1

This section has been designed to give us information as to how your NECK PAIN has affected your ability to manage everyday life. Please answer every question and mark with a cross ONLY THE ONE BOX which applies to you. We realise you may consider that two of the statements in any one section relates to you, but please just mark the box which most closely describes your problem.

Remember, just **mark one box** in each question. It is your first response that we are interested in, so please do not think about your answer for too long.

1. NECK PAIN INTENSITY

☐ I have no pain at the moment
☐ The pain is mild at the moment
☐ The pain is moderate at the moment
☐ The pain is severe at the moment
☐ The pain is the worst imaginable at the moment

---

2. NECK PAIN AND SLEEPING

☐ My sleep is never disturbed by pain
☐ My sleep is occasionally disturbed by pain
☐ My sleep is regularly disturbed by pain
☐ Because of pain I have less than 5 hours of sleep in total
☐ Because of pain I have less than 2 hours of sleep in total

---

3. PINS & NEEDLES OR NUMBNESS IN THE ARMS AT NIGHT

☐ I have no pins & needles or numbness at night
☐ I have occasional pins & needles or numbness at night
☐ My sleep is regularly disturbed by pins & needles or numbness
☐ Because of pins & needles I have less than 5 hours sleep in total
☐ Because of pins & needles or numbness I have less than 2 hours sleep in total

---

4. DURATION OF SYMPTOMS

☐ My neck and arms feel normal all day
☐ I have symptoms in my neck or arms on waking, which last less than 1 hour
☐ Symptoms are present on and off for a total period of 1-4 hours
☐ Symptoms are present on and off for a total period of more than 4 hours
☐ Symptoms are present continuously all day

5. CARRYING

- ☐ I can carry heavy objects without extra pain
- ☐ I can carry heavy objects, but they give me extra pain
- ☐ Pain prevents me from carrying heavy objects, but I can manage medium weight objects
- ☐ I can only lift lightweight objects
- ☐ I cannot lift anything at all

---

6. READING & WATCHING T.V.

- ☐ I can do this as long as I wish with no problems
- ☐ I can do this as long as I wish, if I'm in a suitable position
- ☐ I can do this as long as I wish, but it causes extra pain
- ☐ Pain causes me to stop doing this sooner than I would like
- ☐ Pain prevents me from doing this at all

---

7. WORKING / HOUSEWORK ETC

- ☐ I can do my usual work without extra pain
- ☐ I can do my usual work, but it gives me extra pain
- ☐ Pain prevents me from doing my usual work for more than half the usual time
- ☐ Pain prevents me from doing my usual work for more than a quarter the usual time
- ☐ Pain prevents me from working at all

---

8. SOCIAL ACTIVITIES

- ☐ My social life is normal and causes me no extra pain
- ☐ My social life is normal, but increases the degree of pain
- ☐ Pain has restricted my social life, but I am still able to go out
- ☐ Pain has restricted my social life to the home
- ☐ I have no social life because off pain

---

9. DRIVING (Omit this section if you never drive a car)

- ☐ I can drive whenever necessary without discomfort
- ☐ I can drive whenever necessary, but with discomfort
- ☐ Neck pain or stiffness limits my driving occasionally
- ☐ Neck pain or stiffness limits my driving frequently
- ☐ I cannot drive at all due to neck symptoms

Please turn over...

☐ Section2

This section asks you about your symptoms as well as your ability to perform certain activities. Please answer every question, based on your condition in the last week. If you did not have the opportunity to perform an activity in the past week, please make your best estimate on which response would be the most accurate. It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

Please rate your ability to do the following activities in the last week by crossing the boxes below the appropriate response.	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
1. Open a tight or new jar	☐	☐	☐	☐	☐
2. Write	☐	☐	☐	☐	☐
3. Turn a key	☐	☐	☐	☐	☐
4. Prepare a meal	☐	☐	☐	☐	☐
5. Push open a heavy door	☐	☐	☐	☐	☐
6. Place an object on the shelf above your head	☐	☐	☐	☐	☐
7. Do heavy household chores (e.g. wash walls, wash floors)	☐	☐	☐	☐	☐
8. Garden or do yard work	☐	☐	☐	☐	☐
9. Make a bed	☐	☐	☐	☐	☐
10. Carry a shopping bag or briefcase	☐	☐	☐	☐	☐
11. Carry a heavy object (over 10 lbs)	☐	☐	☐	☐	☐
12. Change a light bulb overhead	☐	☐	☐	☐	☐
13. Wash or blow dry your hair	☐	☐	☐	☐	☐
14. Wash your back	☐	☐	☐	☐	☐
15. Put on a pullover sweater	☐	☐	☐	☐	☐
16. Use a knife to cut food	☐	☐	☐	☐	☐
17. Recreational activities which require little effort (e.g. card playing, knitting etc)	☐	☐	☐	☐	☐
18. Recreational activities in which you take some force or impact through your hand (e.g. golf, hammering, tennis etc)	☐	☐	☐	☐	☐
19. Recreational activities in which you move your arm freely (e.g. playing Frisbee, badminton, etc)	☐	☐	☐	☐	☐
20. Manage transportation needs (getting from one place to another)	☐	☐	☐	☐	☐
21. Sexual activities	☐	☐	☐	☐	☐

	Not at all	Slightly	Moderately	Quite a bit	Extremely
22. During the past week, to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	☐	☐	☐	☐	☐
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	☐	☐	☐	☐	☐

Please rate the severity of the following symptoms in the last week	None	Mild	Moderate	Severe	Extreme
24. Arm, shoulder or hand pain	☐	☐	☐	☐	☐
25. Arm shoulder or hand pain when you perform any specific activity	☐	☐	☐	☐	☐
26. Tingling (pins and needles) in your arm, shoulder or hand	☐	☐	☐	☐	☐
27. Weakness in your arm, shoulder or hand	☐	☐	☐	☐	☐
28. Stiffness in your arm, shoulder or hand	☐	☐	☐	☐	☐

	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	So much that I can't sleep
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand?	☐	☐	☐	☐	☐

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem?	☐	☐	☐	☐	☐

Section3

This section asks you to rate how self-confident you are that you can do the following things at present, despite the pain. Please answer every question and mark with a cross in the box that best describes how confident you are ranging from not 'confident at all' to 'completely confident'.

Remember, this section is not asking whether or not you have been doing these things, but rather, how confident you are that you can do them at the present, despite the pain.

	Not at all confident						Completely confident
1. I can still enjoy things, despite the pain	☐	☐	☐	☐	☐	☐	☐
2. I can still do most of the household chores (eg. tidying up, washing dishes etc) despite the pain	☐	☐	☐	☐	☐	☐	☐
3. I can socialise with my friends or family members as often as I used to, despite the pain	☐	☐	☐	☐	☐	☐	☐
4. I can cope with my pain in most situations	☐	☐	☐	☐	☐	☐	☐
5. I can do some sort of work, despite the pain ("work" includes housework, paid or unpaid work)	☐	☐	☐	☐	☐	☐	☐
6. I can still do many of the things I enjoy doing, such as hobbies or leisure activities despite the pain	☐	☐	☐	☐	☐	☐	☐
7. I can cope with my pain without medication	☐	☐	☐	☐	☐	☐	☐
8. I can still accomplish most of my goals in life, despite the pain	☐	☐	☐	☐	☐	☐	☐
9. I can still live a normal lifestyle, despite the pain	☐	☐	☐	☐	☐	☐	☐
10. I can gradually become more active, despite the pain	☐	☐	☐	☐	☐	☐	☐

Please turn over...

101879-7/020704/KPS

☐ Section4

Clinicians are aware that emotions play an important part in most illness. If your clinician knows about these feelings she or he will be able to help you more. This questionnaire is designed to help your clinician to know how you feel.

Read each item and place a cross in the box for each question, which comes closest to how you have been feeling in the past week. Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a thought-out response.

1. I feel tense or 'wound up':

☐ Most of the time ☐ A lot of the time ☐ From time to time, occasionally ☐ Not at all

2. I still enjoy the things I used to enjoy:

☐ Definitely as much ☐ Not quite so much ☐ Only a little ☐ Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen:

☐ Very definitely and quite badly ☐ A lot of the time ☐ From time to time, occasionally ☐ Not at all

4. I can laugh and see the funny side of things:

☐ As much as I always could . ☐ Not quite so much now ☐ Definitely not so much now ☐ Not at all

5. Worrying thoughts go through my mind:

☐ A great deal of the time ☐ A lot of the time ☐ From time to time but not too often ☐ Only occasionally

6. I feel cheerful:

☐ Not at all ☐ Not often ☐ Sometimes ☐ Most of the time

7. I can sit at ease and feel relaxed:

☐ Definitely ☐ Usually ☐ Not often ☐ Not at all

8. I feel as if I am slowed down:

☐ Nearly all the time ☐ Very often ☐ Sometimes ☐ Not at all

9. I get a sort of frightened feeling like 'butterflies' in the stomach:

☐ Not at all ☐ Occasionally ☐ Quite often ☐ Very often

10. I have lost interest in my appearance:

☐ Definitely ☐ I don't take as much care as I should ☐ I may not take quite as much care ☐ I take just as much care as ever

11. I feel restless as if I have to be on the move:

☐ Very much indeed ☐ Quite a lot ☐ Not very much ☐ Not at all

12. I look forward with enjoyment to things:

☐ As much as I ever did ☐ Rather less than I used to ☐ Definitely less than I used to ☐ Hardly at all

13. I get sudden feelings of panic:

☐ Very often indeed ☐ Quite often ☐ Not very often ☐ Not at all

14. I can enjoy a good book or radio or TV programme:

☐ Often ☐ Sometimes ☐ Not often ☐ Very Seldom

Section5

This is a list of phrases that other people have used to express how they view their condition. Please indicate the extent to which you agree with each statement by placing a cross in the appropriate box.

	Strongly disagree	Somewhat disagree	Somewhat agree	Strongly agree
1. I'm afraid that I might injure myself if I exercise	☐	☐	☐	☐
2. If I were to try to overcome it, my pain would increase	☐	☐	☐	☐
3. My body is telling me I have something dangerously wrong	☐	☐	☐	☐
4. My pain would probably be relieved if I were to exercise	☐	☐	☐	☐
5. People aren't taking my medical condition seriously enough	☐	☐	☐	☐
6. My condition has put my body at risk for the rest of my life	☐	☐	☐	☐
7. Pain always means I have injured my body	☐	☐	☐	☐
8. Just because something aggravates my pain does not mean it is dangerous	☐	☐	☐	☐
9. I'm afraid that I might injure myself accidentally	☐	☐	☐	☐
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	☐	☐	☐	☐
11. I wouldn't have this much pain if there wasn't something potentially dangerous going on in my body	☐	☐	☐	☐
12. Although my condition is painful, I would be better off if I were physically active	☐	☐	☐	☐
13. Pain lets me know when to stop exercises so that I don't injure myself	☐	☐	☐	☐
14. It's really not safe for a person with a condition like mine to be physically active	☐	☐	☐	☐
15. I can't do all the things normal people do because it's too easy for me to get injured	☐	☐	☐	☐
16. Even though something is causing me a lot of pain, I don't think its actually dangerous	☐	☐	☐	☐
17. No one should have to exercise when he/she is in pain	☐	☐	☐	☐

Please turn over...

Section6

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 put a cross in the box that best describes your level of activity ranging from 0 'never do that' to 6 'always do that'.

When I feel pain.....	Never		Sometimes				Always
	0	1	2	3	4	5	6
1. I try to feel distant from the pain, almost as if the pain was in somebody else's body.	☐	☐	☐	☐	☐	☐	☐
2. I leave the house and do something, such as going to the cinema or shopping	☐	☐	☐	☐	☐	☐	☐
3. I try to think of something pleasant	☐	☐	☐	☐	☐	☐	☐
4. I don't think of it as pain but rather as a dull or warm feeling	☐	☐	☐	☐	☐	☐	☐
5. It is terrible and I feel it is never going to get any better	☐	☐	☐	☐	☐	☐	☐
6. I tell myself to be brave and carry on despite the pain	☐	☐	☐	☐	☐	☐	☐
7. I read	☐	☐	☐	☐	☐	☐	☐
8. I tell myself that I can overcome the pain	☐	☐	☐	☐	☐	☐	☐
9. I count numbers in my head or run a song through my mind	☐	☐	☐	☐	☐	☐	☐
10. I just think of it as another sensation, such as numbness	☐	☐	☐	☐	☐	☐	☐
11. It is awful and I feel that it overwhelms me	☐	☐	☐	☐	☐	☐	☐
12. I play mental games with myself to keep my mind off the pain	☐	☐	☐	☐	☐	☐	☐
13. I feel my life isn't worth living	☐	☐	☐	☐	☐	☐	☐
14. I know someday someone will be here to help me and it will go away for a while	☐	☐	☐	☐	☐	☐	☐
15. I pray to god it won't last long	☐	☐	☐	☐	☐	☐	☐
16. I try not to think of it as my body, but rather as something separate from me	☐	☐	☐	☐	☐	☐	☐
17. I don't think about the pain	☐	☐	☐	☐	☐	☐	☐
18. I try to think years ahead, what everything will be like after I have got rid of the pain	☐	☐	☐	☐	☐	☐	☐
19. I tell myself it doesn't hurt	☐	☐	☐	☐	☐	☐	☐
20. I tell myself I can't let the pain stand in the way of what I have to do	☐	☐	☐	☐	☐	☐	☐
21. I don't pay any attention to it	☐	☐	☐	☐	☐	☐	☐
22. I have faith in doctors that someday there will be a cure for my pain	☐	☐	☐	☐	☐	☐	☐

When I feel pain.....	Never						Always
	0	1	2	3	4	5	6
23. No matter how bad it gets, I know I can handle it	☐	☐	☐	☐	☐	☐	☐
24. I pretend it is not there	☐	☐	☐	☐	☐	☐	☐
25. I worry all the time about whether it will end	☐	☐	☐	☐	☐	☐	☐
26. I replay in my mind pleasant experiences in the past	☐	☐	☐	☐	☐	☐	☐
27. I think of people I enjoy doing things with	☐	☐	☐	☐	☐	☐	☐
28. I pray for the pain to stop	☐	☐	☐	☐	☐	☐	☐
29. I imagine that the pain is outside of my body	☐	☐	☐	☐	☐	☐	☐
30. I just go on as if nothing happened	☐	☐	☐	☐	☐	☐	☐
31. I see it as a challenge and don't let it bother me	☐	☐	☐	☐	☐	☐	☐
32. Although it hurts, I just keep on going	☐	☐	☐	☐	☐	☐	☐
33. I feel I can't stand it anymore	☐	☐	☐	☐	☐	☐	☐
34. I try to be around other people	☐	☐	☐	☐	☐	☐	☐
35. I ignore it	☐	☐	☐	☐	☐	☐	☐
36. I rely on my faith in god	☐	☐	☐	☐	☐	☐	☐
37. I feel I can't go on	☐	☐	☐	☐	☐	☐	☐
38. I think of things I enjoy doing	☐	☐	☐	☐	☐	☐	☐
39. I do anything to get my mind off the pain	☐	☐	☐	☐	☐	☐	☐
40. I do something I enjoy, such as watching television or listening to music	☐	☐	☐	☐	☐	☐	☐
41. I pretend it is not part of me	☐	☐	☐	☐	☐	☐	☐
42. I do something like household chores or projects	☐	☐	☐	☐	☐	☐	☐

	No Control			Some Control			Complete Control
	0	1	2	3	4	5	6
43. Based on all the things you do to cope or deal with your pain, on an average day, how much control do you feel you have over it	☐	☐	☐	☐	☐	☐	☐

	Can't decrease it at all			Can decrease it somewhat			Can decrease it completely
	0	1	2	3	4	5	6
44. Based on all the things you do to cope with your pain, on an average day, how much are you able to decrease it?	☐	☐	☐	☐	☐	☐	☐

Thank you for completing this questionnaire

Get up Neck Trial

Baseline Questionnaire

THE UNIVERSITY OF HULL

The Institute of Rehabilitation
215 Anlaby Road, Hull HU3 2PG

Wycombe NHS
Primary Care Trust

Northern Lincolnshire and Goole Hospitals NHS
NHS Trust

Hull and East Yorkshire Hospitals NHS
Anlaby Road, Hull HU3 2JZ
NHS Trust

Nottingham City Hospital NHS
NHS Trust

Headed Paper

INFORMED CONSENT

A Randomised Controlled Study of Graded Exercise Therapy and "Usual Physiotherapy" for Patients with Mechanical Neck Pain

Protocol number/identifier

NAME OF LOCAL LEAD RESEARCHER:_____

SUBJECT ID or HOSPITAL NO:

		Please initial box
1	I confirm that I have read and understand the information sheet dated 01 Nov 03 (version 1) for the above study and have had the opportunity to ask questions.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3	I understand that sections of any of my medical notes relating to my taking part in the study may be looked at by responsible individuals from the Institute of Rehabilitation or from the appropriate regulatory authority(ies). I give permission for these individuals to have access to my records.	☐
4	I agree to take part in the above study.	☐

Name of Subject (BLOCK CAPITALS)	Date	Signature

Name of Person taking consent	Date	Signature

Researcher/witness	Date	Signature

1 copy for subject; 1 for researcher; 1 to be kept with hospital notes

Institute of Rehabilitation
215 Anlaby Road
Hull
HU3 2PG
Telephone: 01482-675643
Fax: 01482-675636
Email: S.M.McLean@hull.ac.uk

19th October 2004

Dear Dr

Re:

A Randomised Controlled Study of Graded Exercise Therapy and "Usual Physiotherapy" for Patients with Mechanical Neck Pain
Reference No.

I am writing to inform you that your patient has been enrolled into the above research study.

The purpose of the study is to evaluate the long term effectiveness of physiotherapy and exercise on 150 patients with neck pain. Patients will be randomised to receive one of two interventions: Usual physiotherapy or a graded neck and upper limb exercise programme, for a period of about 6-8 weeks. Once treatment has been completed the patients will be discharged from the physiotherapy department in the usual way. Patients will be followed up with postal questionnaires at the end of treatment, after 6 months and 1 year.

If you have any questions regarding any of the above, please feel free to contact me on 01482-675643

Yours sincerely

Sionnadh McLean
Superintendent II Physiotherapist

Neck Exercise Class – Information Sheet

You have agreed to participate in an exercise class which has been designed for patients with neck and upper limb problems. This class will run twice every week for 6 weeks, in the physiotherapy department at Castle Hill Hospital. You have been asked to attend between 6-12 sessions. It is important that you attend at least 6 sessions. Each class will last between 20-60 minutes depending upon your neck pain and general fitness levels.

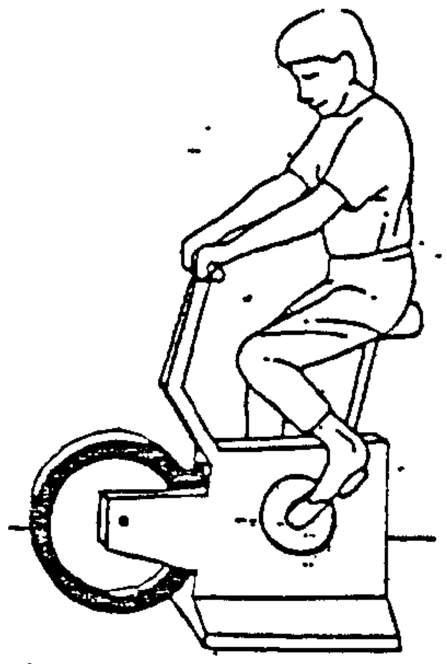
The class is supervised by a specially trained physiotherapist. The exercises will include some warm up exercise, gentle stretching exercises to get your neck and arm joints moving and finally some general fitness and strengthening exercises. The programme is designed to improve your postural control and strengthen the postural muscle of your neck and arms. The programme is done at your pace and is progressed at a pace that is suitable for you. You will be given a copy of the exercise programme to take home with you and you are encouraged to try these exercises at home.

You may experience a little post exercise soreness for a day or two after the exercise class. This is quite normal and you should not worry about this. Your physiotherapist will be available to answer any questions or concerns that you may have. The physiotherapist responsible for running this class is Joanne Minshall.

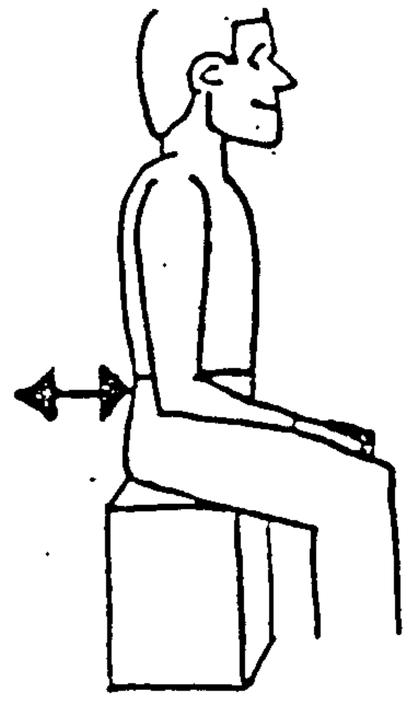
You should wear loose comfortable clothing which is easy to move around in.

The classes will take place at the times stated below.

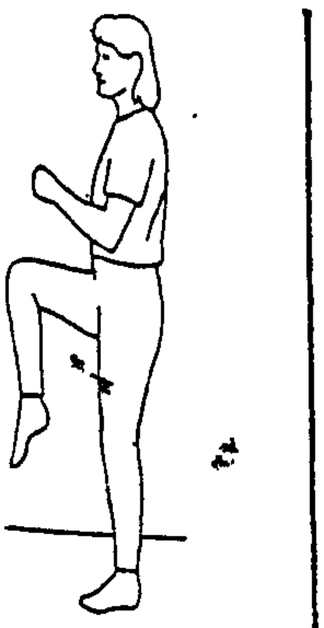
Day	Date	Time
Friday	12/11/04	3.00-4.00 pm
Monday	15/11/04	3.00-4.00 pm
Friday	19/11/04	3.00-4.00 pm
Monday	22/11/04	3.00-4.00 pm
Friday	26/11/04	3.00-4.00 pm
Monday	29/11/04	3.00-4.00 pm
Friday	3/12/04	3.00-4.00 pm
Monday	6/12/04	3.00-4.00 pm
Friday	10/12/04	3.00-4.00 pm
Monday	13/12/04	3.00-4.00 pm
Friday	17/12/04	3.00-4.00 pm
Monday	20/12/04	3.00-4.00 pm



Cycling



Pelvic Tilting



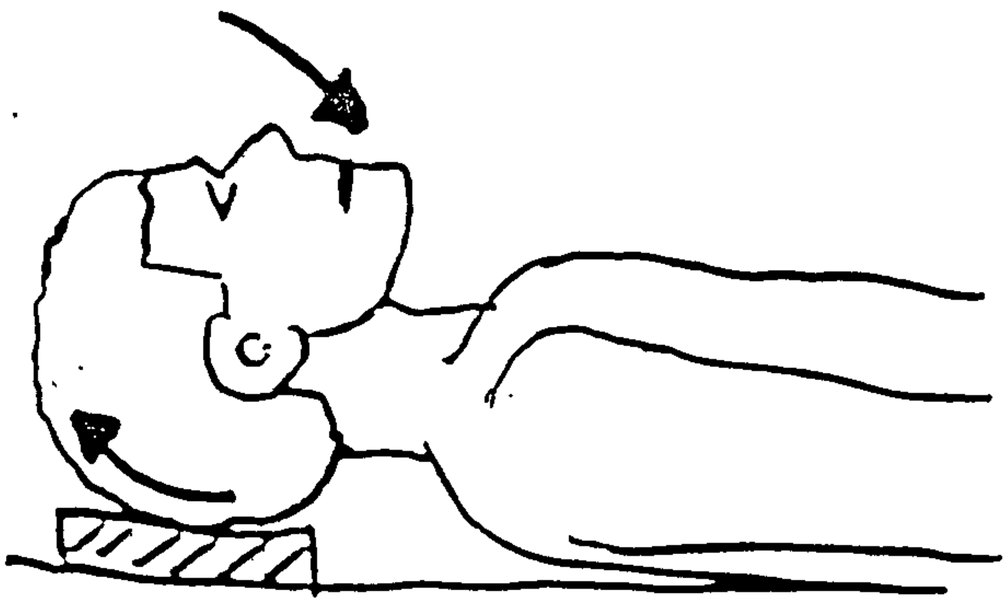
Marching on the Spot

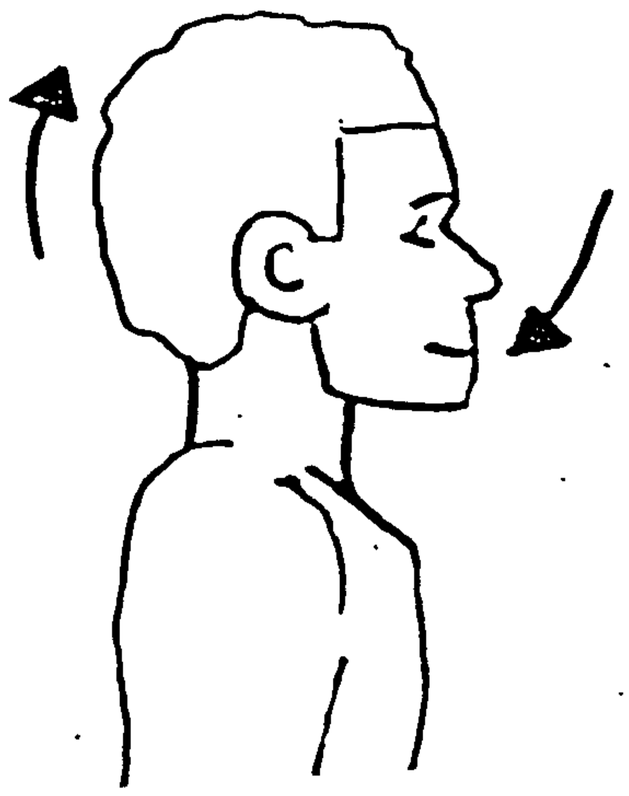
OR

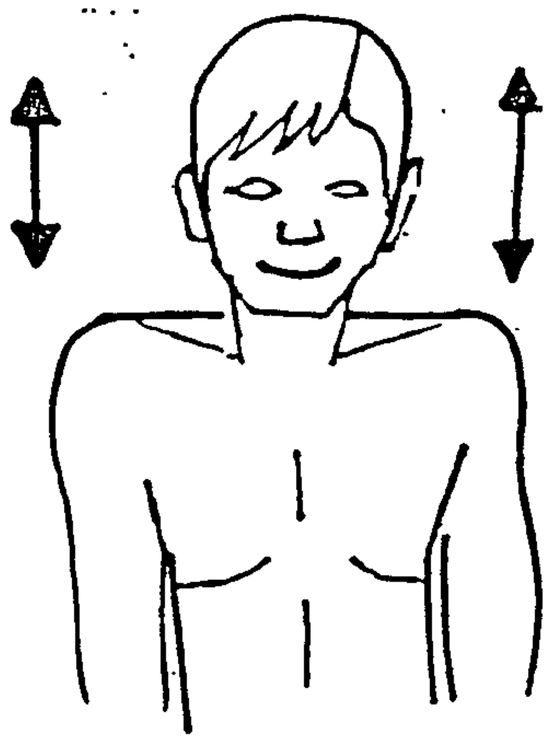
Jogging on the Spot

OR

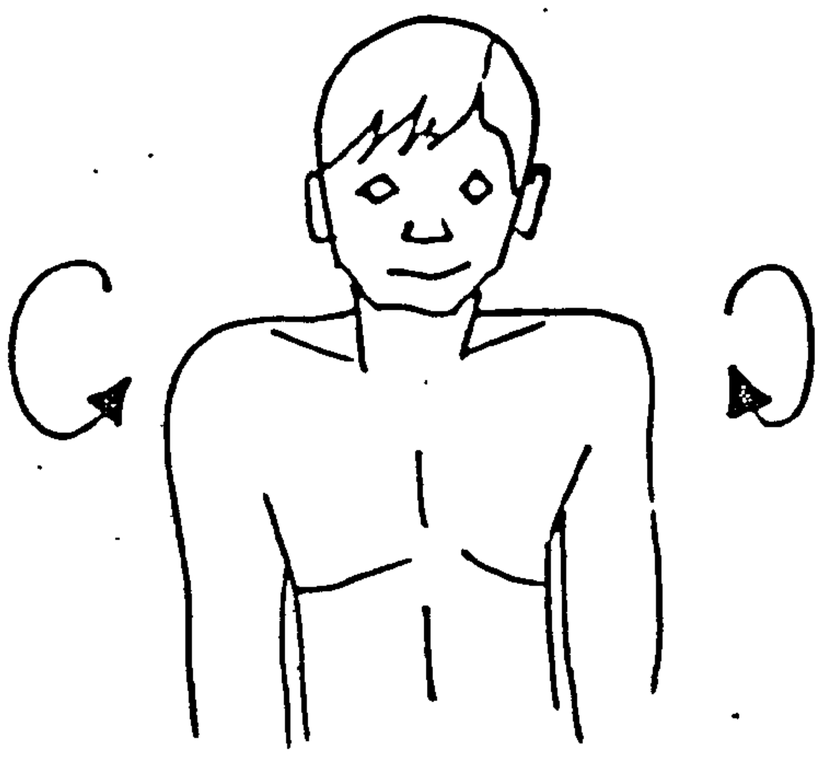
Jogging



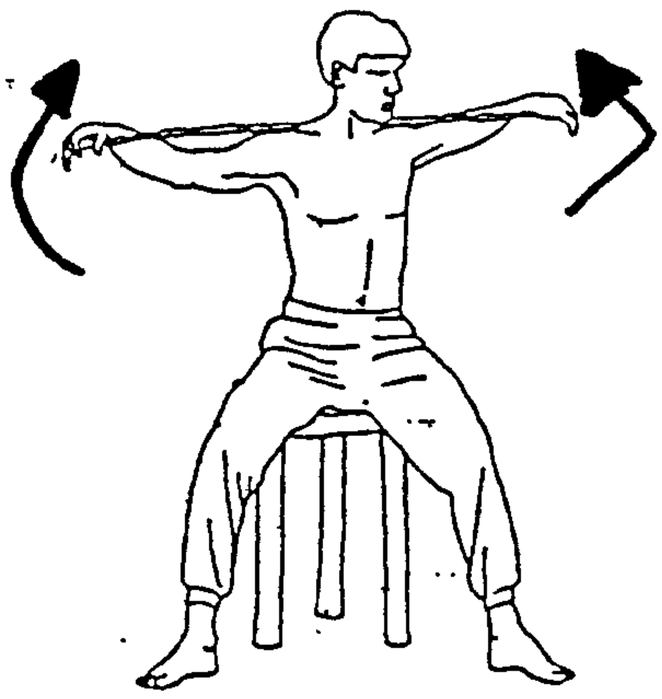




Shrug your shoulders up and down

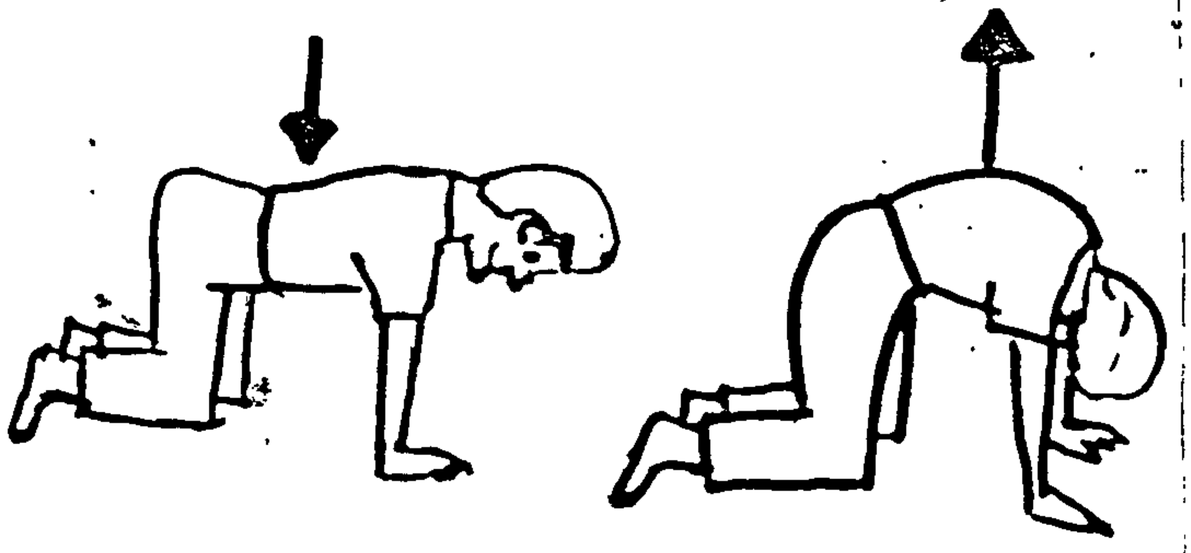


Circle your shoulders

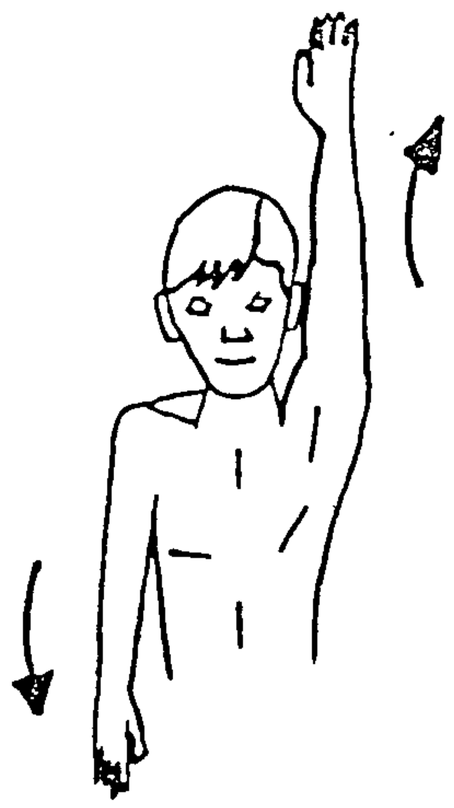


Sit on chair and turn your trunk left and then right

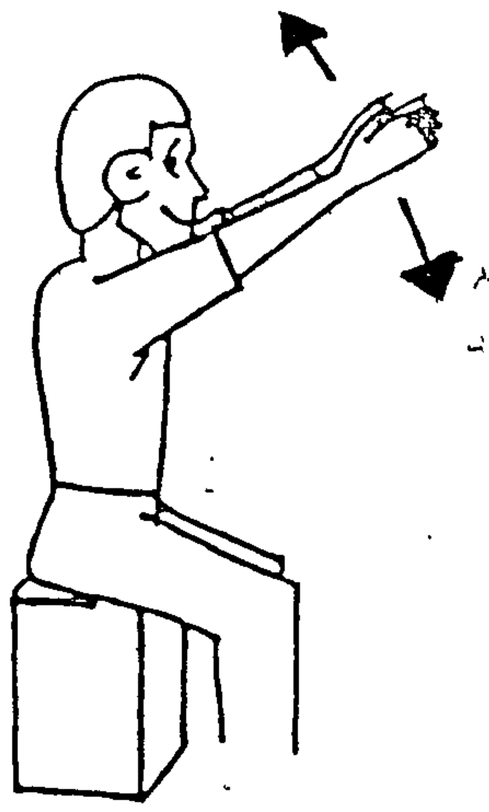
Bend to the side



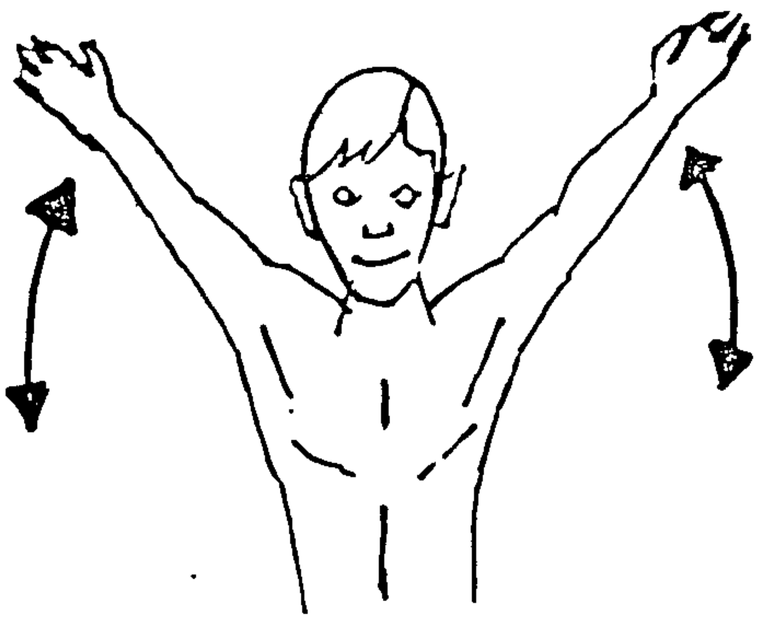
Humping & Hollowing



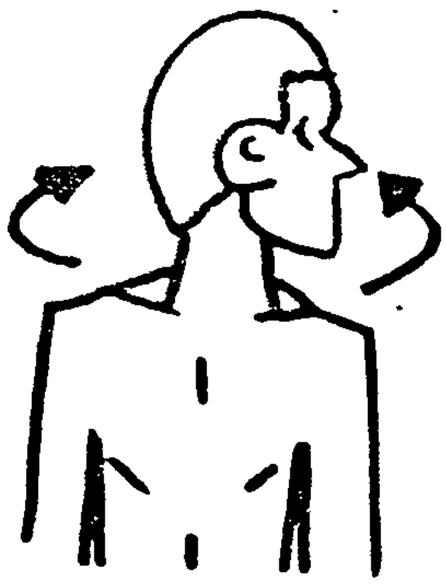
Alternate Arm Swings



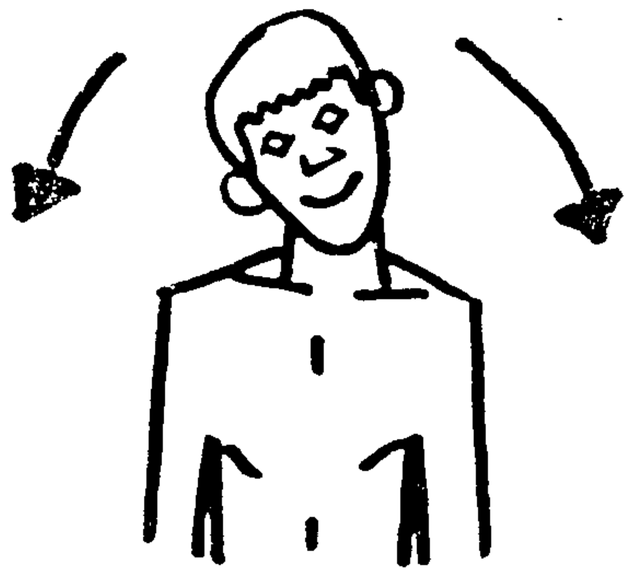
Raise and lower arms



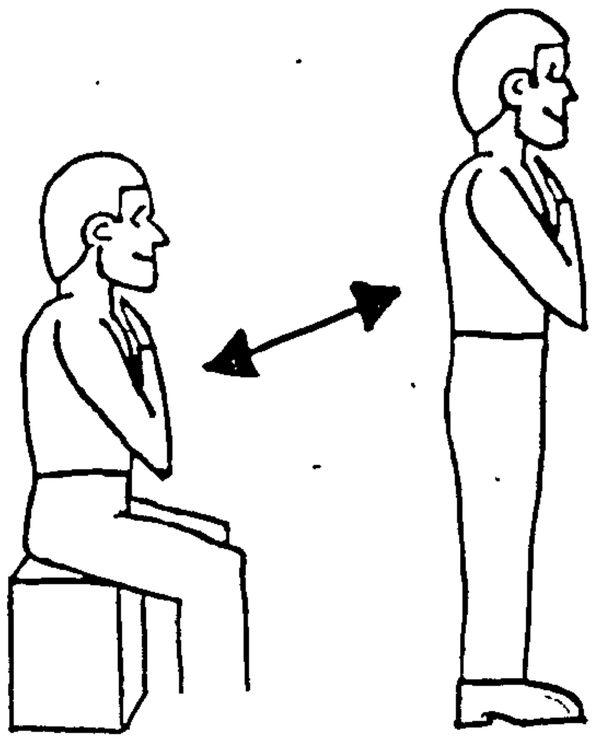
Raise your arms up and down



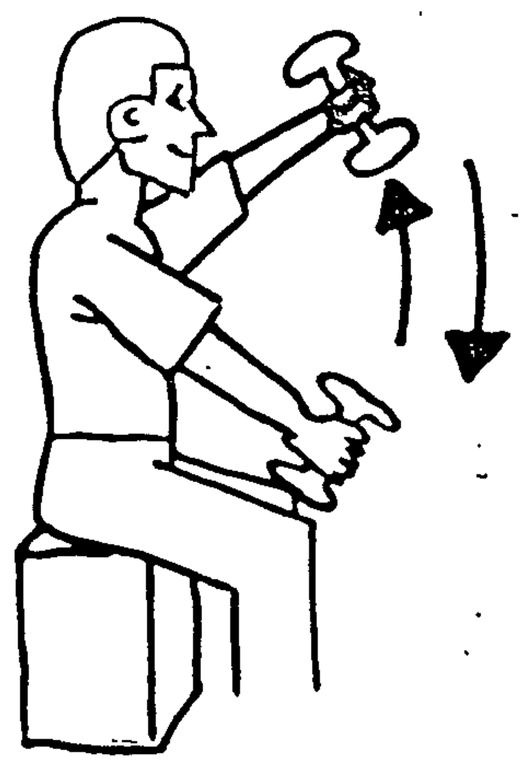
Turn Head Left & Right



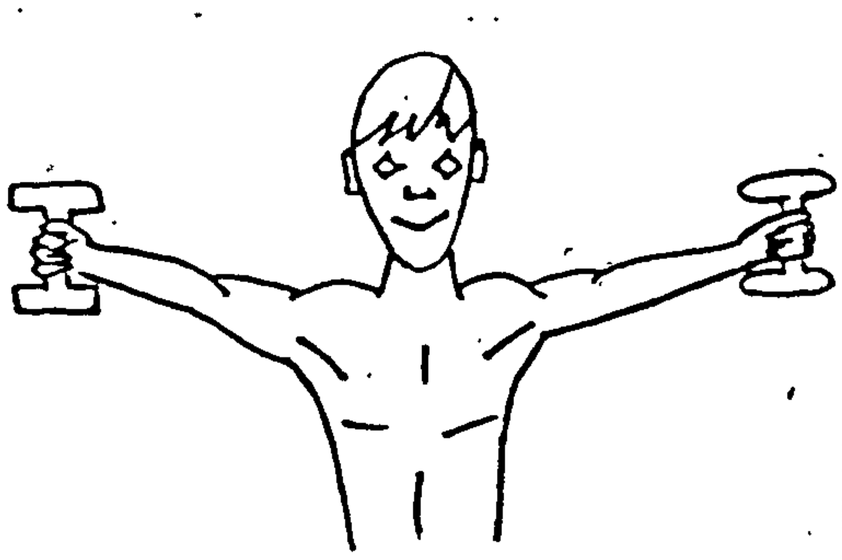
Side Bend Head Left & Right



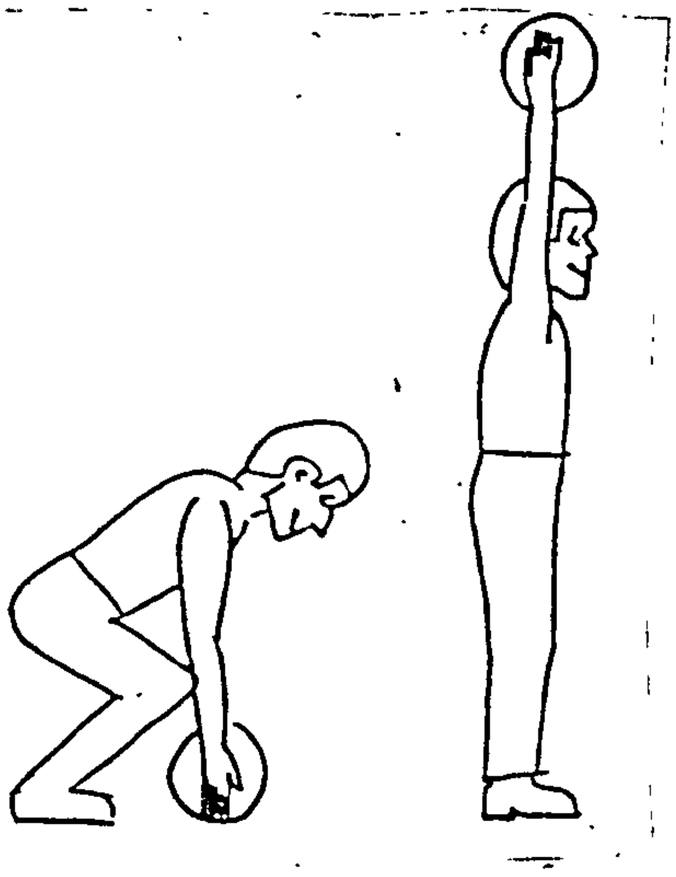
Sit to Stand



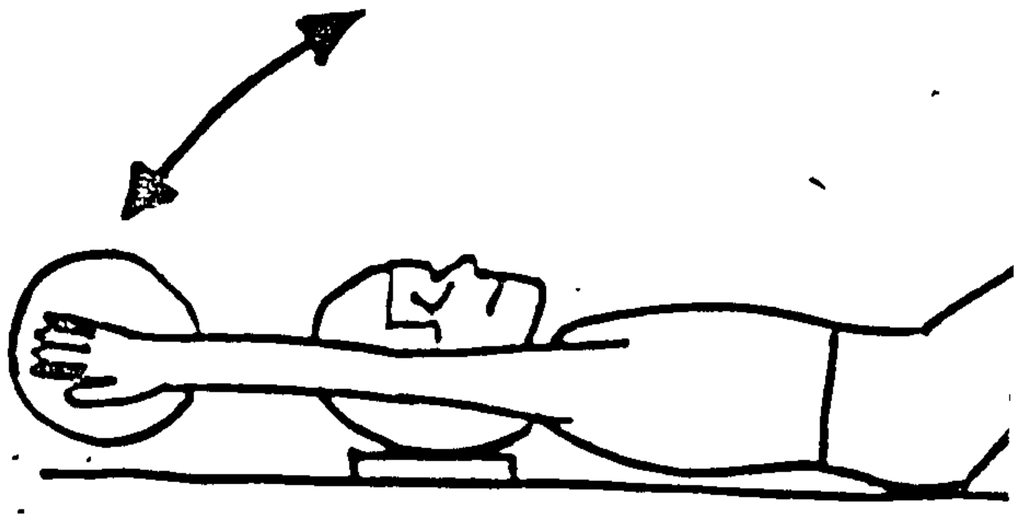
Alternate Arm Swings



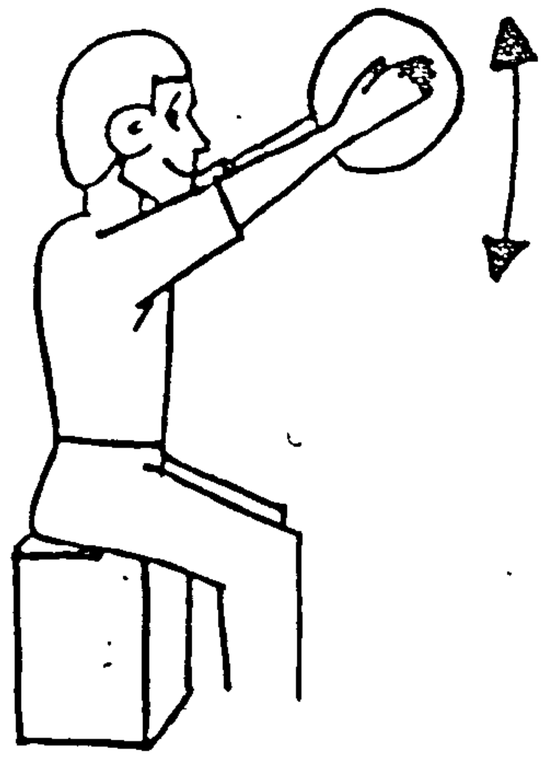
Raise arms out to side and lower



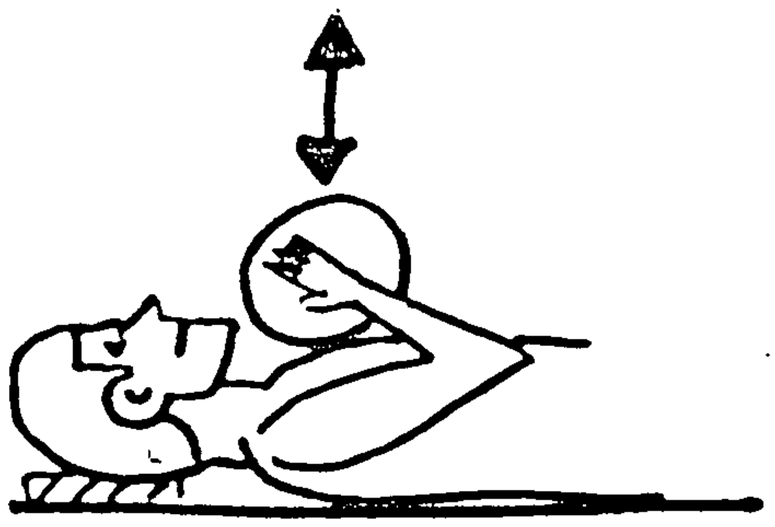
Medicine ball lift floor→above head



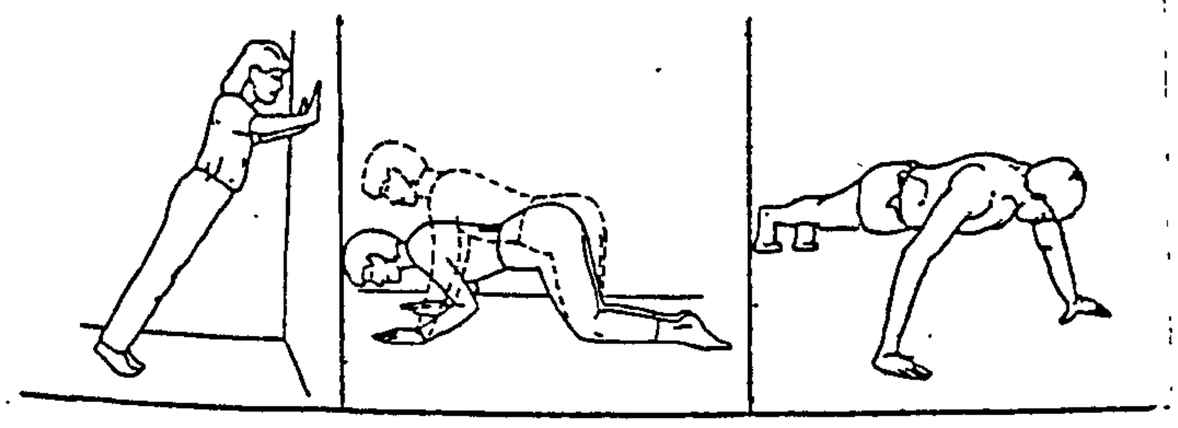
Raise and lower medicine ball



Lift & Lower Medicine Ball



Chest press with medicine ball



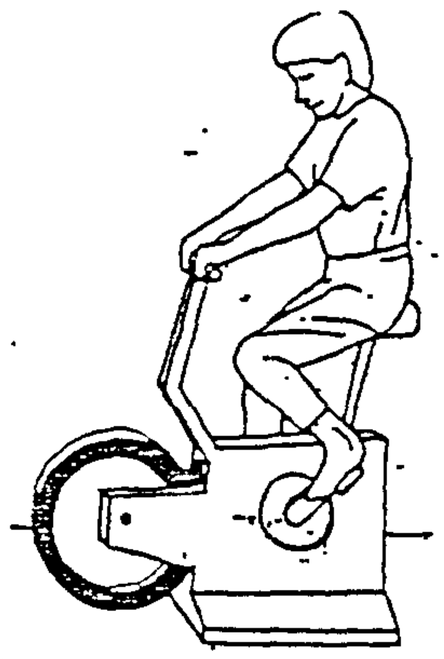
Press ups

Neck & upper limb exercise class notes for trial physiotherapists

Main Points:

- Patients will attend this exercise class twice weekly for six weeks. They have been asked to attend a minimum of six sessions and a maximum of 12.
- Sessions will last between 30-60 minutes, depending upon the patients level of fitness.
- Patients should be asked to progress through the exercise at their own pace, with weights of their own choosing. Gentle encouragement and advice about progression should be given.
- All exercises are based on core stabilisation principals, segmental and global control of spinal curves in various postures. Diaphragmatic breathing and transversus abdominus activation may be encouraged as necessary. Neutral pelvic postures and lumbar, thoracic and spinal curves are encouraged as standard for all exercises.
- The use of verbal, physical and visual biofeedback as required in order to retrain normal movement with appropriate control. These feedbacks should be withdrawn as soon as possible.
- The only treatment that trial patients will receive is the exercise class. However you may use heat or ice interventions as appropriate, since this is treatment that the patient can normally manage at home.
- You may give patients advice about post-exercise soreness and self-management of neck and upper limb dysfunction. Post-exercise soreness is a normal experience for people undertaking exercise and just because the patients are sore from doing the exercise does not mean that they are hurting themselves. Patients should be reminded that this post exercise soreness will normally wear off in 4 or 5 days and should not put them off doing the exercises.
- SOAP notes should be maintained for trial patients in accordance with your own departmental practices for class based patients.

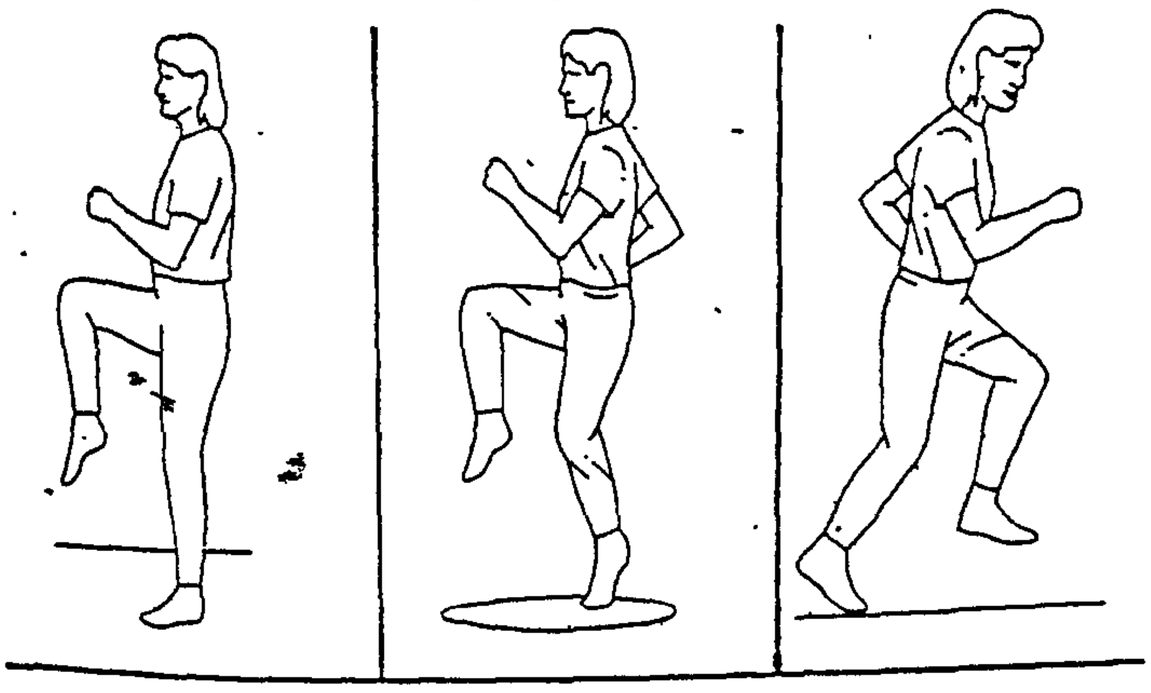
For specific points about each exercise see overleaf



Cycling

Possible compensations:
- Loss of neutral spinal curves, posterior pelvic tilt, lumbar flexion and excessive thoracic kyphosis.
- Excessive lateral trunk movements

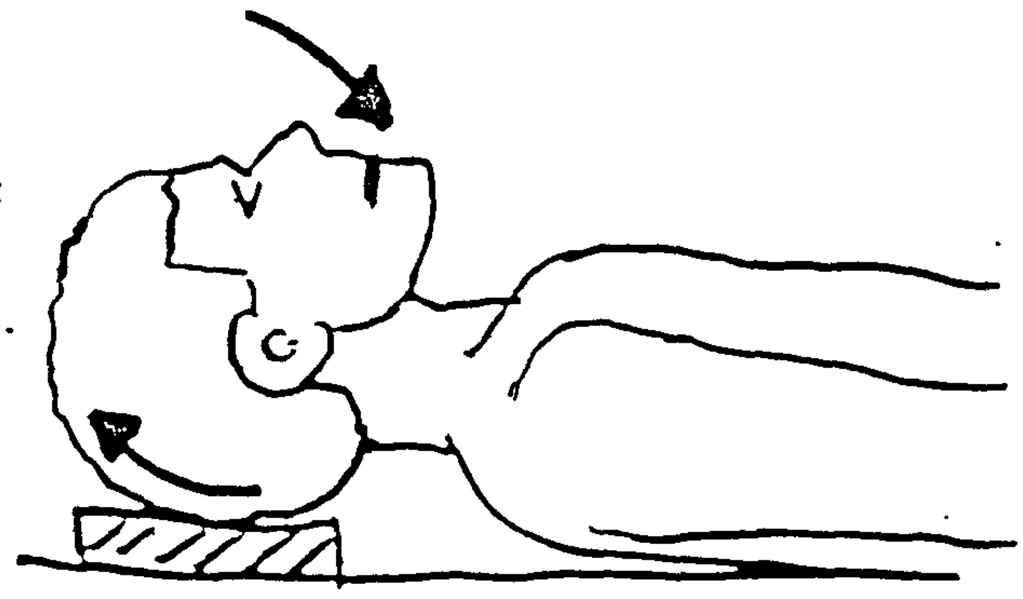
Corrections:
- Encourage anterior/neutral pelvic tilt with lumbar, thoracic and cervical spinal neutral postures.
- Diaphragmatic breathing & TrA contraction
- Encourage reduction of trunk lateral sway



Marching on the Spot OR Jogging on the Spot OR Jogging

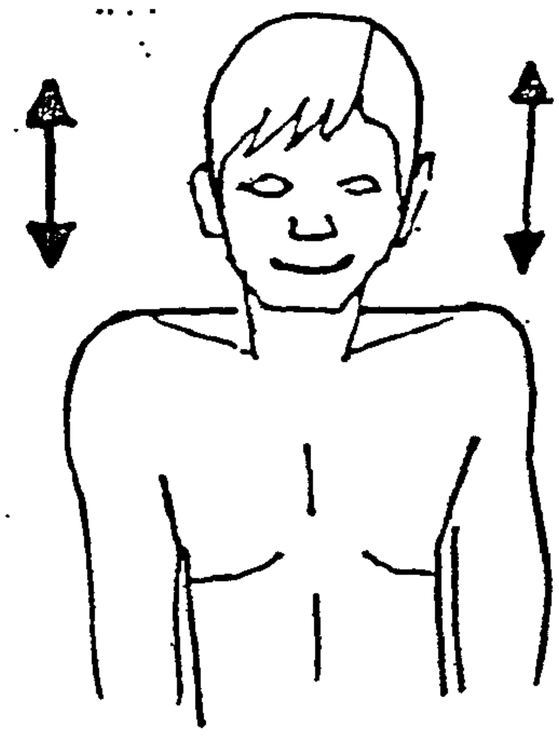
Possible compensations:
- Sway back posture, excessive pelvic posterior tilt and lumbar flexion
- Excessive lateral body sway or side flexion of trunk

Corrections:
- Control of pelvis, lumbar, thoracic and cervical posture
- Diaphragmatic breathing & TrA contraction
- Encourage activation of hip extensors/abductor activity on supporting leg
- Limit hip flexion on unsupported leg



Possible compensations:
- Cervical flexion/extension or retraction

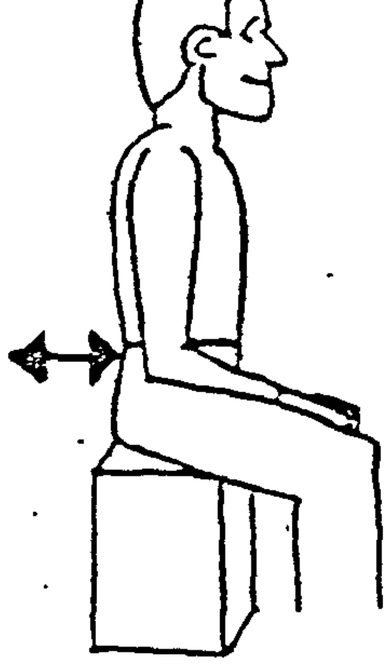
Corrections:
- Encourage neutral pelvis, lumbar, thoracic and cervical posture
- Diaphragmatic breathing & TrA contraction
- Encourage "easy" nodding, monitor retraction by palpating C2, facilitate using hands on chin or back of head



Shrug your shoulders up and down

Possible compensations:
- Overusing arms, may lack smoothness and range

Corrections:
- Set deep neck flexors (DNF) and neutral spinal curves
- Use mirror and hands to facilitate as necessary



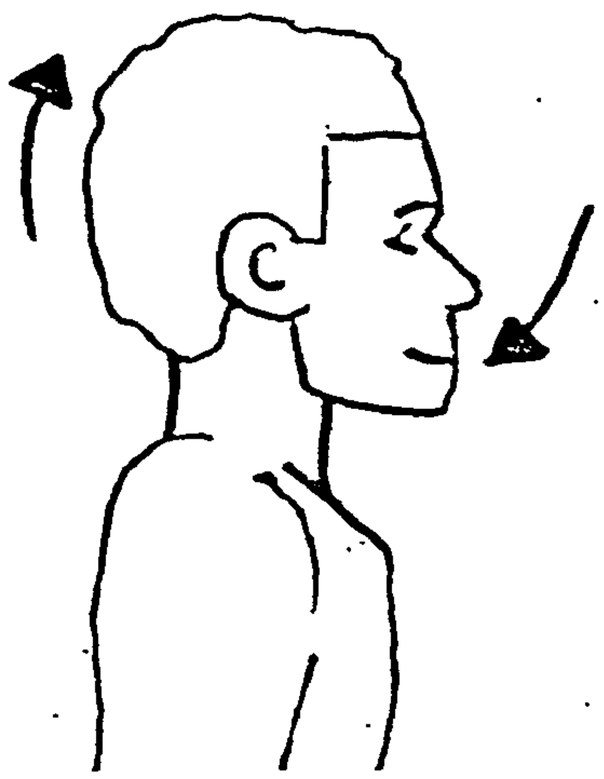
Pelvic Tilting

Possible compensations:

- Excessive thoraco-lumbar or thoracic flexion/ extension.
- Excessive use of shoulder girdle retraction and protraction

Corrections:

- Encourage L5/S1 flexion/extension, with rolling over ischial tuberosities of pelvis.
- Use your thumb on L5 spinous process to facilitate segmental flexion and extension. Use hands on pelvis to facilitate anterior pelvic tilting
- Use hand on sternum to inhibit thoracic flexion and extension

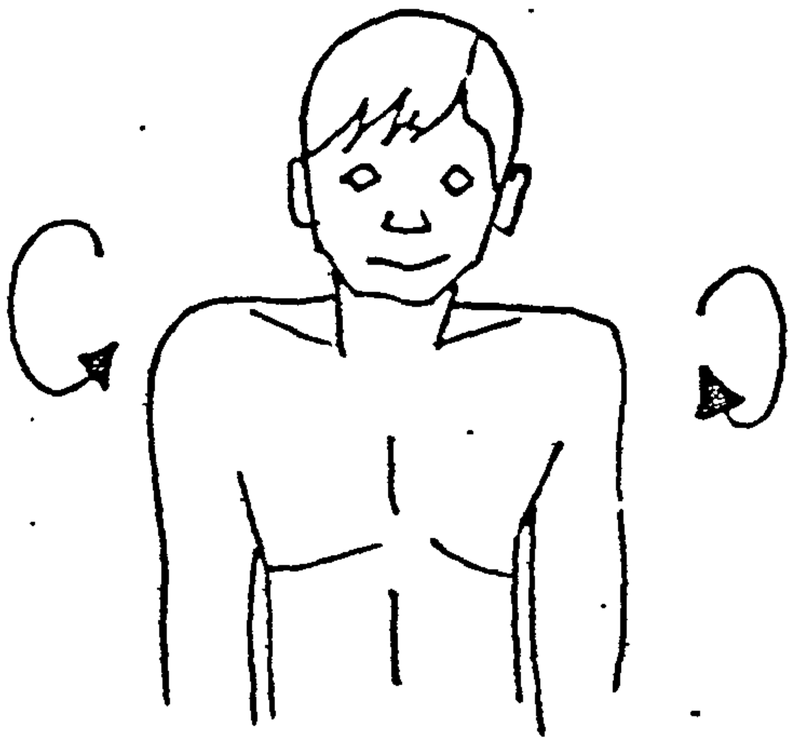


Possible compensations:

- Cervical flexion/extension or retraction

Corrections:

- Encourage neutral pelvis, lumbar, thoracic and cervical posture
- Diaphragmatic breathing & TrA contraction
- Encourage "easy" nodding, monitor retraction by palpating C2, facilitate using hands on chin or back head

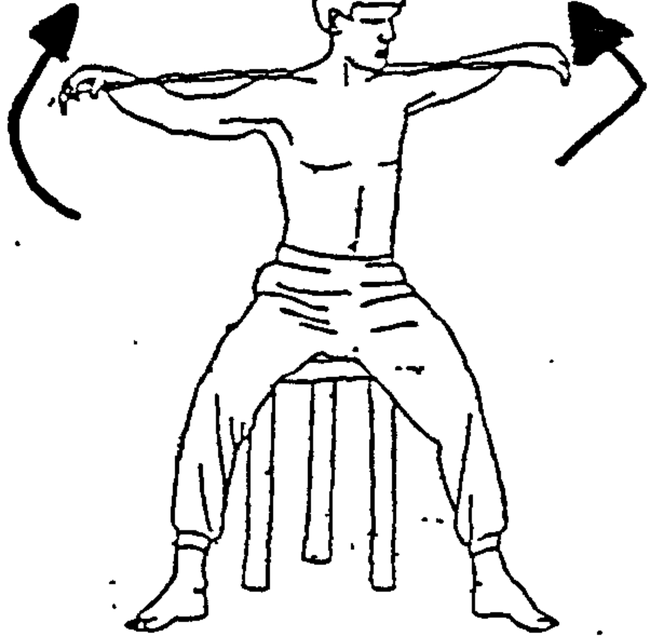


Possible compensations:

- Overusing arms, may lack smoothness and range
- Tendency to use a poking chin

Corrections:

- Set deep neck flexors (DNF) and neutral spinal curve
- Use mirror and hands to facilitate as necessary
- Use a thumb on chin to inhibit a poking chin



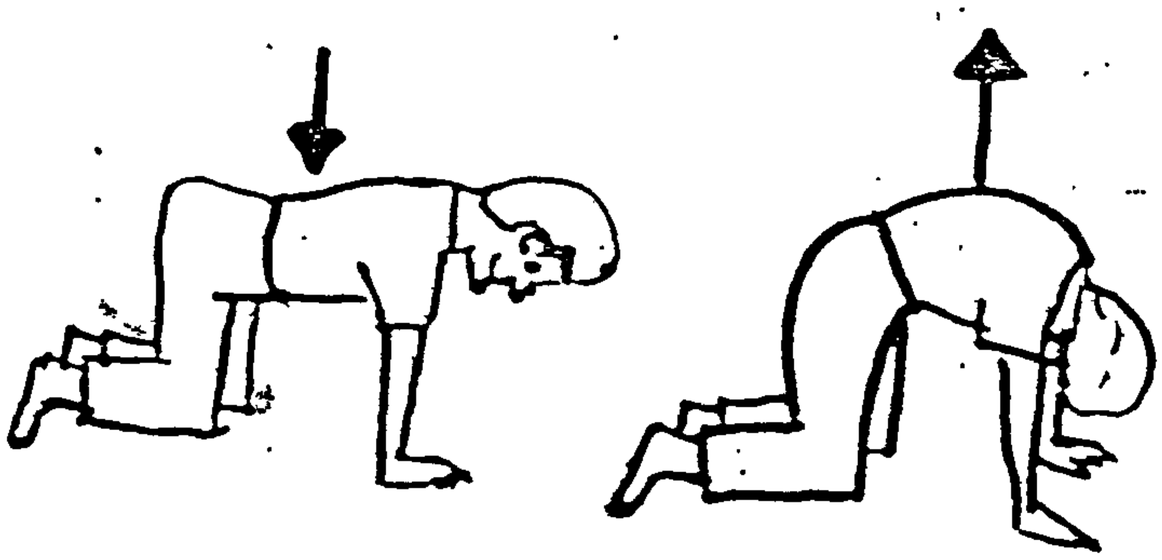
Sit on chair and turn your trunk left and then right

Possible compensations:

- Thoracic side flexion or flexion, rather than pure rotation
- Rotating head simultaneously

Corrections:

- Maintain all spinal curves
- Stay as tall as possible
- Do not rotate cervical spine



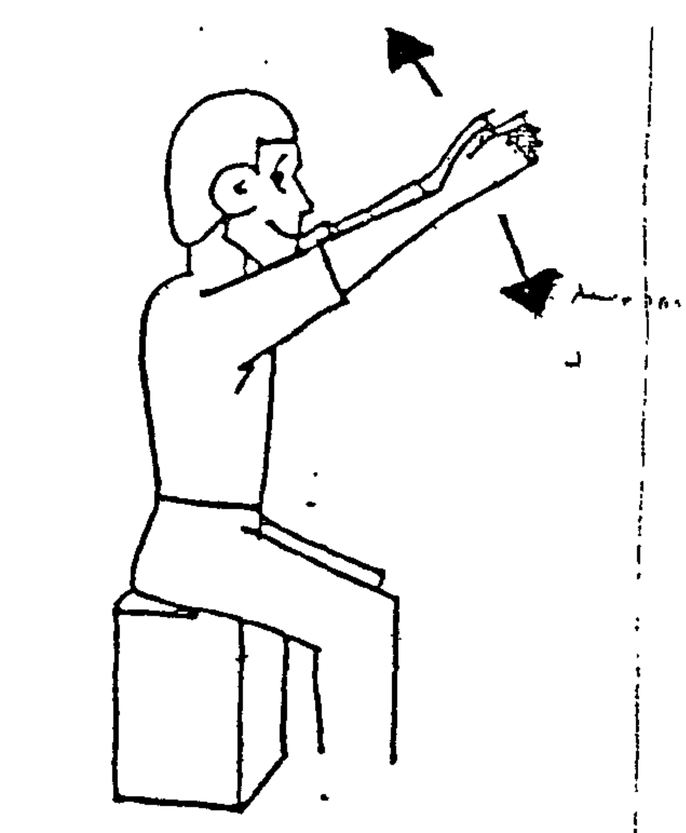
Humping & Hollowing

Possible compensations:

- Over flexing or extending the cervical spine
- Collapsing between the scapulae

Corrections:

- Maintain cervical spine neutral
- Maintain scapula neutral position



Raise and lower arms

Possible compensations:

- Overextending lumbar and thoracic spine

Corrections:

- Maintain all spinal curves
- Limit shoulder range of motion if necessary
- Allow scaption to reduce pain if necessary

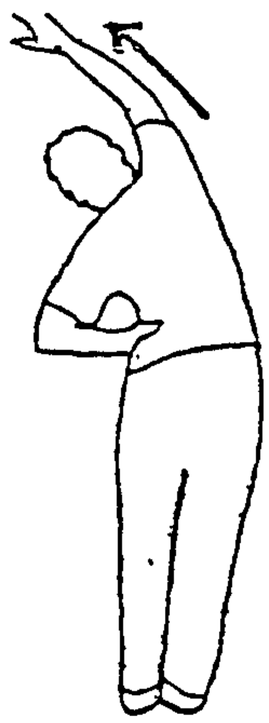
Turn Head Left & Right

Possible compensations:

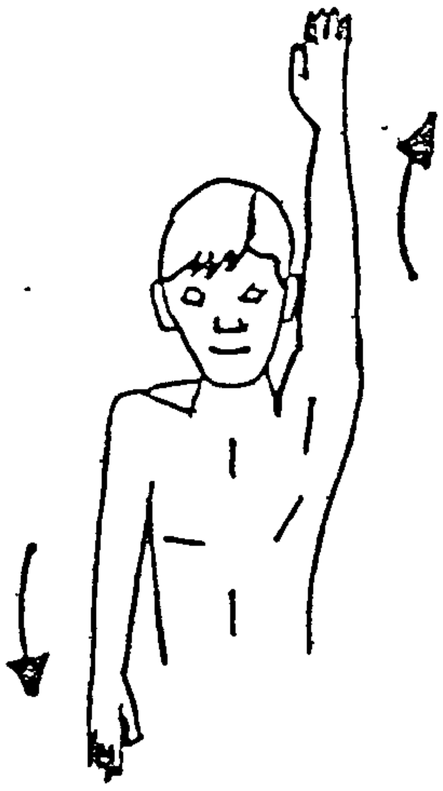
- cervical side flexion rather than pure rotation
- buckling of the cervical spine at end of range
- Rotating trunk simultaneously

Corrections:

- Maintain all spinal curves
- Stay as tall as possible



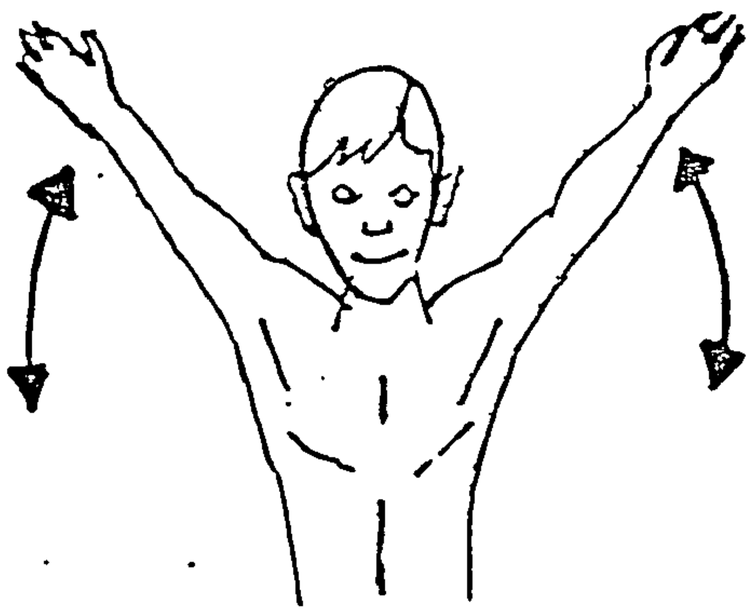
Bend to the side



Alternate Arm Swings

Possible compensations:
- Overextending lumbar and thoracic spine
- Poking chin

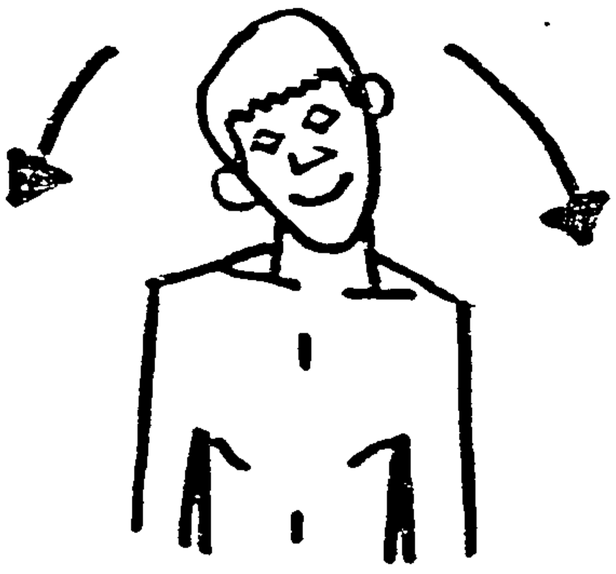
Corrections:
- Maintain all spinal curves
- Limit shoulder range of motion if necessary
- Allow scaption to reduce pain if necessary



Raise your arms up and down

Possible compensations:
- Overextending lumbar and thoracic spine

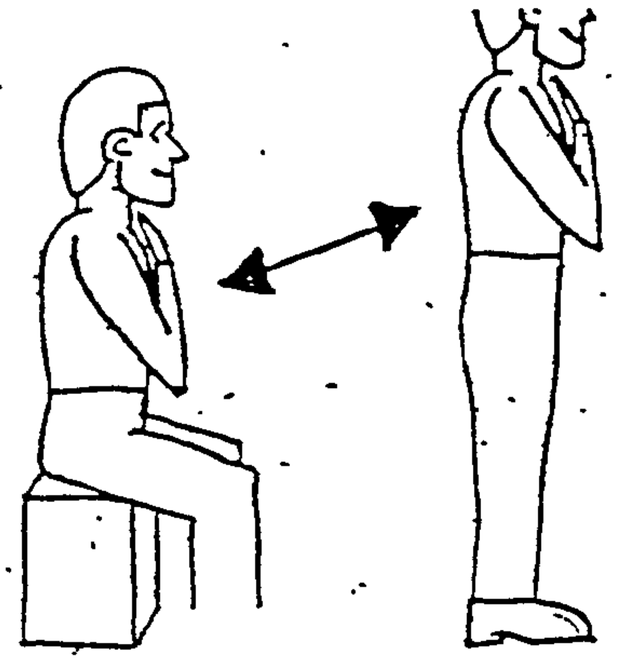
Corrections:
- Maintain all spinal curves
- Limit shoulder range of motion if necessary
- Allow scaption to reduce pain if necessary



Side Bend Head Left & Right

Possible compensations:
- Rotation of cervical spine
- Trunk sideflexion

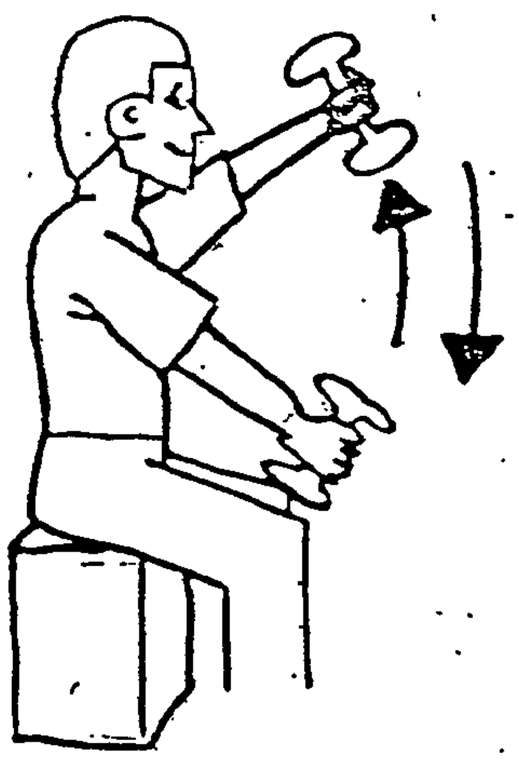
Corrections:
- Maintain all spinal curves



Sit to Stand

Possible compensations:
- Using momentum to initiate standing
- Overextending cervical spine
- Over flexion lumbar and thoracic spine

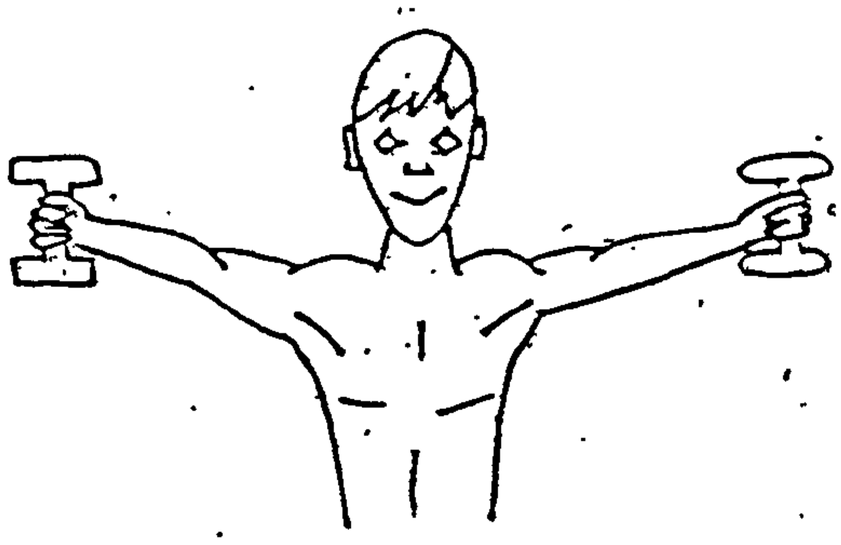
Corrections:
- Maintain all spinal curves and initiate motion from hips and knees
- Aim for controlled lowering



Alternate Arm Swings

Possible compensations:
- Overextending lumbar and thoracic spine
- Poking chin

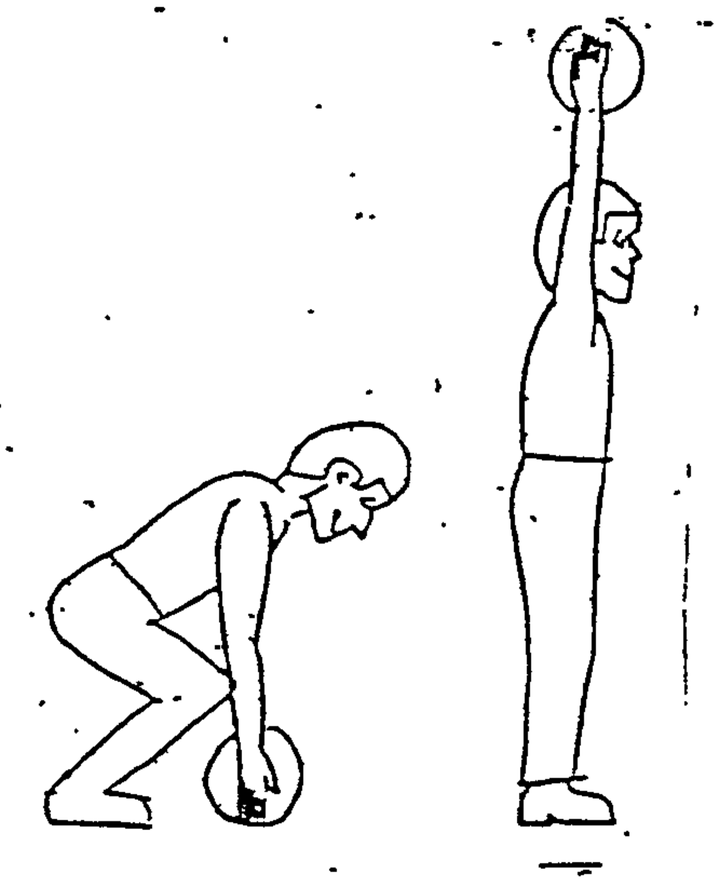
Corrections:
- Maintain all spinal curves
- Limit shoulder range of motion if necessary
- Allow scaption to reduce pain if necessary



Raise arms out to side and lower

Possible compensations:
- Overextending lumbar and thoracic spine

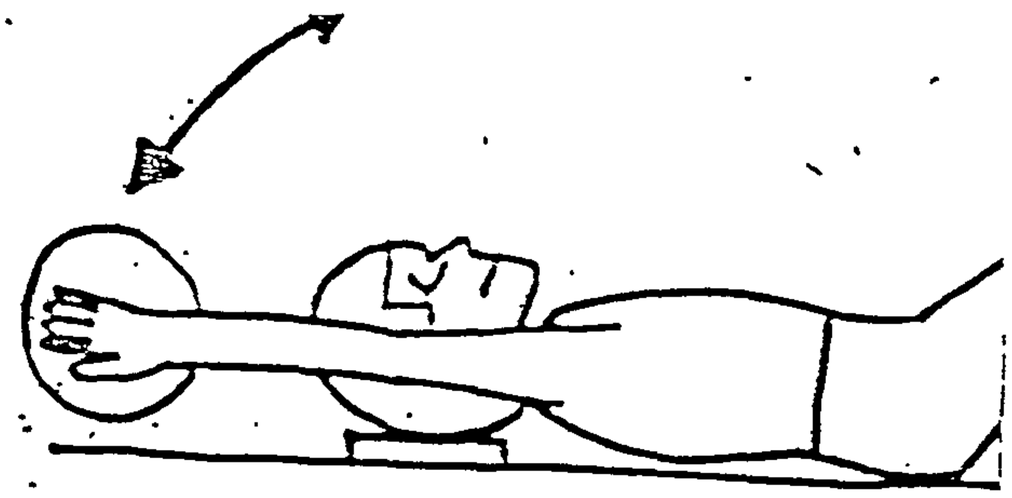
Corrections:
- Maintain all spinal curves
- Limit shoulder range of motion if necessary
- Allow scaption to reduce pain if necessary



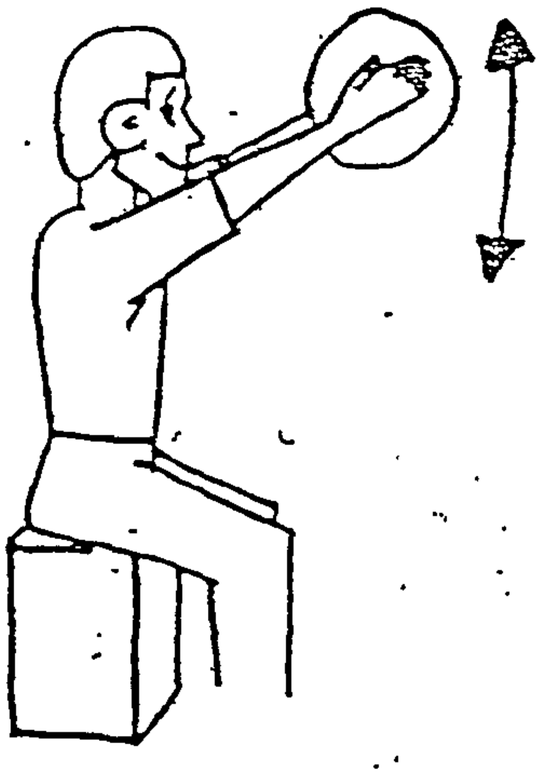
Medicine ball lift floor→above head

Possible compensations:
- Over flexing lumbar and thoracic spine
- Under flexing hips and knees

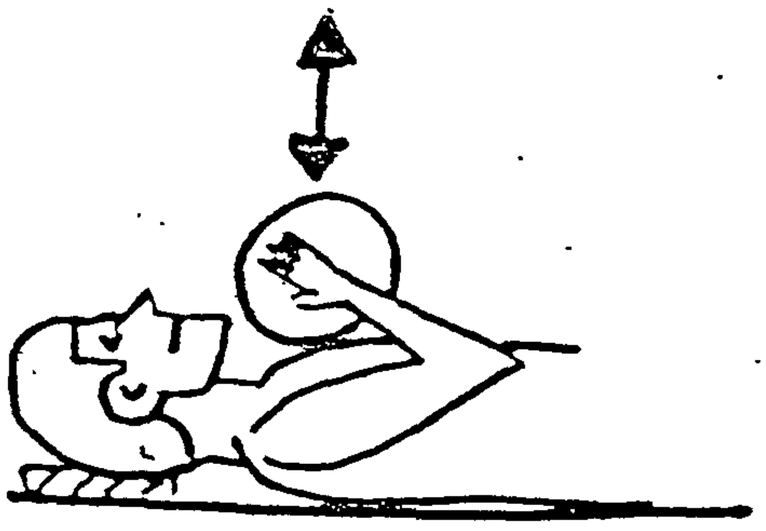
Corrections:
- Maintain all spinal curves
- Reduce distance to ground by using a false floor in front of patient



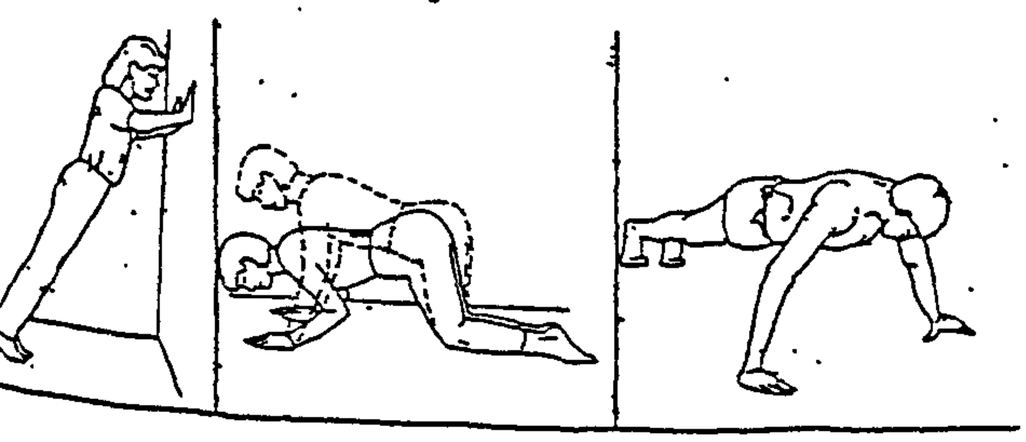
Raise and lower medicine ball



Lift & Lower Medicine Ball



Chest press with medicine ball



Press ups

Possible compensations:

- Overextending lumbar and thoracic spine
- Poking chin

Corrections:

- Maintain all spinal curves
- Limit shoulder range of motion if necessary
- Allow scaption to reduce pain if necessary

Possible compensations:

- Pushing bottom into the air
- Poking chin

Corrections:

- Maintain all spinal curves

Confidential **Usual Physiotherapy**

Individual Treatment Record Form

Date of Discharge:_____

Participant's Name: _____Participant study ID no. _____

Physiotherapist's Name: _____Grade: _____

1. Number of treatment sessions _____ (if none please indicate a reason below)

.....

2. Was the patient instructed in any exercises to do <u>at home</u>? ☐ Yes ☐ No

3. Was the patient given any exercises? ☐ Yes ☐ No

a) If so please indicate any <u>specific</u> exercises (tick all that apply)

☐ McKenzie
☐ Strengthening of the neck
☐ Stretching
☐ Stabilisation Exercise
☐ Upper Limb Strengthening
☐ Other (please specify below)

.....

.....

b) Please specify below any <u>general</u> exercises that were given:

.....

.....

4. Which of the following treatments were used? (tick all that apply)

Articular Bias
☐ Manipulations
☐ Mobilisations

☐ **Neural Bias**

☐ **Muscle Bias**

Modalities
☐ Traction
☐ SWD
☐ Ultrasound
☐ Interferential
☐ TENS
☐ Acupuncture
☐ Ice and Heat
☐ Other (please state).....

Physiotherapists Curriculum Vitae

In order to help us to interpret the data we collect in the GET UP Trial, I would be grateful if you could answer the following questions.

Name _____

Gender: Male Female

Age (in years): _____

Please indicate your grade by ticking the relevant box:

Junior	
Senior II	
Senior I	
Superintendent	

Please tick the relevant box to indicate how many years of experience you have as a musculoskeletal physiotherapist. (If you have had a year or more off for a career break, or experienced prolonged sick leave, please deduct this from the total.)

0-5 years	
6-10 years	
11-20 years	
21-30 years	
31-40 years	
41 years or above	

Please tick the relevant box to indicate any extra neck or shoulder training you have undertaken, over and above your undergraduate training.

No extra training	
Junior In-service training on the cervical spine	
Senior In-Service Training on the cervical spine	
Weekend/Postgraduate neck or shoulder course (1-2 day)	
3+ days specialist neck or shoulder course	
Manual Therapy Qualification (by Examination) eg. MSc in musculoskeletal physiotherapy, MACP or equivalent eg. McKenzie	
Any other postgraduate qualifications (please specify below)	

Many thanks for your help.

Reception Staff Tasks

1) When a referral for a patient with neck pain first comes, follow your normal procedures for having the referrals prioritised and adding it to the waiting list.

2) The physiotherapist who checks the referrals will have identified the patients who are suitable for the study and will ask you to tag them with a coloured sticker.

3) Tag the referrals and then store them as normal, with the waiting list referrals.

4) Sionnadh McLean will agree with the senior physiotherapist when the next patient interviews and group exercise classes are scheduled to begin. You will receive about 4 weeks notice of when the patient interviews are scheduled. You will be asked to book a room for 2-3 days, where Sionnadh can undertake these patient interviews.

5) As soon as possible within the next week you should retrieve about 30 of the tagged referrals from the waiting list. The following activities then need completing:

a. Complete a standard form for each patient. This form is at Appendix ? This needs to be faxed or mailed to Sionnadh McLean at the Institute of Rehabilitation as soon as possible.
b. Send a trial information pack to each patient.
c. Store these referrals on a trial waiting list, separate from the waiting list.

6) Sionnadh will communicate with the patients either by telephone or by mail. If the patient is not suitable or not willing to participate in the trial, Sionnadh will immediately let you know, so that the patient can be "untagged", taken off the research waiting list, returned to the regular waiting list and given an appointment in the usual way.

7) If the patient is suitable for the trial, Sionnadh will make an appointment to see the patient in your department. Within a few days of the patient interviews, Sionnadh will give you a list of the patients she is interviewing, the dates and times for your reception diary.

8) You should gather the referral cards for the patients for each day, ready to give to Sionnadh when she arrives at you department.

9) After Sionnadh interviews the patient, she will come to the front desk with the patient. The patient and Sionnadh will sign a consent form, in front of the receptionist. This is to show that the patient has understood the requirements of the trial and is happy to be a subject in the trial. The receptionist will be asked to witness the consent form.

10) The department will store a set of sealed envelopes which allocates the patient to one of two treatment groups. Sionnadh will ask the receptionist to retrieve the next envelope at the front of the list and she will inform the patient which treatment they have been allocated to.

11) If the patient is allocated to the "usual physiotherapy" group, the receptionist will make an appointment for the patient to see a physiotherapist in the usual way. If the patient is allocated to the "Neck exercise" group, the receptionist will give the patient an information leaflet about the date, time and venue of the exercise class.

12) Sionnadh will return the patient's referral to the reception desk. The coloured sticker will be marked to indicate which intervention the patient is receiving ("GET" for the Graded Exercise Treatment or "UP" for Usual Physiotherapy). The patient's trial number will also be written on the top of the referral. At this time you will also be given:

- A copy of the consent form
- A copy of the patients initial assessment

These should be kept together with the patients referral.

13) For the group receiving "usual physiotherapy" patient's notes should then be passed to the treating physiotherapist in the usual way. For the group receiving exercise, the patients notes should be kept together and passed to the physiotherapist responsible for that group.

14) Once the patient has completed the trial treatment, the notes will be returned to you for discharge in the normal way. The physiotherapy notes for all the trial patients should be retained separately, to allow Sionnadh to collect some information about the treatment given. After this these notes can be filed as usual.

Physiotherapists Tasks

1) The senior physiotherapist will "tag" referrals with a coloured sticker to identify potentially eligible trial subjects. The inclusion and exclusion criterion at page** should be used in order to make this judgement.

2) All physiotherapists, who see any of the trial patients, will be asked to complete a brief summary (1 page) about your physiotherapy background and experience. This will be retained by Sionnadh McLean, for purposes of data analysis.

3) By the time you meet the patient he/she will have been randomised to one of two interventions, either Usual Physiotherapy (there will be a coloured sticker on the front of the patient's notes which says "UP") or to Graded Exercise Treatment (there will be a coloured sticker which says "GET")

4) When you receive the patient's notes, which have been entered into the study, there will be several attachments:

- A copy of the consent form.
- A copy of the patient's initial trial assessment.

These should be retained with the patient's notes.

5) **Usual Physiotherapy**. If you are treating patients in this group, then please assess and treat these patients in the usual way. There are no restrictions to treatment, except that **the patient should not participate in the exercise class**. You may give patients your usual range of advice including advice about exercise and you may ask your patients to perform the range of specific neck or shoulder exercise that you feel are relevant to the patient's problem. For further information, please see section 6 of this manual

6) **Graded Exercise Treatment**. If you are treating this group of patients, you will receive a batch of notes from your receptionist prior to the classes beginning. There will be no need to formally assess them, although you should perform a brief subjective examination on each occasion that the patient attends. This should be documented. The only treatment that the patient's will receive will be the exercise class. You may give the patient advice about self management of post exercise soreness if you feel they need it. You may give the patient advice on any queries they may have. For further information, please see section 5 of this manual.

7) **Withdrawing Trial Participants**. All attempts will have been made to screen patients for their suitability for the trial before they are seen by you. On rare occasions patients may need to be withdrawn from the trial or may choose to withdraw from the trial themselves. Reasons may be:

- You are not able to treat them on clinical grounds.
- They develop a complication.
- They decide to have different treatment (ie usual physiotherapy)
- They DNA.
- Patients may withdraw from the study without giving a reason.

The patient will still be followed up at 6 weeks, 6 months and 1 year. It is important that you clarify with the patient whether they are still willing to be followed up. If the patient clearly states that they do not wish to be followed up, please inform Sionnadh as soon as possible

8) Once treatment has been completed the patient should be discharged in the usual way and the notes returned to the receptionist.

Get up

Follow-up Questionnaire

In confidence

Get up Neck Trial

Follow-up Questionnaire

Please carefully read all the instructions in each section before completing the questionnaire.

Please answer **all** the questions by placing a cross (☒) in the relevant box. Although it may seem that questions are asked more than once, it is still important that you answer everyone.

In each section it is your first response that we are interested in, so please do not think about your answer for too long.

In confidence

THE UNIVERSITY OF HULL

The Institute of Rehabilitation
215 Anlaby Road, Hull HU3 2PG

Wycombe NHS
Primary Care Trust

Northern Lincolnshire and Goole Hospitals NHS
NHS Trust

Hull and East Yorkshire Hospitals NHS
Anlaby Road, Hull HU3 2JZ
NHS Trust

Nottingham City Hospital NHS
NHS Trust

Section1

This section has been designed to give us information as to how your NECK PAIN has affected your ability to manage everyday life. Please answer every question and mark with a cross ONLY THE ONE BOX which applies to you. We realise you may consider that two of the statements in any one section relates to you, but please just mark the box which most closely describes your problem.

Remember, just **mark one box** in each question. It is your first response that we are interested in, so please do not think about your answer for too long.

1. NECK PAIN INTENSITY

- ☐ I have no pain at the moment
- ☐ The pain is mild at the moment
- ☐ The pain is moderate at the moment
- ☐ The pain is severe at the moment
- ☐ The pain is the worst imaginable at the moment

2. NECK PAIN AND SLEEPING

- ☐ My sleep is never disturbed by pain
- ☐ My sleep is occasionally disturbed by pain
- ☐ My sleep is regularly disturbed by pain
- ☐ Because of pain I have less than 5 hours of sleep in total
- ☐ Because of pain I have less than 2 hours of sleep in total

3. PINS & NEEDLES OR NUMBNESS IN THE ARMS AT NIGHT

- ☐ I have no pins & needles or numbness at night
- ☐ I have occasional pins & needles or numbness at night
- ☐ My sleep is regularly disturbed by pins & needles or numbness
- ☐ Because of pins & needles I have less than 5 hours sleep in total
- ☐ Because of pins & needles or numbness I have less than 2 hours sleep in total

4. DURATION OF SYMPTOMS

- ☐ My neck and arms feel normal all day
- ☐ I have symptoms in my neck or arms on waking, which last less than 1 hour
- ☐ Symptoms are present on and off for a total period of 1-4 hours
- ☐ Symptoms are present on and off for a total period of more than 4 hours
- ☐ Symptoms are present continuously all day

Please turn over...

101880-3020704/KPS

☐

5. CARRYING

- ☐ I can carry heavy objects without extra pain
- ☐ I can carry heavy objects, but they give me extra pain
- ☐ Pain prevents me from carrying heavy objects, but I can manage medium weight objects
- ☐ I can only lift lightweight objects
- ☐ I cannot lift anything at all

---

6. READING & WATCHING T.V.

- ☐ I can do this as long as I wish with no problems
- ☐ I can do this as long as I wish, if I'm in a suitable position
- ☐ I can do this as long as I wish, but it causes extra pain
- ☐ Pain causes me to stop doing this sooner than I would like
- ☐ Pain prevents me from doing this at all

---

7. WORKING / HOUSEWORK ETC

- ☐ I can do my usual work without extra pain
- ☐ I can do my usual work, but it gives me extra pain
- ☐ Pain prevents me from doing my usual work for more than half the usual time
- ☐ Pain prevents me from doing my usual work for more than a quarter the usual time
- ☐ Pain prevents me from working at all

---

8. SOCIAL ACTIVITIES

- ☐ My social life is normal and causes me no extra pain
- ☐ My social life is normal, but increases the degree of pain
- ☐ Pain has restricted my social life, but I am still able to go out
- ☐ Pain has restricted my social life to the home
- ☐ I have no social life because off pain

---

9. DRIVING (Omit this section if you never drive a car)

- ☐ I can drive whenever necessary without discomfort
- ☐ I can drive whenever necessary, but with discomfort
- ☐ Neck pain or stiffness limits my driving occasionally
- ☐ Neck pain or stiffness limits my driving frequently
- ☐ I cannot drive at all due to neck symptoms

Section2

This section asks you about your symptoms as well as your ability to perform certain activities. Please answer every question, based on your condition in the last week. If you did not have the opportunity to perform an activity in the past week, please make your best estimate on which response would be the most accurate. It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

Please rate your ability to do the following activities in the last week by crossing the boxes below the appropriate response.

	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
1. Open a tight or new jar	☐	☐	☐	☐	☐
2. Write	☐	☐	☐	☐	☐
3. Turn a key	☐	☐	☐	☐	☐
4. Prepare a meal	☐	☐	☐	☐	☐
5. Push open a heavy door	☐	☐	☐	☐	☐
6. Place an object on the shelf above your head	☐	☐	☐	☐	☐
7. Do heavy household chores (e.g. wash walls, wash floors)	☐	☐	☐	☐	☐
8. Garden or do yard work	☐	☐	☐	☐	☐
9. Make a bed	☐	☐	☐	☐	☐
10. Carry a shopping bag or briefcase	☐	☐	☐	☐	☐
11. Carry a heavy object (over 10 lbs)	☐	☐	☐	☐	☐
12. Change a light bulb overhead	☐	☐	☐	☐	☐
13. Wash or blow dry your hair	☐	☐	☐	☐	☐
14. Wash your back	☐	☐	☐	☐	☐
15. Put on a pullover sweater	☐	☐	☐	☐	☐
16. Use a knife to cut food	☐	☐	☐	☐	☐
17. Recreational activities which require little effort (e.g. card playing, knitting etc)	☐	☐	☐	☐	☐
18. Recreational activities in which you take some force or impact through your hand (e.g. golf, hammering, tennis etc)	☐	☐	☐	☐	☐
19. Recreational activities in which you move your arm freely (e.g. playing Frisbee, badminton, etc)	☐	☐	☐	☐	☐
20. Manage transportation needs (getting from one place to another)	☐	☐	☐	☐	☐
21. Sexual activities	☐	☐	☐	☐	☐

	Not at all	Slightly	Moderately	Quite a bit	Extremely
22. During the past week, to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	☐	☐	☐	☐	☐
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	☐	☐	☐	☐	☐

Please turn over...

Please rate the severity of the following symptoms in the last week	None	Mild	Moderate	Severe	Extreme
24. Arm, shoulder or hand pain	☐	☐	☐	☐	☐
25. Arm shoulder or hand pain when you perform any specific activity	☐	☐	☐	☐	☐
26. Tingling (pins and needles) in your arm, shoulder or hand	☐	☐	☐	☐	☐
27. Weakness in your arm, shoulder or hand	☐	☐	☐	☐	☐
28. Stiffness in your arm, shoulder or hand	☐	☐	☐	☐	☐

	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	So much that I can't sleep
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand?	☐	☐	☐	☐	☐

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem?	☐	☐	☐	☐	☐

Section3

Please answer the following questions relating to you neck pain problem over the last 6 months.

1. **Over the last 6 months how many times have you seen an NHS HEALTH CARE PROFESSIONAL for your neck pain problem** *(please **do not include** treatment you received as part of this study).*

	Number of Visits *(if none enter 0)*		Number of Visits *(if none enter 0)*
GP	☐☐	Other (specify) ▶ ☐☐☐☐☐☐☐☐☐☐	☐☐
Physiotherapist	☐☐	Other (specify) ▶ ☐☐☐☐☐☐☐☐☐☐	☐☐
Consultant	☐☐	Other (specify) ▶ ☐☐☐☐☐☐☐☐☐☐	☐☐

2. **Over the last 6 months how many times (if any) have you consulted a PRIVATE HEALTH PROFESSIONAL for your neck pain problem.**

	Number of Visits *(if none enter 0)*	Cost (£) *(Excluding Travel)*		Number of Visits *(if none enter 0)*	Cost (£) *(Excluding Travel)*
GP	☐☐	☐☐☐☐	Chiropractor	☐☐	☐☐☐☐
Physiotherapist	☐☐	☐☐☐☐	Acupuncturist	☐☐	☐☐☐☐
Consultant	☐☐	☐☐☐☐	Other (specify) ▶ ☐☐☐☐☐☐☐☐☐☐	☐☐	☐☐☐☐
Osteopath	☐☐	☐☐☐☐	Other (specify) ▶ ☐☐☐☐☐☐☐☐☐☐	☐☐	☐☐☐☐

OFFICE USE ONLY I.D. Number ☐☐—☐☐☐ Date ☐☐/☐☐/☐☐☐☐

3. **EQUIPMENT – Over the past 6 months have you bought anything to help your neck such as a pillow, bed, chair etc.**

Item	Cost (£)

4. **Please answer <u>one</u> of the following questions.**

a. If you are in paid work, how many working days have you had off work because of your neck in the last 6 months. ☐☐ Days

b. If you are not working, how many days in the last 6 months have you been unable to carry out your usual activities (eg household chores, taking children to school etc) because of your neck. ☐☐ Days

5. **If you have any comments on the questionnaire, the study or the treatment you have received as part of the study, please enter them below.**

Thank you for completing this questionnaire

OFFICE USE ONLY I.D. Number ☐☐—☐☐☐ Date ☐☐/☐☐/☐☐☐☐

Get up Neck Trial

Follow-up Questionnaire

THE UNIVERSITY OF HULL

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Northern Lincolnshire and Goole Hospitals NHS NHS Trust

Hull and East Yorkshire Hospitals NHS NHS Trust
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Nottingham City Hospital NHS NHS Trust

Repeated measures ANOVA on NPQ score at baseline, 6 weeks and 6 month follow-up including boxplot analysis and analysis of residuals

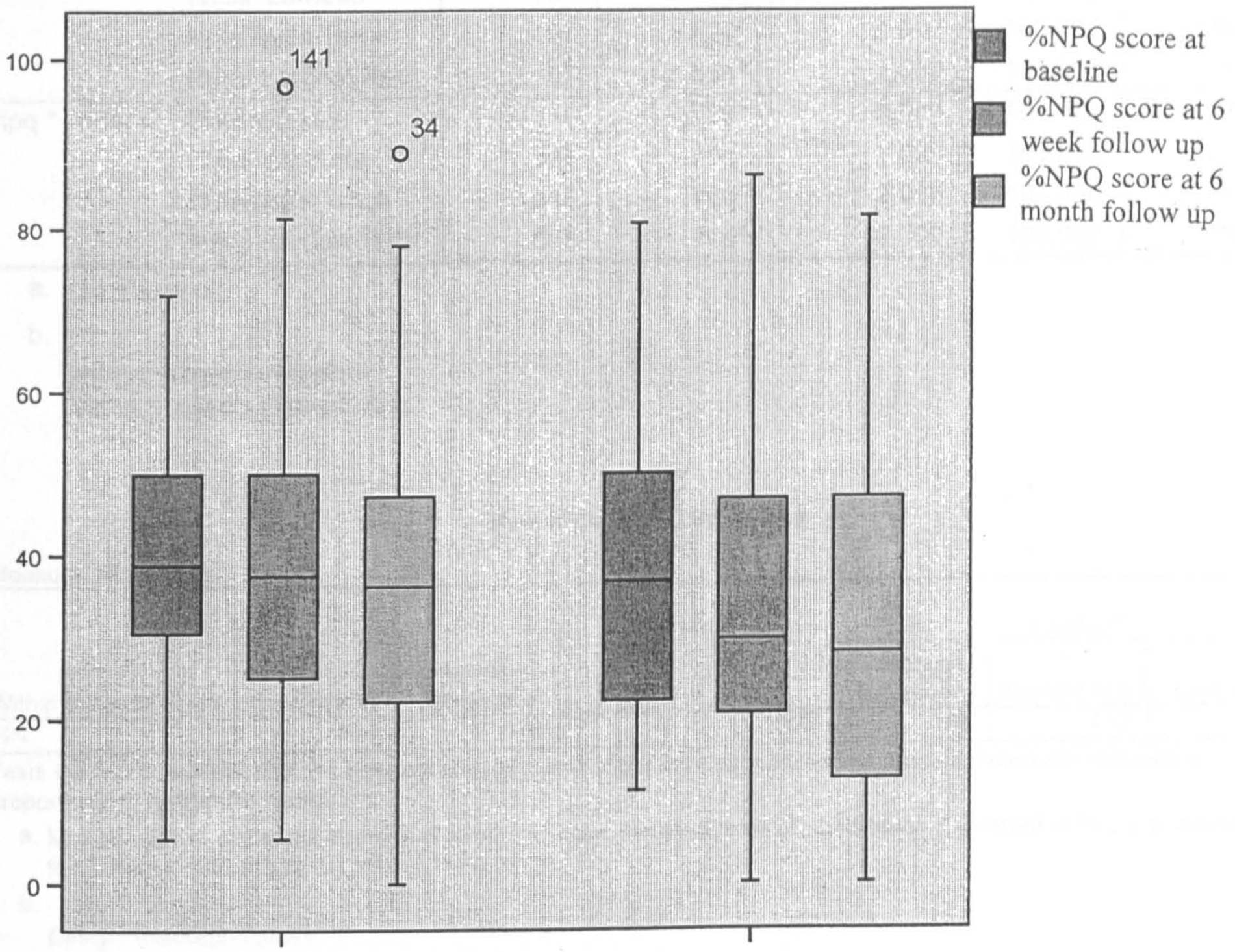
intervention

Case Processing Summary

	intervention	Cases					
		Valid		Missing		Total	
		N	Percent	N	Percent	N	Percent
%NPQ scores at baseline	graded exercise treatment	46	61.3%	29	38.7%	75	100.0%
	usual physiotherapy	60	78.9%	16	21.1%	76	100.0%
%NPQ scores at 6 weeks follow-up	graded exercise treatment	46	61.3%	29	38.7%	75	100.0%
	usual physiotherapy	60	78.9%	16	21.1%	76	100.0%
%NPQ scores at 6 month follow-up	graded exercise treatment	46	61.3%	29	38.7%	75	100.0%
	usual physiotherapy	60	78.9%	16	21.1%	76	100.0%

Descriptives

	intervention			Statistic	Std. Error
%NPQ scores at baseline	graded exercise treatment	Mean		38.3681	2.29330
		95% Confidence Interval for Mean	Lower Bound	33.7491	
			Upper Bound	42 9870	
		5% Trimmed Mean		38 3488	
		Median		38.8889	
		Variance		241.924	
		Std. Deviation		15.55389	
		Minimum		5.56	
		Maximum		71 88	
		Range		66.32	
		Interquartile Range		19 44	
		Skewness		-.199	.350
		Kurtosis		-.148	688
	usual physiotherapy	Mean		37.1577	2.02839
		95% Confidence Interval for Mean	Lower Bound	33 0989	
			Upper Bound	41.2165	
		5% Trimmed Mean		36 5924	
		Median		36.6056	
		Variance		246.861	
		Std. Deviation		15.71180	
		Minimum		11.11	
		Maximum		80 56	
		Range		69 44	
		Interquartile Range		27.78	
		Skewness		.403	.309
		Kurtosis		- 495	608
%NPQ scores at 6 weeks follow-up	graded exercise treatment	Mean		38 5643	2 72506
		95% Confidence Interval for Mean	Lower Bound	33.0758	
			Upper Bound	44.0529	
		5% Trimmed Mean		37.6074	
		Median		37.5000	
		Variance		341.593	
		Std. Deviation		18 48223	
		Minimum		5.56	
		Maximum		96 88	
		Range		91.32	
		Interquartile Range		25.00	
		Skewness		.851	.350
		Kurtosis		1 386	.688
	usual physiotherapy	Mean		32.7422	2 48457
		95% Confidence Interval for Mean	Lower Bound	27.7706	
			Upper Bound	37.7138	
		5% Trimmed Mean		31.8985	
		Median		29 6875	
		Variance		370 386	
		Std. Deviation		19.24541	
		Minimum		.00	
		Maximum		86.11	
		Range		86.11	
		Interquartile Range		26 82	
		Skewness		.572	.309
		Kurtosis		- 022	.608
%NPQ scores at 6 month follow-up	graded exercise treatment	Mean		35 0528	2 83883
		95% Confidence Interval for Mean	Lower Bound	29.3351	
			Upper Bound	40.7705	
		5% Trimmed Mean		34 4589	
		Median		36.1111	
		Variance		370.713	
		Std. Deviation		19.25391	
		Minimum		00	
		Maximum		88 89	
		Range		88 89	
		Interquartile Range		25 00	
		Skewness		.345	.350
		Kurtosis		403	.688
	usual physiotherapy	Mean		29.6499	2.72278
		95% Confidence Interval for Mean	Lower Bound	24.2016	
			Upper Bound	35 0982	
		5% Trimmed Mean		28.7905	
		Median		27 9514	
		Variance		444.813	
		Std. Deviation		21.09059	
		Minimum		00	
		Maximum		81.25	
		Range		81.25	
		Interquartile Range		35.33	
		Skewness		.473	.309
		Kurtosis		- 615	608



General Linear Model

Within-Subjects Factors

Measure: MEASURE_1

npq	Dependent Variable
1	npqbase
2	npq6week
3	npq6mth

Between-Subjects Factors

		Value Label	N
intervention	1	graded exercise treatment	46
	2	usual physiotherapy	60

Multivariate Tests[b]

Effect		Value	F	Hypothesis df	Error df	Sig.
npq	Pillai's Trace	.097	5.534[a]	2.000	103.000	.005
	Wilks' Lambda	.903	5.534[a]	2.000	103.000	.005
	Hotelling's Trace	.107	5.534[a]	2.000	103.000	.005
	Roy's Largest Root	.107	5.534[a]	2.000	103.000	.005
npq * coderx	Pillai's Trace	.015	.766[a]	2.000	103.000	.467
	Wilks' Lambda	.985	.766[a]	2.000	103.000	.467
	Hotelling's Trace	.015	.766[a]	2.000	103.000	.467
	Roy's Largest Root	.015	.766[a]	2.000	103.000	.467

a. Exact statistic

b.
Design: Intercept+coderx
Within Subjects Design: npq

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
npq	.694	37.676	2	.000	.765	.782	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b.
Design: Intercept+coderx
Within Subjects Design: npq

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
npq	Sphericity Assumed	1549.691	2	774.846	5.118	.007
	Greenhouse-Geisser	1549.691	1.531	1012.217	5.118	.013
	Huynh-Feldt	1549.691	1.564	990.708	5.118	.012
	Lower-bound	1549.691	1.000	1549.691	5.118	.026
npq * coderx	Sphericity Assumed	338.684	2	169.342	1.119	.329
	Greenhouse-Geisser	338.684	1.531	221.219	1.119	.317
	Huynh-Feldt	338.684	1.564	216.518	1.119	.318
	Lower-bound	338.684	1.000	338.684	1.119	.293
Error(npq)	Sphericity Assumed	31489.544	208	151.392		
	Greenhouse-Geisser	31489.544	159.223	197.771		
	Huynh-Feldt	31489.544	162.679	193.568		
	Lower-bound	31489.544	104.000	302.784		

Multivariate Tests[b]

Effect		Value	F	Hypothesis df	Error df	Sig.
npq	Pillai's Trace	.097	5.534[a]	2.000	103.000	.005
	Wilks' Lambda	.903	5.534[a]	2.000	103.000	.005
	Hotelling's Trace	.107	5.534[a]	2.000	103.000	.005
	Roy's Largest Root	.107	5.534[a]	2.000	103.000	.005
npq * coderx	Pillai's Trace	.015	.766[a]	2.000	103.000	.467
	Wilks' Lambda	.985	.766[a]	2.000	103.000	.467
	Hotelling's Trace	.015	.766[a]	2.000	103.000	.467
	Roy's Largest Root	.015	.766[a]	2.000	103.000	.467

a. Exact statistic

b.

Design: Intercept+coderx
Within Subjects Design: npq

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
npq	.694	37.676	2	.000	.765	.782	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b.

Design: Intercept+coderx
Within Subjects Design: npq

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
npq	Sphericity Assumed	1549.691	2	774.846	5.118	.007
	Greenhouse-Geisser	1549.691	1.531	1012.217	5.118	.013
	Huynh-Feldt	1549.691	1.564	990.708	5.118	.012
	Lower-bound	1549.691	1.000	1549.691	5.118	.026
npq * coderx	Sphericity Assumed	338.684	2	169.342	1.119	.329
	Greenhouse-Geisser	338.684	1.531	221.219	1.119	.317
	Huynh-Feldt	338.684	1.564	216.518	1.119	.318
	Lower-bound	338.684	1.000	338.684	1.119	.293
Error(npq)	Sphericity Assumed	31489.544	208	151.392		
	Greenhouse-Geisser	31489.544	159.223	197.771		
	Huynh-Feldt	31489.544	162.679	193.568		
	Lower-bound	31489.544	104.000	302.784		

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	npq	Type III Sum of Squares	df	Mean Square	F	Sig.
npq	Linear	1525.015	1	1525.015	7.410	.008
	Quadratic	24.676	1	24.676	.254	.615
npq * coderx	Linear	228.848	1	228.848	1.112	.294
	Quadratic	109.835	1	109.835	1.133	.290
Error(npq)	Linear	21404.777	104	205.815		
	Quadratic	10084.767	104	96.969		

Tests of Between-Subjects Effects

Measure: MEASURE_1

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	388370.884	1	388370.884	544.991	.000
coderx	1342.141	1	1342.141	1.883	.173
Error	74112.308	104	712.618		

Explore

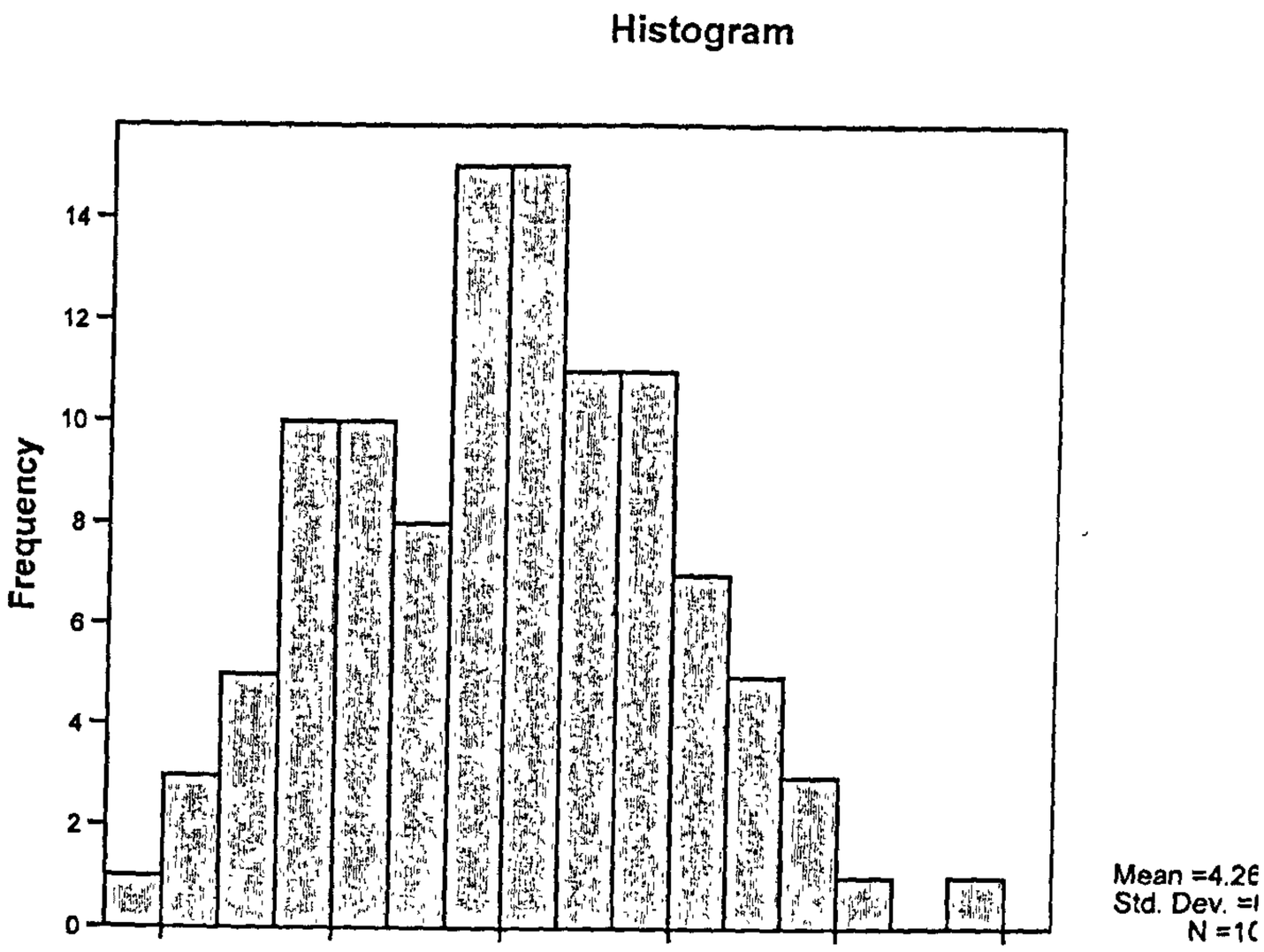
Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Standardized Residual for npqbase	106	70.2%	45	29.8%	151	100.0%
Standardized Residual for npq6week	106	70.2%	45	29.8%	151	100.0%
Standardized Residual for npq6mth	106	70.2%	45	29.8%	151	100.0%

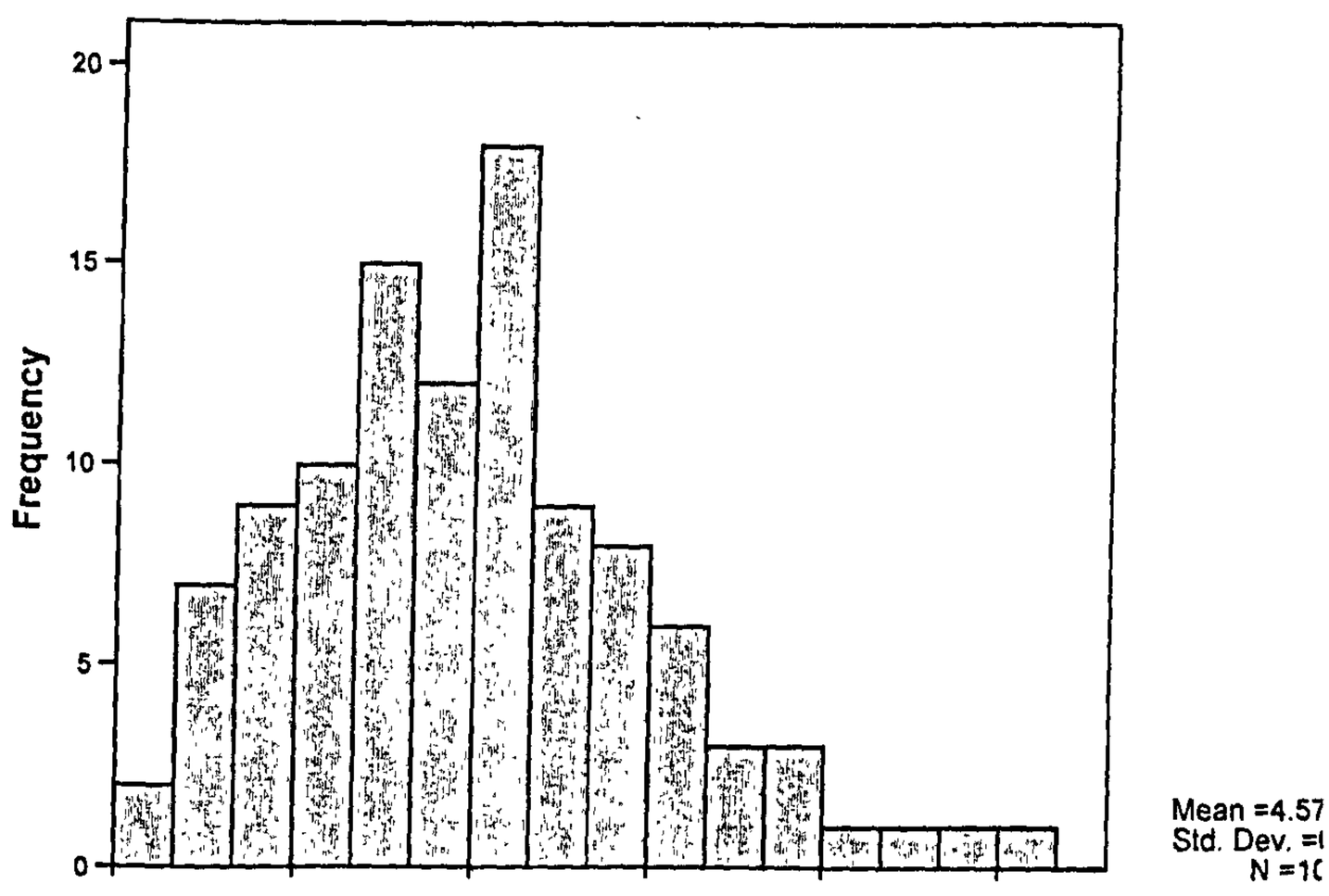
Descriptives

			Statistic	Std. Error
Standardized Residual for npqbase	Mean		.0000	.09666
	95% Confidence Interval for Mean	Lower Bound	-.1917	
		Upper Bound	.1917	
	5% Trimmed Mean		-.0138	
	Median		.0219	
	Variance		.990	
	Std. Deviation		.99523	
	Minimum		-2.10	
	Maximum		2.77	
	Range		4.87	
	Interquartile Range		1.62	
	Skewness		.147	.235
	Kurtosis		-.391	.465
Standardized Residual for npq6week	Mean		.0000	.09666
	95% Confidence Interval for Mean	Lower Bound	-.1917	
		Upper Bound	.1917	
	5% Trimmed Mean		-.0471	
	Median		-.0563	
	Variance		.990	
	Std. Deviation		.99523	
	Minimum		-1.74	
	Maximum		3.08	
	Range		4.83	
	Interquartile Range		1.31	
	Skewness		.674	.235
	Kurtosis		.447	.465
Standardized Residual for npq6mth	Mean		.0000	.09666
	95% Confidence Interval for Mean	Lower Bound	-.1917	
		Upper Bound	.1917	
	5% Trimmed Mean		-.0374	
	Median		-.0388	
	Variance		.990	
	Std. Deviation		.99523	
	Minimum		-1.73	
	Maximum		2.65	
	Range		4.38	
	Interquartile Range		1.37	
	Skewness		.422	.235
	Kurtosis		-.289	.465

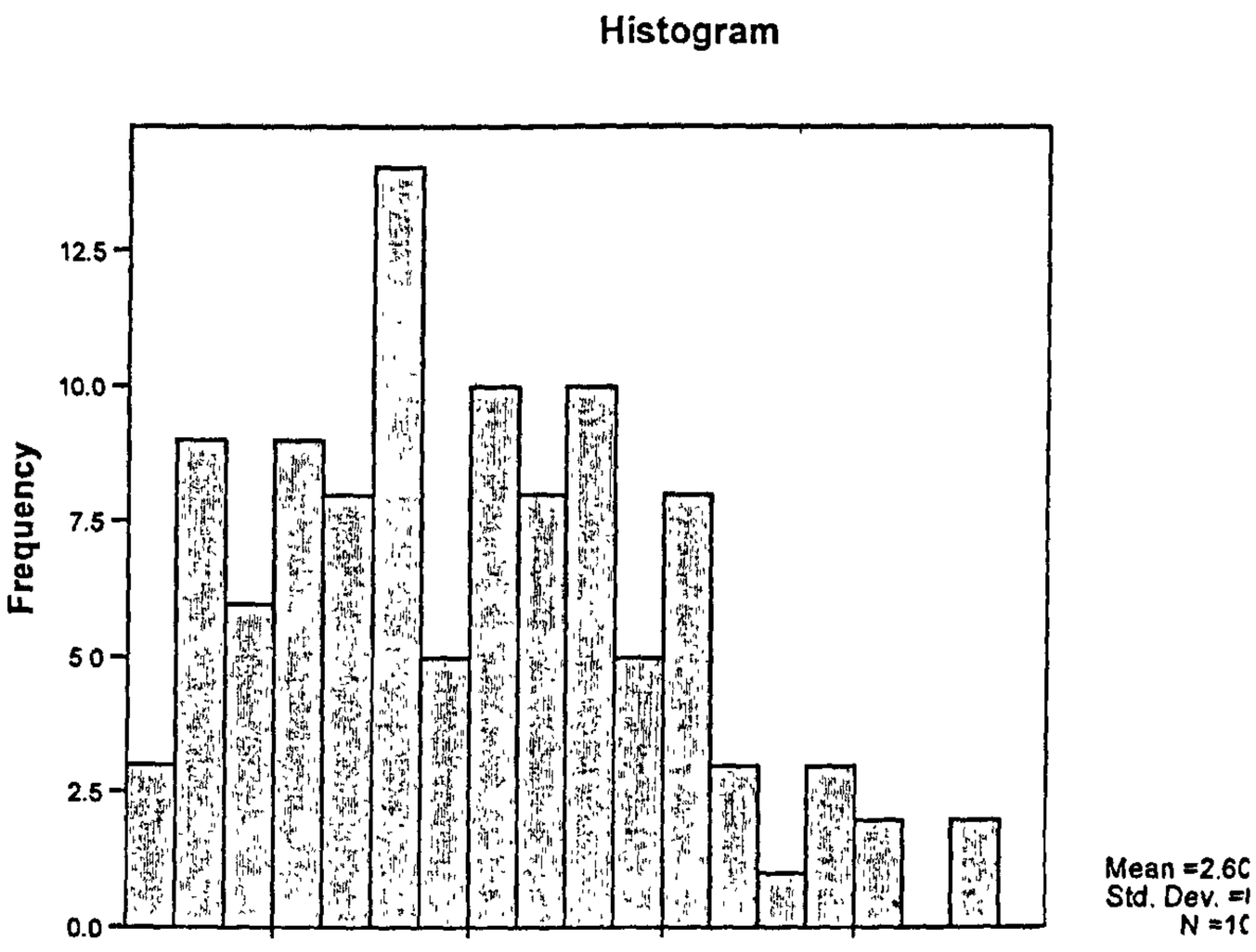
Standardized Residual for npqbase



Standardized Residual for npq6week



Standardized Residual for npq6mth



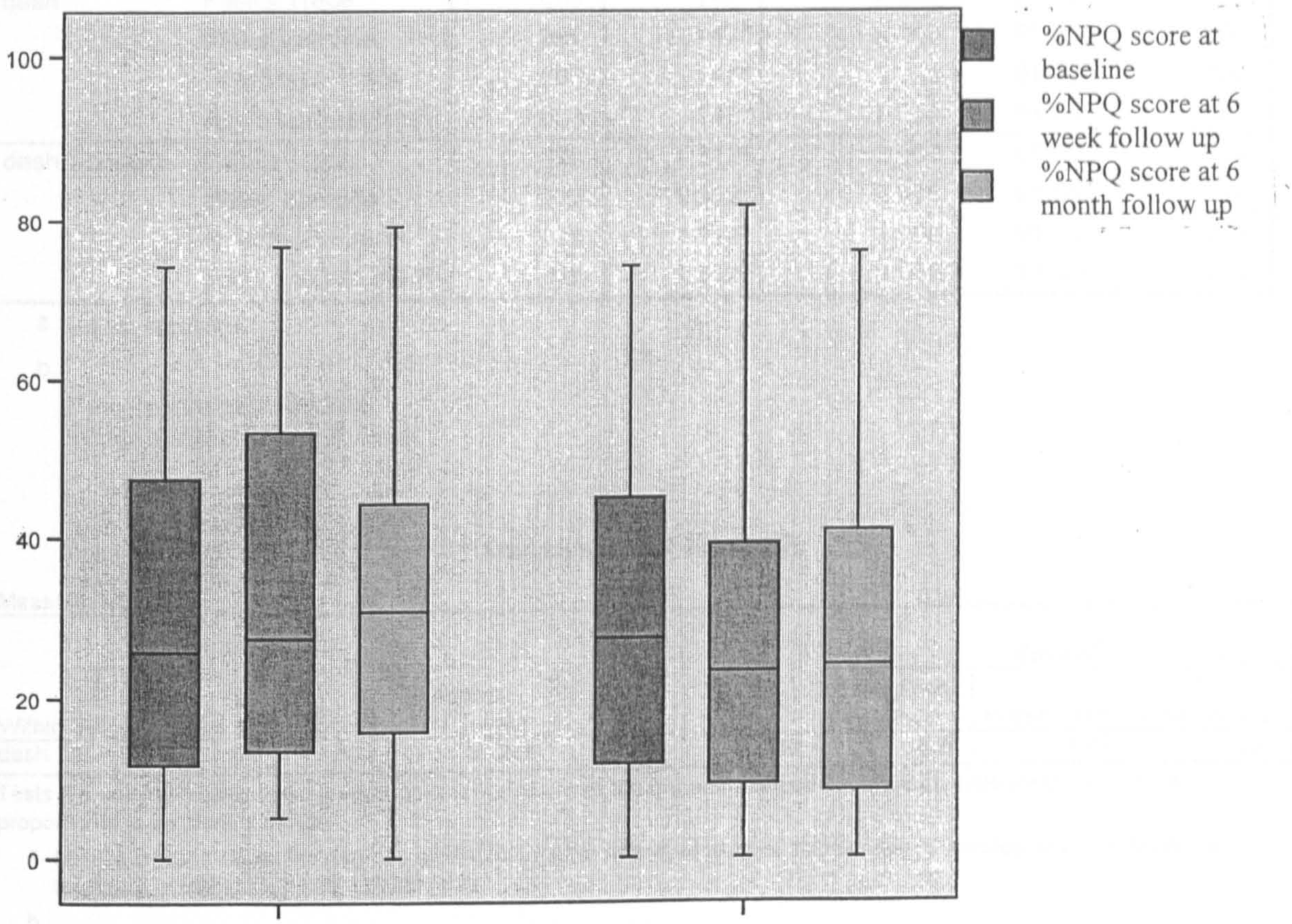
Repeated measures ANOVA for DASH score at baseline, 6 weeks and 6 months including boxplot analysis and analysis of residuals

Case Processing Summary

		Cases					
		Valid		Missing		Total	
	intervention	N	Percent	N	Percent	N	Percent
%DASH score at baseline	graded exercise treatment	41	54.7%	34	45.3%	75	100.0%
	usual physiotherapy	53	69.7%	23	30.3%	76	100.0%
% DASH scores at 6 weeks follow-up	graded exercise treatment	41	54.7%	34	45.3%	75	100.0%
	usual physiotherapy	53	69.7%	23	30.3%	76	100.0%
% DASH scores at 6 month follow-up	graded exercise treatment	41	54.7%	34	45.3%	75	100.0%
	usual physiotherapy	53	69.7%	23	30.3%	76	100.0%

Descriptives

	intervention			Statistic	Std. Error
%DASH score at baseline	graded exercise treatment	Mean		29.9868	3.14393
		95% Confidence Interval for Mean	Lower Bound	23.6327	
			Upper Bound	36.3409	
		5% Trimmed Mean		29.1905	
		Median		25.8333	
		Variance		405.258	
		Std. Deviation		20.13098	
		Minimum		.00	
		Maximum		74.17	
		Range		74.17	
		Interquartile Range		36.25	
		Skewness		.510	.369
		Kurtosis		-.724	.724
	usual physiotherapy	Mean		29.7416	2.79023
		95% Confidence Interval for Mean	Lower Bound	24.1428	
			Upper Bound	35.3406	
		5% Trimmed Mean		29.0927	
		Median		27.5000	
		Variance		412.624	
		Std. Deviation		20.31315	
		Minimum		.00	
		Maximum		74.17	
		Range		74.17	
		Interquartile Range		35.00	
		Skewness		.469	.327
		Kurtosis		-.749	.644
% DASH scores at 6 weeks follow-up	graded exercise treatment	Mean		33.6444	3.38954
		95% Confidence Interval for Mean	Lower Bound	26.7939	
			Upper Bound	40.4949	
		5% Trimmed Mean		32.9352	
		Median		27.5000	
		Variance		471.048	
		Std. Deviation		21.70364	
		Minimum		5.17	
		Maximum		76.67	
		Range		71.49	
		Interquartile Range		41.34	
		Skewness		.367	.369
		Kurtosis		-1.268	.724
	usual physiotherapy	Mean		26.2579	2.71102
		95% Confidence Interval for Mean	Lower Bound	20.8178	
			Upper Bound	31.6980	
		5% Trimmed Mean		25.2324	
		Median		23.3333	
		Variance		389.530	
		Std. Deviation		19.73652	
		Minimum		.00	
		Maximum		81.67	
		Range		81.67	
		Interquartile Range		31.23	
		Skewness		.774	.327
		Kurtosis		-.158	.644
% DASH scores at 6 month follow-up	graded exercise treatment	Mean		31.9293	3.02458
		95% Confidence Interval for Mean	Lower Bound	25.8164	
			Upper Bound	38.0422	
		5% Trimmed Mean		31.3546	
		Median		30.8333	
		Variance		375.071	
		Std. Deviation		19.36676	
		Minimum		.00	
		Maximum		79.17	
		Range		79.17	
		Interquartile Range		29.50	
		Skewness		.312	.369
		Kurtosis		-.373	.724
	usual physiotherapy	Mean		26.8368	2.61869
		95% Confidence Interval for Mean	Lower Bound	21.1807	
			Upper Bound	32.4929	
		5% Trimmed Mean		25.8427	
		Median		24.1667	
		Variance		421.085	
		Std. Deviation		20.52035	
		Minimum		.00	
		Maximum		75.86	
		Range		75.86	
		Interquartile Range		33.75	
		Skewness		.554	327
		Kurtosis		-.570	.644



General Linear Model

Within-Subjects Factors

Measure: MEASURE_1

dash	Dependent Variable
1	dashbase
2	dash6wk
3	dash6mth

Between-Subjects Factors

		Value Label	N
intervention	1	graded exercise treatment	41
	2	usual physiotherapy	53

Multivariate Tests[b]

Effect		Value	F	Hypothesis df	Error df	Sig.
dash	Pillai's Trace	.003	.147[a]	2.000	91.000	.863
	Wilks' Lambda	.997	.147[a]	2.000	91.000	.863
	Hotelling's Trace	.003	.147[a]	2.000	91.000	.863
	Roy's Largest Root	.003	.147[a]	2.000	91.000	.863
dash * coderx	Pillai's Trace	.028	1.312[a]	2.000	91.000	.274
	Wilks' Lambda	.972	1.312[a]	2.000	91.000	.274
	Hotelling's Trace	.029	1.312[a]	2.000	91.000	.274
	Roy's Largest Root	.029	1.312[a]	2.000	91.000	.274

a. Exact statistic

b.

Design: Intercept+coderx
Within Subjects Design: dash

Mauchly's Test of Sphericity[b]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
dash	.521	59.269	2	.000	.676	.690	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b.

Design: Intercept+coderx
Within Subjects Design: dash

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
dash	Sphericity Assumed	17.315	2	8.658	.050	.952
	Greenhouse-Geisser	17.315	1.353	12.801	.050	.890
	Huynh-Feldt	17.315	1.381	12.542	.050	.894
	Lower-bound	17.315	1.000	17.315	.050	.824
dash * coderx	Sphericity Assumed	614.588	2	307.294	1.762	.175
	Greenhouse-Geisser	614.588	1.353	454.375	1.762	.185
	Huynh-Feldt	614.588	1.381	445.172	1.762	.185
	Lower-bound	614.588	1.000	614.588	1.762	.188
Error(dash)	Sphericity Assumed	32088.839	184	174.396		
	Greenhouse-Geisser	32088.839	124.439	257.868		
	Huynh-Feldt	32088.839	127.012	252.645		
	Lower-bound	32088.839	92.000	348.792		

Tests of Within-Subjects Contrasts

Measure: MEASURE_1

Source	dash	Type III Sum of Squares	df	Mean Square	F	Sig.
dash	Linear	10.704	1	10.704	.049	.826
	Quadratic	6.612	1	6.612	.051	.822
dash * coderx	Linear	271.593	1	271.593	1.238	.269
	Quadratic	342.995	1	342.995	2.651	.107
Error(dash)	Linear	20186.989	92	219.424		
	Quadratic	11901.850	92	129.368		

Tests of Between-Subjects Effects

Measure: MEASURE_1

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	245236.315	1	245236.315	276.578	.000
coderx	1247.578	1	1247.578	1.407	.239
Error	81574.616	92	886.681		

Explore

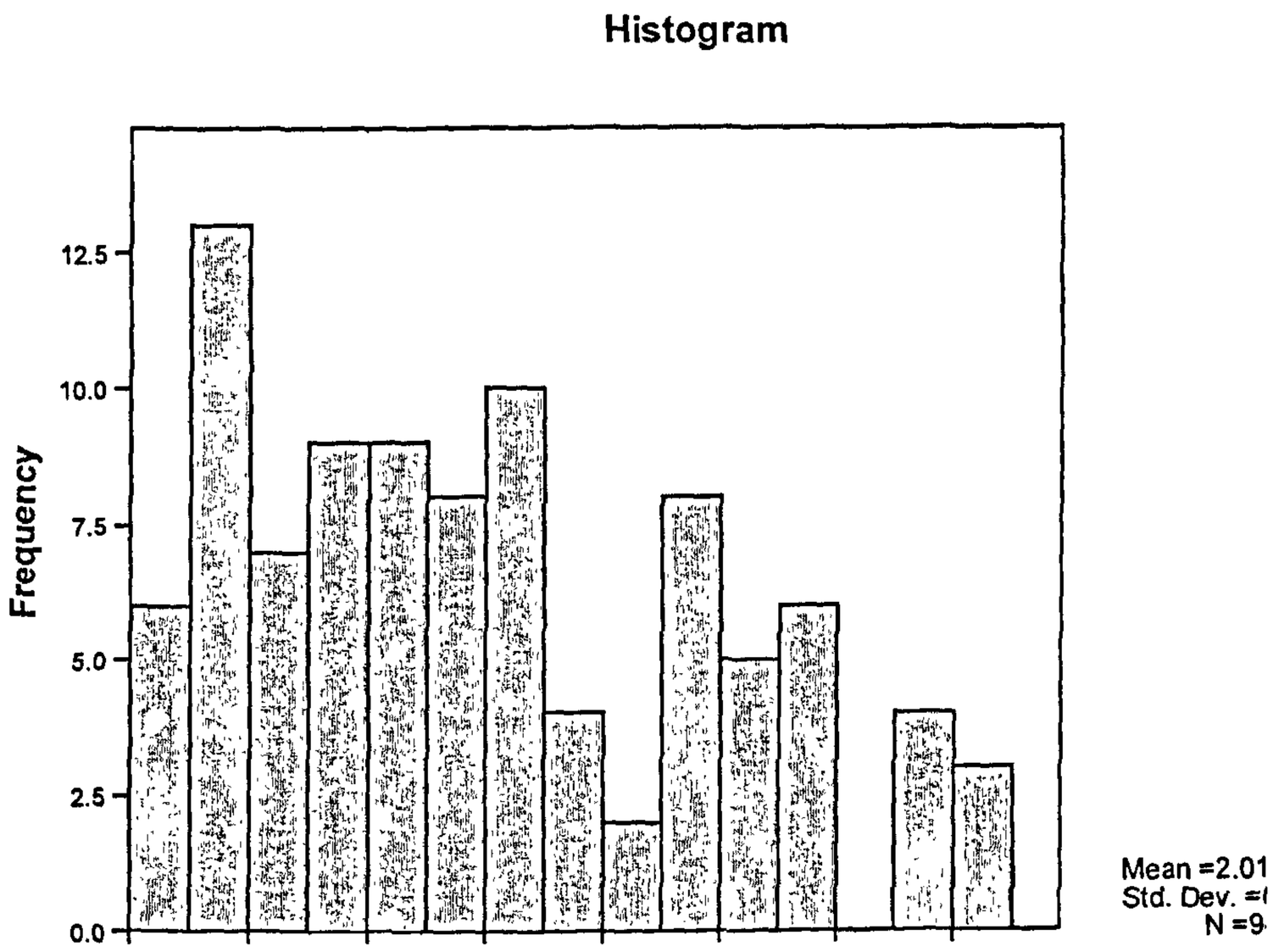
Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Standardized Residual for dashbase	94	62.3%	57	37.7%	151	100.0%
Standardized Residual for dash6wk	94	62.3%	57	37.7%	151	100.0%
Standardized Residual for dash6mth	94	62.3%	57	37.7%	151	100.0%

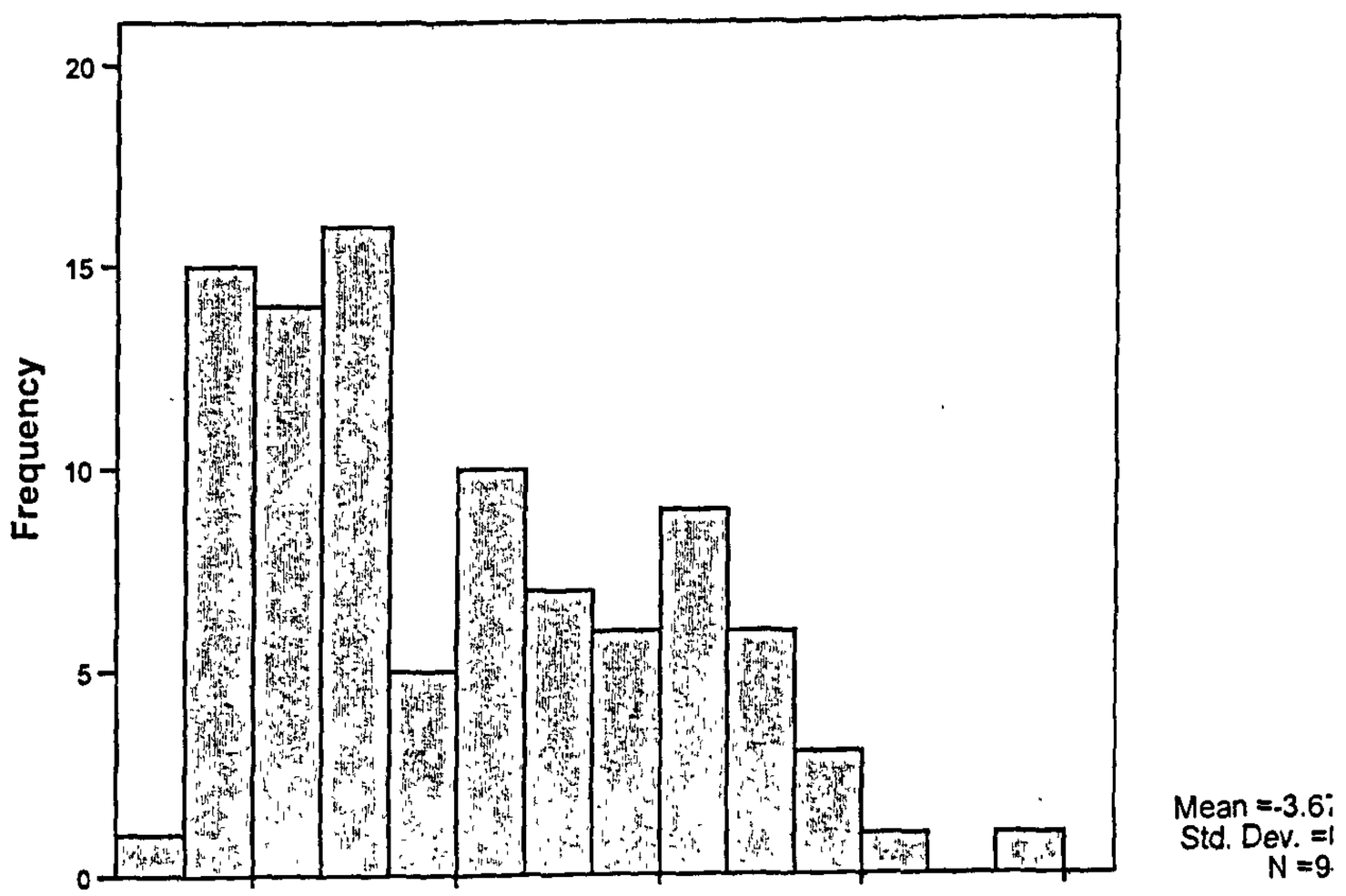
Descriptives

			Statistic	Std. Error
Standardized Residual for dashbase	Mean		.0000	.10259
	95% Confidence Interval for Mean	Lower Bound	-.2037	
		Upper Bound	.2037	
	5% Trimmed Mean		-.0353	
	Median		-.1374	
	Variance		.989	
	Std. Deviation		.99461	
	Minimum		-1.48	
	Maximum		2.20	
	Range		3.68	
	Interquartile Range		1.78	
	Skewness		.479	.249
	Kurtosis		-.763	.493
Standardized Residual for dash6wk	Mean		.0000	.10259
	95% Confidence Interval for Mean	Lower Bound	-.2037	
		Upper Bound	.2037	
	5% Trimmed Mean		-.0425	
	Median		-.2981	
	Variance		.989	
	Std. Deviation		.99461	
	Minimum		-1.38	
	Maximum		2.69	
	Range		4.07	
	Interquartile Range		1.67	
	Skewness		.562	.249
	Kurtosis		-.743	.493
Standardized Residual for dash6mth	Mean		.0000	.10259
	95% Confidence Interval for Mean	Lower Bound	-.2037	
		Upper Bound	.2037	
	5% Trimmed Mean		-.0387	
	Median		-.0940	
	Variance		.989	
	Std. Deviation		.99461	
	Minimum		-1.59	
	Maximum		2.45	
	Range		4.04	
	Interquartile Range		1.59	
	Skewness		.453	.249
	Kurtosis		-.525	.493

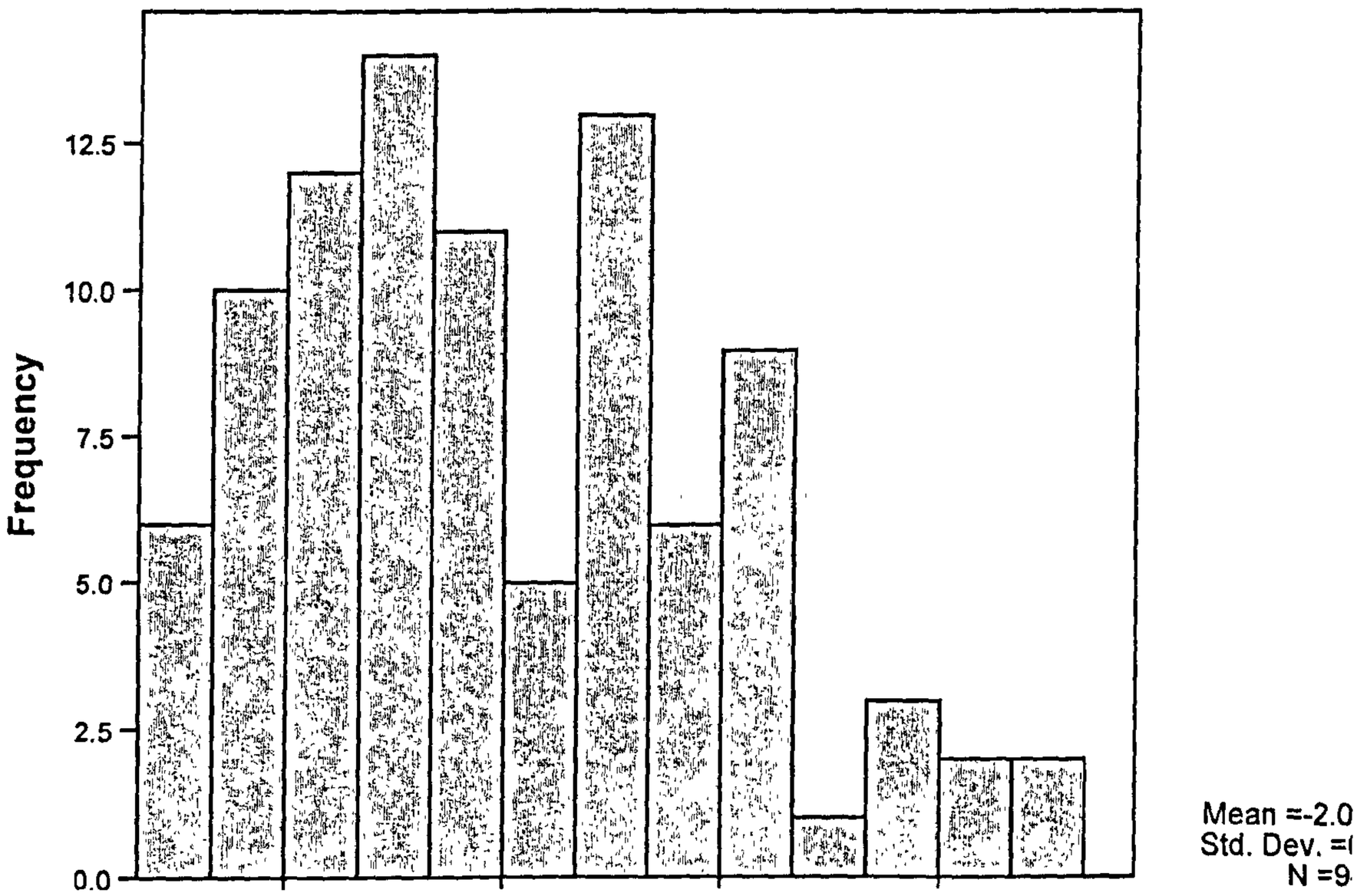
Standardized Residual for DASH at baseline



Standardized Residual for DASH at 6weeks



Standardized Residual for DASH at 6 months



Components of usual physiotherapy treatment given

Number of patients who did not attend assessment (DNA)		9
Number of patients who did not complete treatment		12
Number of patients who completed treatment		55
Average number of treatments per patient (excludes DNA)		5.7
Treatment	Specific	No of patients who received this treatment
Exercises	Home exercises	57[1]
	McKenzie exercises	31
	Neck strengthening	0
	Stretches	25[2]
	Cervical stabilisation	24
	Upper limb strengthening	4
	Other specific exercises	33[3]
	General exercise	3
Manual Therapy	Manipulation	0
	Mobilisation	42
	Neural biased	4
	Muscle biased	20
	Massage	1
Modalities	Traction	3
	Shortwave diathermy	7
	Ultrasound	3
	Interferential	0
	TENS	2
	Acupuncture	4
	Ice/heat	15
	Collar	1
	Taping	1
	Ergonomic advice	1

[1]Home exercise programmes were mainly based on exercises that had been performed in the department ie McKenzie, cervical stabilisation etc

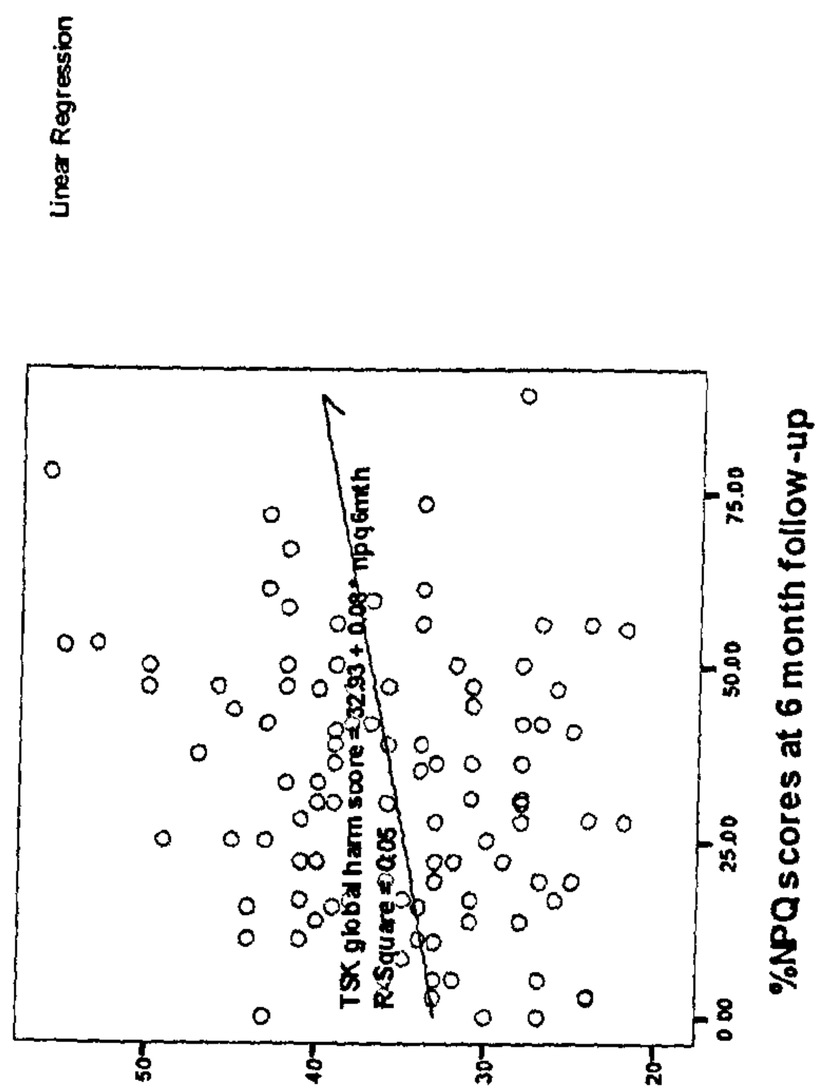
[2]Stretches were either active ranges of motion or muscle stretches

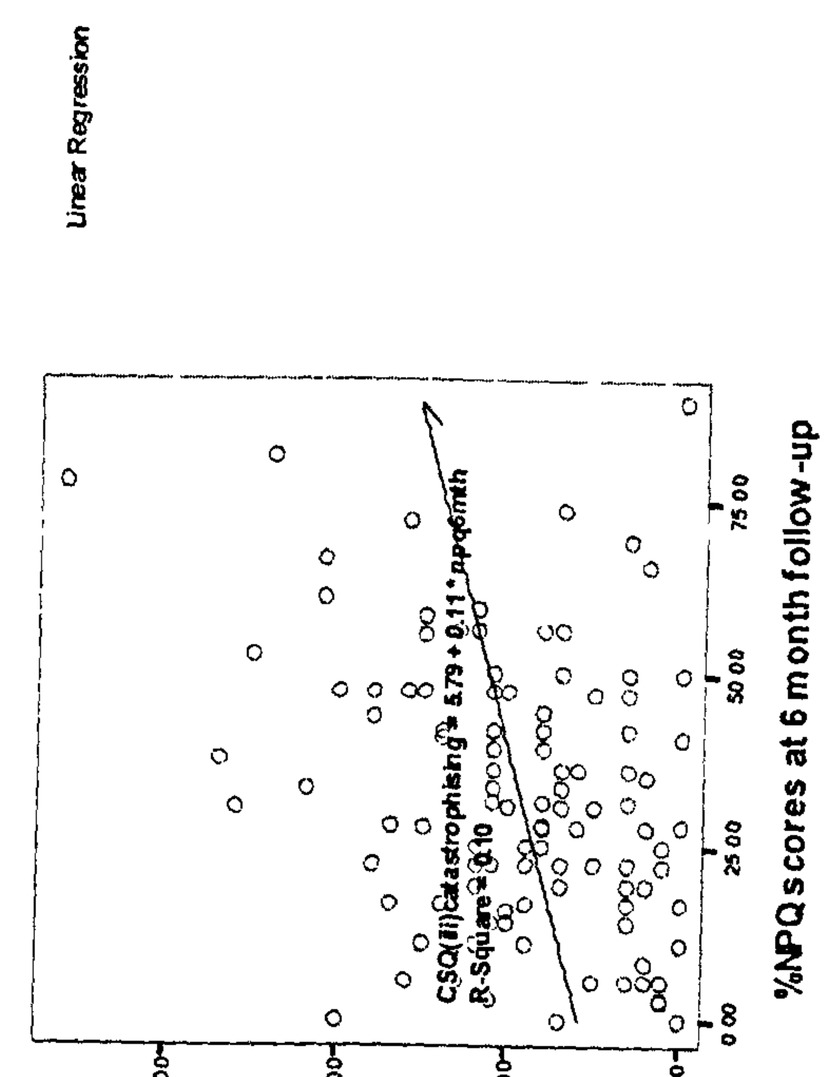
[3]Other specific exercises included scapular, thoracic, postural exercises, relaxation etc

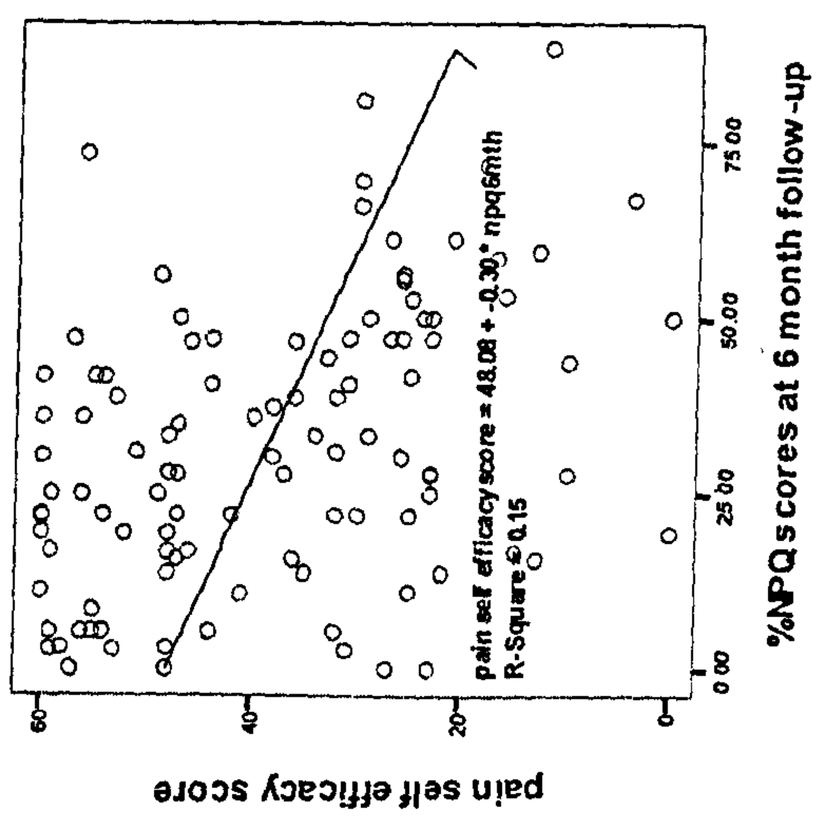
Components of graded exercise treatment

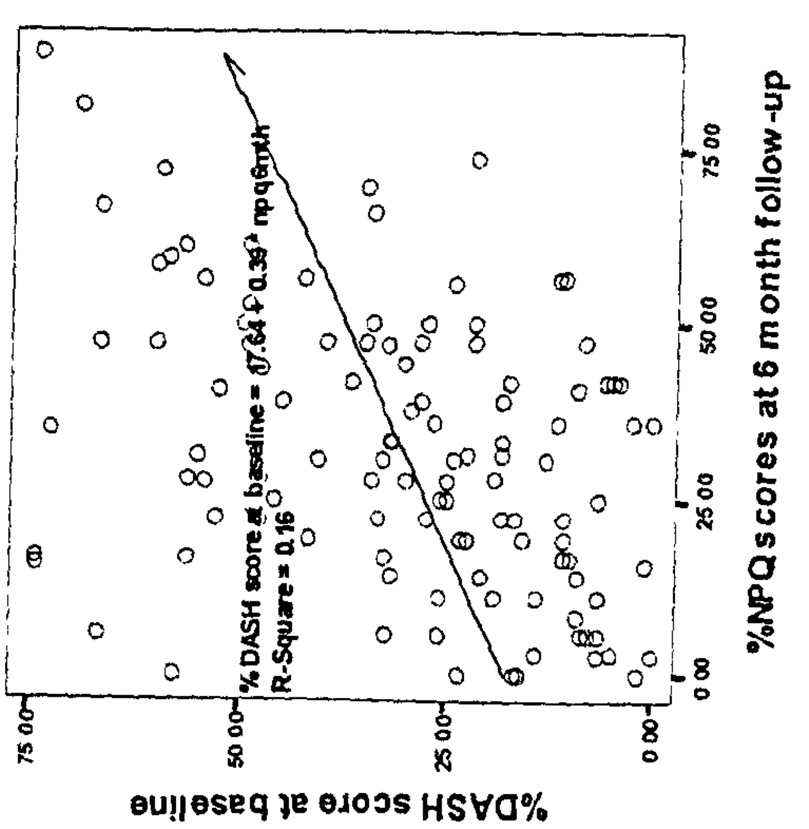
Number of patients who did not attend classes (DNA)	12
Number of patients who withdrew from treatment	4
Number of patients who ended up in UP treatment group	1
Number of patients who did not complete treatment	
• Completed 1 class	3
• Completed 2 classes	8
• Completed 3 classes	2
• Completed 4 classes	6
• Completed 5 classes	4
Total	23
Number of patients who completed treatment as per protocol	35

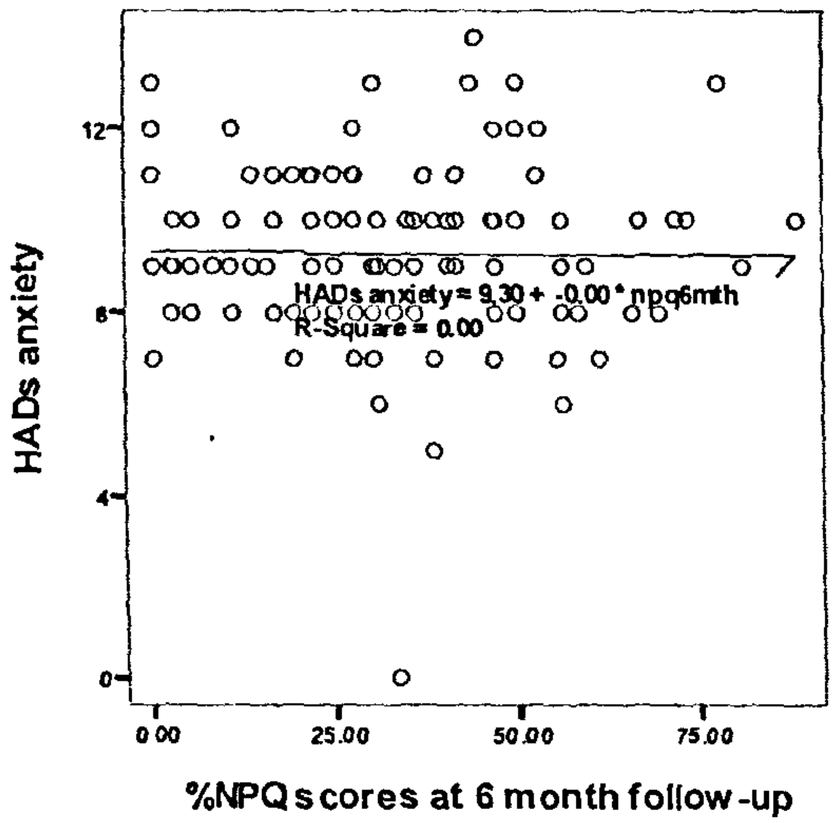
Scatter plots of six month NPQ scores and continuous baseline covariates



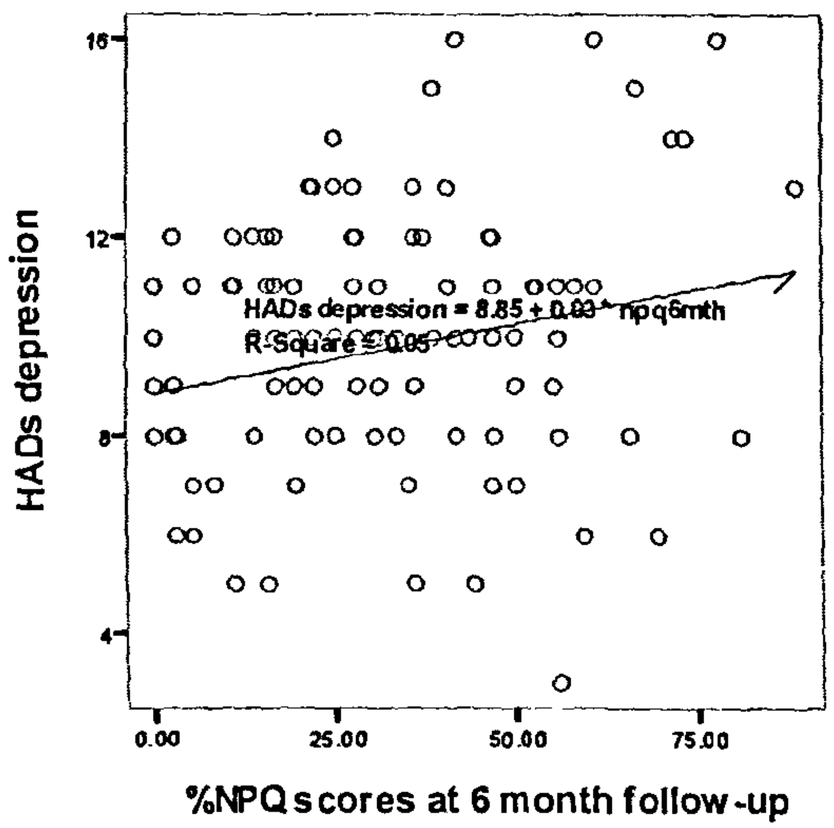




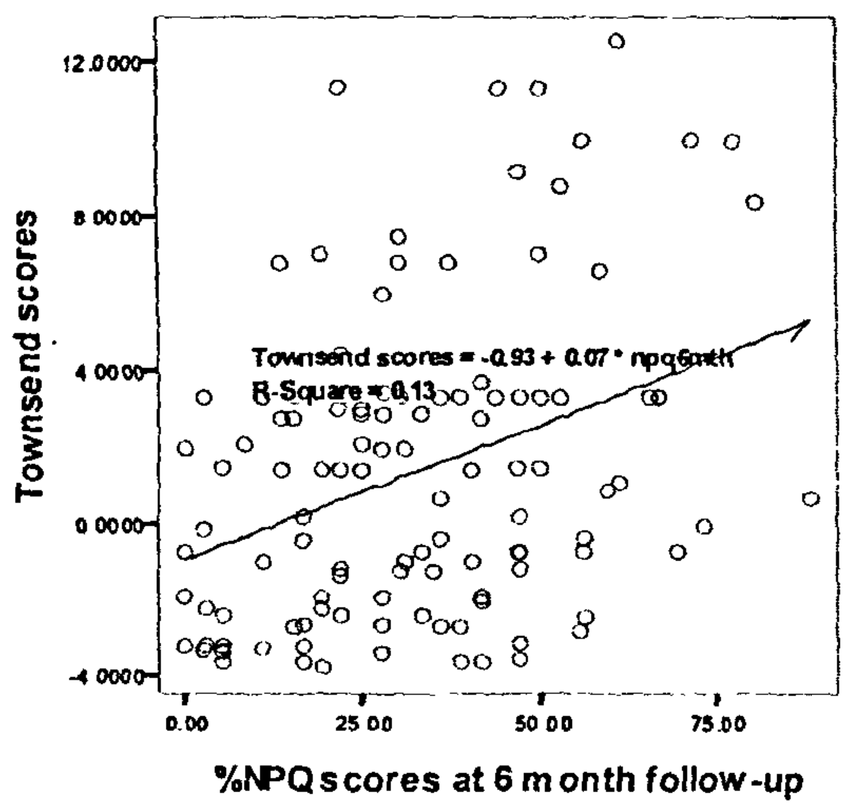




Linear Regression



Linear Regression



Linear Regression

Correlation between six month NPQ scores and baseline covariates

Correlations

		%NPQ scores at baseline	%NPQ scores at 6 month follow-up
%NPQ scores at baseline	Pearson Correlation	1	.384**
	Sig. (2-tailed)		.000
	N	151	117
%NPQ scores at 6 month follow-up	Pearson Correlation	.384**	1
	Sig. (2-tailed)	.000	
	N	117	117
%DASH score at baseline	Pearson Correlation	.799**	.394**
	Sig. (2-tailed)	.000	.000
	N	142	111
pain self efficacy score	Pearson Correlation	-.600**	-.386**
	Sig. (2-tailed)	.000	.000
	N	145	111
CSQ(iii)catastrophising	Pearson Correlation	.378**	.313**
	Sig. (2-tailed)	.000	.001
	N	141	110
TSK global harm score	Pearson Correlation	.249**	.218*
	Sig. (2-tailed)	.003	.023
	N	139	109
HADs anxiety	Pearson Correlation	.107	-.008
	Sig. (2-tailed)	.192	.934
	N	151	117
HADs depression	Pearson Correlation	.242**	.225*
	Sig. (2-tailed)	.003	.015
	N	149	116
Townsend scores	Pearson Correlation	.058	.355**
	Sig. (2-tailed)	.478	.000
	N	150	116

Correlations

		%DASH score at baseline	pain self efficacy score
%NPQ scores at baseline	Pearson Correlation	.799**	-.600**
	Sig. (2-tailed)	.000	.000
	N	142	145
%NPQ scores at 6 month follow-up	Pearson Correlation	.394**	-.386**
	Sig. (2-tailed)	.000	.000
	N	111	111
%DASH score at baseline	Pearson Correlation	1	-.666**
	Sig. (2-tailed)		.000
	N	142	137
pain self efficacy score	Pearson Correlation	-.666**	1
	Sig. (2-tailed)	.000	
	N	137	145
CSQ(iii)catastrophising	Pearson Correlation	.367**	-.372**
	Sig. (2-tailed)	.000	.000
	N	135	135
TSK global harm score	Pearson Correlation	.204*	-.286**
	Sig. (2-tailed)	.020	.001
	N	131	133
HADs anxiety	Pearson Correlation	.104	-.178*
	Sig. (2-tailed)	.220	.032
	N	142	145
HADs depression	Pearson Correlation	.245**	-.197*
	Sig. (2-tailed)	.004	.019
	N	140	143
Townsend scores	Pearson Correlation	.089	-.208*
	Sig. (2-tailed)	.293	.012
	N	141	144

Correlations

		CSQ(iii)catastrophising	TSK global harm score
%NPQ scores at baseline	Pearson Correlation	.378**	.249**
	Sig. (2-tailed)	.000	.003
	N	141	139
%NPQ scores at 6 month follow-up	Pearson Correlation	.313**	.218*
	Sig. (2-tailed)	.001	.023
	N	110	109
%DASH score at baseline	Pearson Correlation	.367**	.204*
	Sig. (2-tailed)	.000	.020
	N	135	131
pain self efficacy score	Pearson Correlation	-.372**	-.286**
	Sig. (2-tailed)	.000	.001
	N	135	133
CSQ(iii)catastrophising	Pearson Correlation	1	.475**
	Sig. (2-tailed)		.000
	N	141	132
TSK global harm score	Pearson Correlation	.475**	1
	Sig. (2-tailed)	.000	
	N	132	139
HADs anxiety	Pearson Correlation	-.036	.287**
	Sig. (2-tailed)	.673	.001
	N	141	139
HADs depression	Pearson Correlation	.360**	.244**
	Sig. (2-tailed)	.000	.004
	N	140	139
Townsend scores	Pearson Correlation	.161	.274**
	Sig. (2-tailed)	.057	.001
	N	140	138

Correlations

		HADs anxiety	HADs depression
%NPQ scores at baseline	Pearson Correlation	.107	.242**
	Sig. (2-tailed)	.192	.003
	N	151	149
%NPQ scores at 6 month follow-up	Pearson Correlation	-.008	.225*
	Sig. (2-tailed)	.934	.015
	N	117	116
%DASH score at baseline	Pearson Correlation	.104	.245**
	Sig. (2-tailed)	.220	.004
	N	142	140
pain self efficacy score	Pearson Correlation	-.178*	-.197*
	Sig. (2-tailed)	.032	.019
	N	145	143
CSQ(iii)catastrophising	Pearson Correlation	-.036	.360**
	Sig. (2-tailed)	.673	.000
	N	141	140
TSK global harm score	Pearson Correlation	.287**	.244**
	Sig. (2-tailed)	.001	.004
	N	139	139
HADs anxiety	Pearson Correlation	1	.071
	Sig. (2-tailed)		.389
	N	151	149
HADs depression	Pearson Correlation	.071	1
	Sig. (2-tailed)	.389	
	N	149	149
Townsend scores	Pearson Correlation	.109	.173*
	Sig. (2-tailed)	.185	.036
	N	150	148

Correlations

		Townsend scores
%NPQ scores at baseline	Pearson Correlation	.058
	Sig. (2-tailed)	.478
	N	150
%NPQ scores at 6 month follow-up	Pearson Correlation	.355**
	Sig. (2-tailed)	.000
	N	116
%DASH score at baseline	Pearson Correlation	.089
	Sig. (2-tailed)	.293
	N	141
pain self efficacy score	Pearson Correlation	-.208*
	Sig. (2-tailed)	.012
	N	144
CSQ(iii)catastrophising	Pearson Correlation	.161
	Sig. (2-tailed)	.057
	N	140
TSK global harm score	Pearson Correlation	.274**
	Sig. (2-tailed)	.001
	N	138
HADs anxiety	Pearson Correlation	.109
	Sig. (2-tailed)	.185
	N	150
HADs depression	Pearson Correlation	.173*
	Sig. (2-tailed)	.036
	N	148
Townsend scores	Pearson Correlation	1
	Sig. (2-tailed)	
	N	150

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Backward linear regression to determine baseline predictors of NPQ score at six months

Between-Subjects Factors

		Value Label	N
intervention	1	graded exercise treatment	45
	2	usual physiotherapy	48

Tests of Between-Subjects Effects

Dependent Variable: %NPQ scores at 6 month follow-up

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	11264.150[a]	8	1408.019	5.067	.000
Intercept	478.534	1	478.534	1.722	.193
coderx	2356.816	1	2356.816	8.482	.005
npqbase	100.631	1	100.631	.362	.549
townsend	1081.714	1	1081.714	3.893	.052
tskglob	17.056	1	17.056	.061	.805
pseqtot	5.536	1	5.536	.020	.888
dashbase	308.489	1	308.489	1.110	.295
csqcatas	516.826	1	516.826	1.860	.176
coderx * tskglob	1984.095	1	1984.095	7.141	.009
Error	23339.670	84	277.853		
Total	122887.839	93			
Corrected Total	34603.821	92			

a. R Squared = .326 (Adjusted R Squared = .261)

Parameter Estimates

Dependent Variable: %NPQ scores at 6 month follow-up

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-8.692	19.546	-.445	.658	-47.561	30.178
[coderx=1]	57.224	19.648	2.912	.005	18.151	96.297
[coderx=2]	0[a]	.	.	.	.	.
npqbase	.115	.190	.602	.549	-.264	.493
townsend	.952	.483	1.973	.052	-.007	1.912
tskglob	.648	.451	1.437	.154	-.249	1.545
pseqtot	-.025	.177	-.141	.888	-.376	.326
dashbase	.171	.163	1.054	.295	-.152	.495
csqcatas	.447	.328	1.364	.176	-.205	1.099
[coderx=1] * tskglob	-1.453	.544	-2.672	.009	-2.533	-.372
[coderx=2] * tskglob	0[a]	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Univariate Analysis of Variance

Between-Subjects Factors

		Value Label	N
intervention	1	graded exercise treatment	46
	2	usual physiothera py	52

Tests of Between-Subjects Effects

Dependent Variable: %NPQ scores at 6 month follow-up

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	10648.603[a]	7	1521.229	5.638	.000
Intercept	819.789	1	819.789	3.038	.085
coderx	2188.808	1	2188.808	8.112	.005
npqbase	243.414	1	243.414	.902	.345
townsend	1484.774	1	1484.774	5.503	.021
tskglob	7.961	1	7.961	.030	.864
dashbase	225.087	1	225.087	.834	.363
csqcatas	503.388	1	503.388	1.866	.175
coderx * tskglob	1801.644	1	1801.644	6.677	.011
Error	24283.920	90	269.821		
Total	126244.923	98			
Corrected Total	34932.523	97			

a. R Squared = .305 (Adjusted R Squared = .251)

Parameter Estimates

Dependent Variable: %NPQ scores at 6 month follow-up

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-8.370	13.638	-.614	.541	-35.465	18.725
[coderx=1]	51.019	17.913	2.848	.005	15.432	86.606
[coderx=2]	0[a]	.	.	.	.	.
npqbase	.169	.178	.950	.345	-.185	.524
townsend	1.026	.437	2.346	.021	.157	1.894
tskglob	.601	.404	1.490	.140	-.200	1.403
dashbase	.131	.143	.913	.363	-.154	.415
csqcatas	.430	.315	1.366	.175	-.195	1.055
[coderx=1] * tskglob	-1.303	.504	-2.584	.011	-2.304	-.301
[coderx=2] * tskglob	0[a]	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Univariate Analysis of Variance

Between-Subjects Factors

		Value Label	N
intervention	1	graded exercise treatment	47
	2	usual physiothera py	55

Tests of Between-Subjects Effects

Dependent Variable: %NPQ scores at 6 month follow-up

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	12383.471[a]	6	2063.912	7.709	.000
Intercept	476.411	1	476.411	1.780	.185
coderx	2144.204	1	2144.204	8.009	.006
npqbase	2452.909	1	2452.909	9.162	.003
townsend	1891.511	1	1891.511	7.065	.009
tskglob	2.551	1	2.551	.010	.922
csqcatas	850.772	1	850.772	3.178	.078
coderx * tskglob	1708.681	1	1708.681	6.382	.013
Error	25433.548	95	267.722		
Total	135532.274	102			
Corrected Total	37817.019	101			

a. R Squared = .327 (Adjusted R Squared = .285)

Parameter Estimates

Dependent Variable: %NPQ scores at 6 month follow-up

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-11.130	12.276	-.907	.367	-35.501	13.241
[coderx=1]	46.279	16.353	2.830	.006	13.815	78.743
[coderx=2]	0[a]	.	.	.	.	.
npqbase	.325	.107	3.027	.003	.112	.538
townsend	1.140	.429	2.658	.009	.289	1.992
tskglob	.600	.357	1.679	.096	-.110	1.309
csqcatas	.509	.286	1.783	.078	-.058	1.076
[coderx=1] * tskglob	-1.148	.454	-2.526	.013	-2.049	-.246
[coderx=2] * tskglob	0[a]	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Univariate Analysis of Variance

Between-Subjects Factors

		Value Label	N
intervention	1	graded exercise treatment	49
	2	usual physiothera py	59

Tests of Between-Subjects Effects

Dependent Variable: %NPQ scores at 6 month follow-up

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	12244.319[a]	5	2448.864	8.711	.000
Intercept	246.491	1	246.491	.877	.351
coderx	2197.293	1	2197.293	7.817	.006
npqbase	3879.206	1	3879.206	13.800	.000
townsend	2897.459	1	2897.459	10.307	.002
tskglob	200.735	1	200.735	.714	.400
coderx * tskglob	1892.253	1	1892.253	6.731	.011
Error	28673.048	102	281.108		
Total	147197.132	108			
Corrected Total	40917.367	107			

a. R Squared = .299 (Adjusted R Squared = .265)

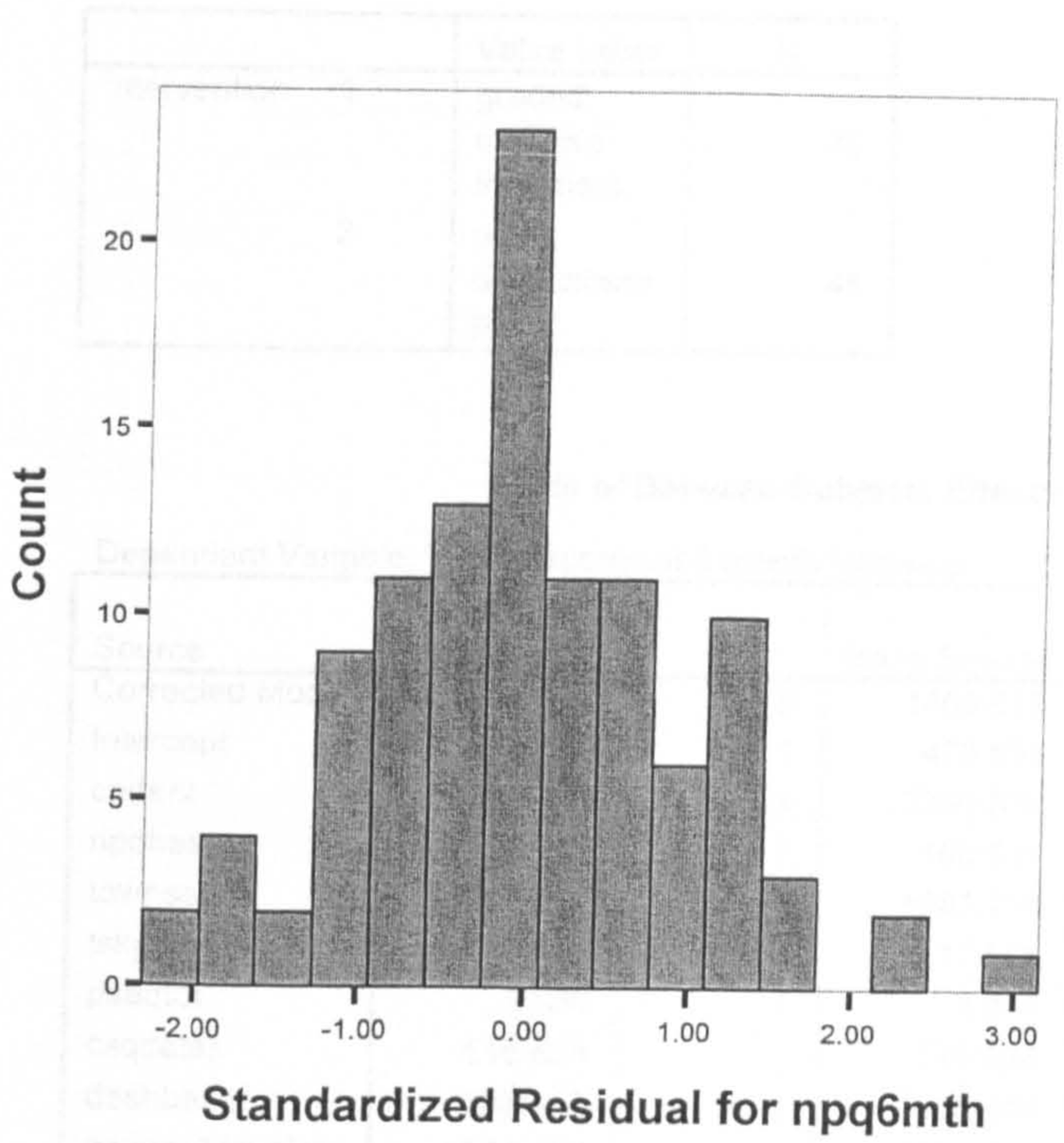
Parameter Estimates

Dependent Variable: %NPQ scores at 6 month follow-up

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-14.542	12.122	-1.200	.233	-38.586	9.503
[coderx=1]	45.198	16.167	2.796	.006	13.132	77.265
[coderx=2]	0[a]	.	.	.	.	.
npqbase	.389	.105	3.715	.000	.181	.597
townsend	1.375	.428	3.210	.002	.525	2.224
tskglob	.781	.340	2.295	.024	.106	1.456
[coderx=1] * tskglob	-1.158	.446	-2.594	.011	-2.044	-.273
[coderx=2] * tskglob	0[a]	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Interactive Graph



Backward linear regression with variables entered en bloc

Between-Subjects Factors

		Value Label	N
intervention	1	graded exercise treatment	45
	2	usual physiotherapy	48

Tests of Between-Subjects Effects

Dependent Variable: %NPQ scores at 6 month follow-up

Source	Type III Sum of Squares	df	Mean Square	F	Sig
Corrected Model	11264.150[a]	8	1408.019	5.067	.000
Intercept	478.534	1	478.534	1.722	.193
coderx	2356.816	1	2356.816	8.482	.005
npqbase	100.631	1	100.631	.362	.549
townsend	1081.714	1	1081.714	3.893	.052
tskglob	17.056	1	17.056	.061	.805
pseqtot	5.536	1	5.536	.020	.888
csqcatas	516.826	1	516.826	1.860	.176
dashbase	308.489	1	308.489	1.110	.295
coderx * tskglob	1984.095	1	1984.095	7.141	.009
Error	23339.670	84	277.853		
Total	122887.839	93			
Corrected Total	34603.821	92			

a. R Squared = .326 (Adjusted R Squared = .261)

Parameter Estimates

Dependent Variable: %NPQ scores at 6 month follow-up

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-8.692	19.546	-.445	.658	-47.561	30.178
[coderx=1]	57.224	19.648	2.912	.005	18.151	96.297
[coderx=2]	0[a]	.	.	.	.	.
npqbase	.115	.190	.602	.549	-.264	.493
townsend	.952	.483	1.973	.052	-.007	1.912
tskglob	.648	.451	1.437	.154	-.249	1.545
pseqtot	-.025	.177	-.141	.888	-.376	.326
csqcatas	.447	.328	1.364	.176	-.205	1.099
dashbase	.171	.163	1.054	.295	-.152	.495
[coderx=1] * tskglob	-1.453	.544	-2.672	.009	-2.533	-.372
[coderx=2] * tskglob	0[a]	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Univariate Analysis of Variance

Warnings

The following factors or covariates are not used in the model: pseqtot

Between-Subjects Factors

		Value Label	N
intervention	1	graded exercise treatment	45
	2	usual physiotherapy	48

Tests of Between-Subjects Effects

Dependent Variable: %NPQ scores at 6 month follow-up

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	11258.614[a]	7	1608.373	5.856	.000
Intercept	810.236	1	810.236	2.950	.090
coderx	2421.331	1	2421.331	8.816	.004
npqbase	113.892	1	113.892	.415	.521
townsend	1105.467	1	1105.467	4.025	.048
tskglob	17.402	1	17.402	.063	.802
csqcatas	561.190	1	561.190	2.043	.157
dashbase	398.486	1	398.486	1.451	.232
coderx * tskglob	2030.773	1	2030.773	7.394	.008
Error	23345.207	85	274.649		
Total	122887.839	93			
Corrected Total	34603.821	92			

a. R Squared = .325 (Adjusted R Squared = .270)

Parameter Estimates

Dependent Variable: %NPQ scores at 6 month follow-up

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-10.370	15.424	-.672	.503	-41.038	20.298
[coderx=1]	57.564	19.387	2.969	.004	19.017	96.112
[coderx=2]	0[a]	.	.	.	.	.
npqbase	.120	.186	.644	.521	-.250	.489
townsend	.959	.478	2.006	.048	.009	1.909
tskglob	.652	.448	1.455	.149	-.239	1.542
csqcatas	.457	.319	1.429	.157	-.178	1.092
dashbase	.180	.150	1.205	.232	-.117	.478
[coderx=1] * tskglob	-1.461	.537	-2.719	.008	-2.529	-.393
[coderx=2] * tskglob	0[a]	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Univariate Analysis of Variance

Warnings

The following factors or covariates are not used in the model: pseqtot, dashbase

Between-Subjects Factors

		Value Label	N
intervention	1	graded exercise treatment	45
	2	usual physiotherapy	48

Tests of Between-Subjects Effects

Dependent Variable: %NPQ scores at 6 month follow-up

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	10860.128[a]	6	1810.021	6.556	.000
Intercept	641.900	1	641.900	2.325	.131
coderx	2522.171	1	2522.171	9.135	.003
npqbase	1977.177	1	1977.177	7.161	.009
townsend	1174.170	1	1174.170	4.253	.042
tskglob	9.792	1	9.792	.035	.851
csqcatas	642.187	1	642.187	2.326	.131
coderx * tskglob	2112.250	1	2112.250	7.651	.007
Error	23743.693	86	276.089		
Total	122887.839	93			
Corrected Total	34603.821	92			

a. R Squared = .314 (Adjusted R Squared = .266)

Parameter Estimates

Dependent Variable: %NPQ scores at 6 month follow-up

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-13.211	15.283	-.864	.390	-43.593	17.170
[coderx=1]	58.683	19.416	3.022	.003	20.086	97.281
[coderx=2]	0[a]	.	.	.	.	.
npqbase	.299	.112	2.676	.009	.077	.521
townsend	.987	.479	2.062	.042	.036	1.938
tskglob	.685	.448	1.529	.130	-.205	1.576
csqcatas	.487	.319	1.525	.131	-.148	1.121
[coderx=1] * tskglob	-1.489	.538	-2.766	.007	-2.558	-.419
[coderx=2] * tskglob	0[a]	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Univariate Analysis of Variance

Warnings

The following factors or covariates are not used in the model: pseqtot, csqcatas, dashbase

Between-Subjects Factors

		Value Label	N
intervention	1	graded exercise treatment	45
	2	usual physiotherapy	48

Tests of Between-Subjects Effects

Dependent Variable: %NPQ scores at 6 month follow-up

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	10217.941[a]	5	2043.588	7.291	.000
Intercept	368.486	1	368.486	1.315	.255
coderx	2869.252	1	2869.252	10.236	.002
npqbase	2573.224	1	2573.224	9.180	.003
townsend	1389.894	1	1389.894	4.959	.029
tskglob	79.761	1	79.761	.285	.595
coderx * tskglob	2462.310	1	2462.310	8.785	.004
Error	24385.880	87	280.297		
Total	122887.839	93			
Corrected Total	34603.821	92			

a. R Squared = .295 (Adjusted R Squared = .255)

Parameter Estimates

Dependent Variable: %NPQ scores at 6 month follow-up

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-19.313	14.862	-1.300	.197	-48.853	10.226
[coderx=1]	62.159	19.428	3.199	.002	23.543	100.774
[coderx=2]	0[a]	.	.	.	.	.
npqbase	.334	.110	3.030	.003	.115	.552
townsend	1.067	.479	2.227	.029	.115	2.020
tskglob	.948	.417	2.276	.025	.120	1.776
[coderx=1] * tskglob	-1.594	.538	-2.964	.004	-2.663	-.525
[coderx=2] * tskglob	0[a]	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

DASH	Frequency of answers (max 151)	Rating scale – number and (percentage)					Mean Score (max 4)
		No difficulty 0	Mild difficulty 1	Moderate difficulty 2	Severe difficulty 3	Unable 4	
Q1 Opening a tight or new jar	150	57(38.0)	35(23.3)	26(17.3)	18(12.0)	14(9.3)	1.31
Q2 Writing	151	111(73.5)	24(15.9)	16(10.6)	0(0)	0(0)	0.37
Q3 Turning a key	144	112(77.8)	19(13.2)	12(8.3)	1(0.7)	0(0)	0.32
Q4 Preparing a meal	150	93(62.0)	33(22.0)	20(13.3)	3(2.0)	1(0.7)	0.58
Q5 Pushing open a heavy door	151	46(30.5)	58(38.4)	35(23.2)	12(7.9)	0(0)	1.09
Q6 Placing an object on a shelf above head	150	46(30.7)	44(29.3)	36(24.0)	18(12.0)	6(4.0)	1.29
Q7 Doing heavy household chores	149	25(16.8)	41(27.5)	45(30.2)	29(19.5)	9(6.0)	1.70
Q8 Gardening or yard work	145	20(13.8)	35(24.1)	46(31.7)	28(19.3)	16(11.0)	1.90
Q9 Making a bed	149	56(37.6)	51(4.2)	34(22.8)	6(4.0)	2(1.3)	0.97
Q10 Carrying shopping bag/ briefcase	147	45(30.6)	37(25.2)	52(35.4)	9(6.1)	4(2.7)	1.25
Q11 Carrying a heavy object (over 10lbs)	148	24(16.2)	35(23.6)	45(30.4)	29(19.6)	15(10.1)	1.84
Q12 Changing an overhead light bulb	148	42(28.4)	41(27.7)	31(20.9)	23(15.5)	11(7.4)	1.46
Q13 Washing or blow drying hair	148	62(41.9)	38(25.7)	34(23.0)	13(8.8)	1(0.7)	1.01
Q14 Washing your back	151	41(27.2)	43(28.5)	34(22.5)	18(11.9)	15(9.9)	1.49
Q15 Putting on a pullover sweater	147	69(46.9)	34(23.1)	30(20.4)	12(8.2)	2(1.4)	0.94
Q16 Using a knife to cut food	147	110(74.8)	20(13.6)	14(9.5)	3(2.0)	0(0)	0.39
Q17 Recreational activities which require little effort (e.g. knitting, cards)	146	88(60.3)	30(20.5))	20(13.7)	5(3.4)	3(2.1)	0.66
Q18 Recreational activities requiring forceful impact through hand (e.g. golf, hammering)	147	20(13.6)	51(34.7)	34(23.1)	26(17.7)	16(10.9)	1.78
Q19 Recreational activities requiring free movement of arm (e.g. badminton)	144	28(19.4)	41(28.5)	31(21.5)	27(18.8)	17(11.8)	1.75
Q20 Manage transport needs	146	96(65.8)	32(21.9)	12(8.2)	6(4.1)	0(0)	0.51
Q21 Sexual activities	135	63(46.7)	41(30.4)	15(11.1)	4(3.0)	12(8.9)	0.97

Correlations

		Age in years	TSK global harm score
Age in years	Pearson Correlation	1	.045
	Sig. (2-tailed)		.603
	N	151	139
TSK global harm score	Pearson Correlation	.045	1
	Sig. (2-tailed)	.603	
	N	139	139
pain self efficacy score	Pearson Correlation	.055	-.286**
	Sig. (2-tailed)	.514	.001
	N	145	133
CSQ(i)diverting atention	Pearson Correlation	.140	.173*
	Sig. (2-tailed)	.097	.047
	N	143	133
CSQ(ii)reinterpreting pain sensation	Pearson Correlation	.010	.115
	Sig. (2-tailed)	.905	.189
	N	142	133
CSQ(iii)catastrophising	Pearson Correlation	-.138	.475**
	Sig. (2-tailed)	.104	.000
	N	141	132
CSQ(iv)ignoring sensation	Pearson Correlation	-.014	.022
	Sig. (2-tailed)	.866	.801
	N	148	137
CSQ(v)praying and hoping	Pearson Correlation	.197*	.247**
	Sig. (2-tailed)	.019	.005
	N	141	131
CSQ(vi)coping self statements	Pearson Correlation	.121	-.064
	Sig. (2-tailed)	.149	.464
	N	143	132
CSQ(vii)increased behaviour activities	Pearson Correlation	.201*	.053
	Sig. (2-tailed)	.016	.547
	N	143	133
HADs depression	Pearson Correlation	-.109	.244**
	Sig. (2-tailed)	.188	.004
	N	149	139
HADs anxiety	Pearson Correlation	.114	.287**
	Sig. (2-tailed)	.163	.001
	N	151	139
%quadruple visual analog score	Pearson Correlation	.031	.211*
	Sig. (2-tailed)	.702	.013
	N	150	138
Townsend scores	Pearson Correlation	.122	.274**
	Sig. (2-tailed)	.136	.001
	N	150	138

Correlations

		pain self efficacy score	CSQ(i)diverting atention
Age in years	Pearson Correlation	.055	.140
	Sig. (2-tailed)	.514	.097
	N	145	143
TSK global harm score	Pearson Correlation	-.286**	.173*
	Sig. (2-tailed)	.001	.047
	N	133	133
pain self efficacy score	Pearson Correlation	1	-.272**
	Sig. (2-tailed)		.001
	N	145	137
CSQ(i)diverting atention	Pearson Correlation	-.272**	1
	Sig. (2-tailed)	.001	
	N	137	143
CSQ(ii)reinterpreting pain sensation	Pearson Correlation	-.035	.563**
	Sig. (2-tailed)	.683	.000
	N	137	138
CSQ(iii)catastrophising	Pearson Correlation	-.372**	.244**
	Sig. (2-tailed)	.000	.004
	N	135	137
CSQ(iv)ignoring sensation	Pearson Correlation	.114	.370**
	Sig. (2-tailed)	.175	.000
	N	142	143
CSQ(v)praying and hoping	Pearson Correlation	-.225**	.560**
	Sig. (2-tailed)	.009	.000
	N	135	137
CSQ(vi)coping self statements	Pearson Correlation	.179*	.402**
	Sig. (2-tailed)	.037	.000
	N	137	138
CSQ(vii)increased behaviour activities	Pearson Correlation	.037	.665**
	Sig. (2-tailed)	.671	.000
	N	137	139
HADs depression	Pearson Correlation	-.197*	.051
	Sig. (2-tailed)	.019	.549
	N	143	142
HADs anxiety	Pearson Correlation	-.178*	.201*
	Sig. (2-tailed)	.032	.016
	N	145	143
%quadruple visual analog score	Pearson Correlation	-.374**	.339**
	Sig. (2-tailed)	.000	.000
	N	144	142
Townsend scores	Pearson Correlation	-.208*	.024
	Sig. (2-tailed)	.012	.778
	N	144	142

Correlations

		CSQ(ii)reinterpreting pain sensation	CSQ(iii)catastrophising
Age in years	Pearson Correlation	.010	-.138
	Sig. (2-tailed)	.905	.104
	N	142	141
TSK global harm score	Pearson Correlation	.115	.475**
	Sig. (2-tailed)	.189	.000
	N	133	132
pain self efficacy score	Pearson Correlation	-.035	-.372**
	Sig. (2-tailed)	.683	.000
	N	137	135
CSQ(i)diverting atention	Pearson Correlation	.563**	.244**
	Sig. (2-tailed)	.000	.004
	N	138	137
CSQ(ii)reinterpreting pain sensation	Pearson Correlation	1	.141
	Sig. (2-tailed)		.101
	N	142	137
CSQ(iii)catastrophising	Pearson Correlation	.141	1
	Sig. (2-tailed)	.101	
	N	137	141
CSQ(iv)ignoring sensation	Pearson Correlation	.557**	-.091
	Sig. (2-tailed)	.000	.282
	N	142	141
CSQ(v)praying and hoping	Pearson Correlation	.423**	.393**
	Sig. (2-tailed)	.000	.000
	N	137	136
CSQ(vi)coping self statements	Pearson Correlation	.430**	-.077
	Sig. (2-tailed)	.000	.371
	N	137	138
CSQ(vii)increased behaviour activities	Pearson Correlation	.469**	.092
	Sig. (2-tailed)	.000	.285
	N	138	138
HADs depression	Pearson Correlation	.059	.360**
	Sig. (2-tailed)	.486	.000
	N	141	140
HADs anxiety	Pearson Correlation	.202*	-.036
	Sig. (2-tailed)	.016	.673
	N	142	141
%quadruple visual analog score	Pearson Correlation	.147	.411**
	Sig. (2-tailed)	.083	.000
	N	141	140
Townsend scores	Pearson Correlation	.051	.161
	Sig. (2-tailed)	.548	.057
	N	141	140

Correlations

		CSQ(iv)ignoring sensation	CSQ(v)praying and hoping
Age in years	Pearson Correlation	-.014	.197*
	Sig. (2-tailed)	.866	.019
	N	148	141
TSK global harm score	Pearson Correlation	.022	.247**
	Sig. (2-tailed)	.801	.005
	N	137	131
pain self efficacy score	Pearson Correlation	.114	-.225**
	Sig. (2-tailed)	.175	.009
	N	142	135
CSQ(i)diverting atention	Pearson Correlation	.370**	.560**
	Sig. (2-tailed)	.000	.000
	N	143	137
CSQ(ii)reinterpreting pain sensation	Pearson Correlation	.557**	.423**
	Sig. (2-tailed)	.000	.000
	N	142	137
CSQ(iii)catastrophising	Pearson Correlation	-.091	.393**
	Sig. (2-tailed)	.282	.000
	N	141	136
CSQ(iv)ignoring sensation	Pearson Correlation	1	.245**
	Sig. (2-tailed)		.003
	N	148	141
CSQ(v)praying and hoping	Pearson Correlation	.245**	1
	Sig. (2-tailed)	.003	
	N	141	141
CSQ(vi)coping self statements	Pearson Correlation	.664**	.368**
	Sig. (2-tailed)	.000	.000
	N	143	136
CSQ(vii)increased behaviour activities	Pearson Correlation	.382**	.335**
	Sig. (2-tailed)	.000	.000
	N	143	138
HADs depression	Pearson Correlation	-.081	.042
	Sig. (2-tailed)	.332	.624
	N	147	140
HADs anxiety	Pearson Correlation	.124	.220**
	Sig. (2-tailed)	.133	.009
	N	148	141
%quadruple visual analog score	Pearson Correlation	-.004	.354**
	Sig. (2-tailed)	.964	.000
	N	147	140
Townsend scores	Pearson Correlation	-.032	.095
	Sig. (2-tailed)	.703	.263
	N	147	140

Correlations

		CSQ(vi)coping self statements	CSQ(vii)increased behaviour activities	HADs depression
Age in years	Pearson Correlation	.121	.201*	-.109
	Sig. (2-tailed)	.149	.016	.188
	N	143	143	149
TSK global harm score	Pearson Correlation	-.064	.053	.244**
	Sig. (2-tailed)	.464	.547	.004
	N	132	133	139
pain self efficacy score	Pearson Correlation	.179*	.037	-.197*
	Sig. (2-tailed)	.037	.671	.019
	N	137	137	143
CSQ(i)diverting atention	Pearson Correlation	.402**	.665**	.051
	Sig. (2-tailed)	.000	.000	.549
	N	138	139	142
CSQ(ii)reinterpreting pain sensation	Pearson Correlation	.430**	.469**	.059
	Sig. (2-tailed)	.000	.000	.486
	N	137	138	141
CSQ(iii)catastrophising	Pearson Correlation	-.077	.092	.360**
	Sig. (2-tailed)	.371	.285	.000
	N	138	138	140
CSQ(iv)ignoring sensation	Pearson Correlation	.664**	.382**	-.081
	Sig. (2-tailed)	.000	.000	.332
	N	143	143	147
CSQ(v)praying and hoping	Pearson Correlation	.368**	.335**	.042
	Sig. (2-tailed)	.000	.000	.624
	N	136	138	140
CSQ(vi)coping self statements	Pearson Correlation	1	.387**	-.167*
	Sig. (2-tailed)		.000	.047
	N	143	139	142
CSQ(vii)increased behaviour activities	Pearson Correlation	.387**	1	.111
	Sig. (2-tailed)	.000		.188
	N	139	143	142
HADs depression	Pearson Correlation	-.167*	.111	1
	Sig. (2-tailed)	.047	.188	
	N	142	142	149
HADs anxiety	Pearson Correlation	.116	.118	.071
	Sig. (2-tailed)	.168	.162	.389
	N	143	143	149
%quadruple visual analog score	Pearson Correlation	-.009	.187*	.187*
	Sig. (2-tailed)	.911	.026	.023
	N	142	142	148
Townsend scores	Pearson Correlation	-.141	.009	.173*
	Sig. (2-tailed)	.094	.917	.036
	N	143	142	148

Correlations

		HADs anxiety	%quadruple visual analog score
Age in years	Pearson Correlation	.114	.031
	Sig. (2-tailed)	.163	.702
	N	151	150
TSK global harm score	Pearson Correlation	.287**	.211*
	Sig. (2-tailed)	.001	.013
	N	139	138
pain self efficacy score	Pearson Correlation	-.178*	-.374**
	Sig. (2-tailed)	.032	.000
	N	145	144
CSQ(i)diverting atention	Pearson Correlation	.201*	.339**
	Sig. (2-tailed)	.016	.000
	N	143	142
CSQ(ii)reinterpreting pain sensation	Pearson Correlation	.202*	.147
	Sig. (2-tailed)	.016	.083
	N	142	141
CSQ(iii)catastrophising	Pearson Correlation	-.036	.411**
	Sig. (2-tailed)	.673	.000
	N	141	140
CSQ(iv)ignoring sensation	Pearson Correlation	.124	-.004
	Sig. (2-tailed)	.133	.964
	N	148	147
CSQ(v)praying and hoping	Pearson Correlation	.220**	.354**
	Sig. (2-tailed)	.009	.000
	N	141	140
CSQ(vi)coping self statements	Pearson Correlation	.116	-.009
	Sig. (2-tailed)	.168	.911
	N	143	142
CSQ(vii)increased behaviour activities	Pearson Correlation	.118	.187*
	Sig. (2-tailed)	.162	.026
	N	143	142
HADs depression	Pearson Correlation	.071	.187*
	Sig. (2-tailed)	.389	.023
	N	149	148
HADs anxiety	Pearson Correlation	1	.052
	Sig. (2-tailed)		.525
	N	151	150
%quadruple visual analog score	Pearson Correlation	.052	1
	Sig. (2-tailed)	.525	
	N	150	150
Townsend scores	Pearson Correlation	.109	.054
	Sig. (2-tailed)	.185	.517
	N	150	149

Correlations

		Townsend scores
Age in years	Pearson Correlation	.122
	Sig. (2-tailed)	.136
	N	150
TSK global harm score	Pearson Correlation	.274**
	Sig. (2-tailed)	.001
	N	138
pain self efficacy score	Pearson Correlation	-.208*
	Sig. (2-tailed)	.012
	N	144
CSQ(i)diverting atention	Pearson Correlation	.024
	Sig. (2-tailed)	.778
	N	142
CSQ(ii)reinterpreting pain sensation	Pearson Correlation	.051
	Sig. (2-tailed)	.548
	N	141
CSQ(iii)catastrophising	Pearson Correlation	.161
	Sig. (2-tailed)	.057
	N	140
CSQ(iv)ignoring sensation	Pearson Correlation	-.032
	Sig. (2-tailed)	.703
	N	147
CSQ(v)praying and hoping	Pearson Correlation	.095
	Sig. (2-tailed)	.263
	N	140
CSQ(vi)coping self statements	Pearson Correlation	-.141
	Sig. (2-tailed)	.094
	N	143
CSQ(vii)increased behaviour activities	Pearson Correlation	.009
	Sig. (2-tailed)	.917
	N	142
HADs depression	Pearson Correlation	.173*
	Sig. (2-tailed)	.036
	N	148
HADs anxiety	Pearson Correlation	.109
	Sig. (2-tailed)	.185
	N	150
%quadruple visual analog score	Pearson Correlation	.054
	Sig. (2-tailed)	.517
	N	149
Townsend scores	Pearson Correlation	1
	Sig. (2-tailed)	
	N	150

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Stepwise linear regression to determine the independant predictors of upper limb disability

Variables Entered/Removed[a]

Model	Variables Entered	Variables Removed	Method
1	%NPQ scores at baseline	.	Stepwise (Criteria: Probability -of- F-to-enter <= .050, Probability -of- F-to-remove >= .100).
2	pain self efficacy score	.	Stepwise (Criteria: Probability -of- F-to-enter <= .050, Probability -of- F-to-remove >= .100).

a. Dependent Variable: %DASH score at baseline

Model Summary[c]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.791[a]	.626	.622	11.71572
2	.845[b]	.713	.708	10.30731

a. Predictors: (Constant), %NPQ scores at baseline

b. Predictors: (Constant), %NPQ scores at baseline, pain self efficacy score

c. Dependent Variable: %DASH score at baseline

ANOVA[c]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	22739.306	1	22739.306	165.668	.000[a]
	Residual	13588.557	99	137.258		
	Total	36327.863	100			
2	Regression	25916.281	2	12958.141	121.970	.000[b]
	Residual	10411.582	98	106.241		
	Total	36327.863	100			

a. Predictors: (Constant), %NPQ scores at baseline

b. Predictors: (Constant), %NPQ scores at baseline, pain self efficacy score

c. Dependent Variable: %DASH score at baseline

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	-8.920	3.218		-2.772	.007
	%NPQ scores at baseline	1.029	.080	.791	12.871	.000
2	(Constant)	20.502	6.080		3.372	.001
	%NPQ scores at baseline	.743	.088	.571	8.471	.000
	pain self efficacy score	-.489	.089	-.369	-5.468	.000

a. Dependent Variable: %DASH score at baseline

Excluded Variables[c]

Model		Beta In	t	Sig.	Partial Correlation	Collinearity Statistics
						Tolerance
1	TSK global harm score	.090[a]	1.461	.147	.146	.990
	pain self efficacy score	-.369[a]	-5.468	.000	-.484	.644
	CSQ(i)diverting atention	.089[a]	1.323	.189	.132	.830
	CSQ(ii)reinterpreting pain sensation	.016[a]	.250	.803	.025	.889
	CSQ(iii)catastrophising	.148[a]	2.366	.020	.232	.926
	CSQ(v)praying and hoping	.049[a]	.754	.453	.076	.897
	CSQ(vii)increased behaviour activities	.071[a]	1.102	.273	.111	.912
	HADs depression	.117[a]	1.852	.067	.184	.931
	%quadruple visual analog score	-.002[a]	-.029	.977	-.003	.670
	gender	.156[a]	2.580	.011	.252	.973
	longer v shoter episode of current neck pain	.048[a]	.766	.445	.077	.977
	neck shoulder v neck shoulder and arm	-.019[a]	-.296	.768	-.030	.922
	lower v higher activity	-.075[a]	-1.177	.242	-.118	.924
	smoker or non-smoker	-.082[a]	-1.331	.186	-.133	.983
2	TSK global harm score	.038[b]	.688	.493	.070	.959
	CSQ(i)diverting atention	.070[b]	1.174	.243	.118	.827
	CSQ(ii)reinterpreting pain sensation	.083[b]	1.420	.159	.143	.853
	CSQ(iii)catastrophising	.069[b]	1.175	.243	.118	.856
	CSQ(v)praying and hoping	.052[b]	.907	.367	.092	.897
	CSQ(vii)increased behaviour activities	.095[b]	1.691	.094	.169	.907
	HADs depression	.054[b]	.947	.346	.096	.889
	%quadruple visual analog score	-.022[b]	-.327	.744	-.033	.669
	gender	.097[b]	1.754	.083	.175	.929
	longer v shoter episode of current neck pain	.011[b]	.200	.842	.020	.962
	neck shoulder v neck shoulder and arm	-.003[b]	-.056	.956	-.006	.920
	lower v higher activity	-.016[b]	-.276	.783	-.028	.889
	smoker or non-smoker	-.032[b]	-.575	.567	-.058	.954

a. Predictors in the Model: (Constant), %NPQ scores at baseline

b. Predictors in the Model: (Constant), %NPQ scores at baseline, pain self efficacy score

c. Dependent Variable: %DASH score at baseline

Residuals Statistics[a]

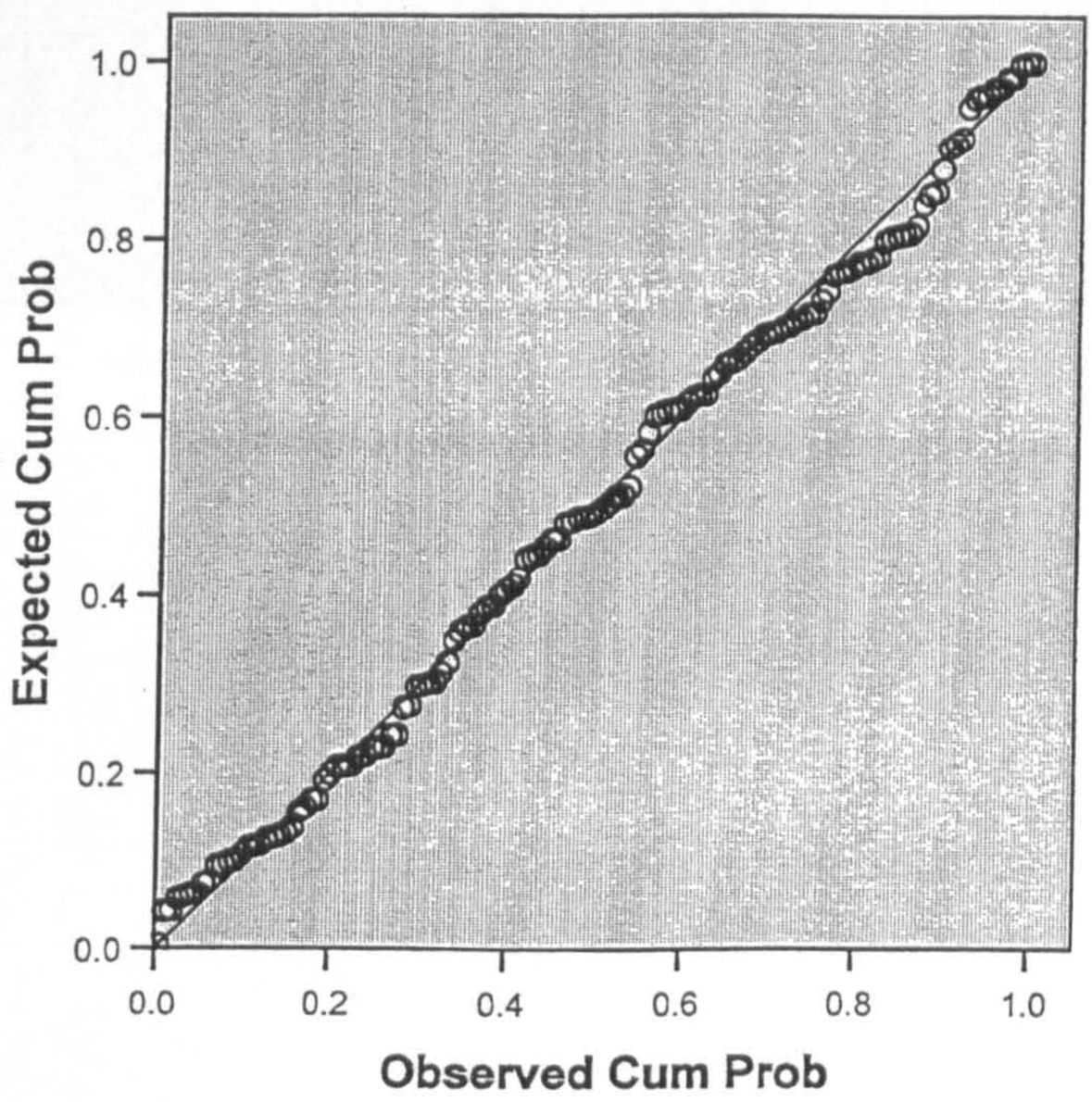
	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	-4.7145	78.4000	30.8606	16.82501	137
Residual	-27.19879	37.74717	.31229	10.65151	137
Std. Predicted Value	-2.137	3.026	.073	1.045	137
Std. Residual	-2.639	3.662	.030	1.033	137

a. Dependent Variable: %DASH score at baseline

Charts

Normal P-P Plot of Regression Standardized Residual

Dependent Variable: %DASH score at baseline



Scatterplot

Dependent Variable: %DASH score at baseline