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## Neck Pain: a pain in the neck?

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## ***Summary***

Is neck pain a "pain in the neck" for clinicians and therapists ?

To answer this question the focus of this thesis is twofold. The first part of this thesis concerns an overview of interventions and describes the design and the results of a randomised clinical trial. The second part concerns clinimetric properties of frequently used clinical tests and questionnaires.

## **1. Introduction**

In Chapter 1 an outline of topics covered in this thesis is given. Furthermore, the research questions are described.

Considering neck pain, a common musculoskeletal disorder, there still is a lack of evidence in favour of any treatment modality. Also with regards to the quality of various frequently used clinical test and questionnaires there are still many questions unanswered.

Sub-acute non-specific neck pain patients are an interesting subgroup, since from 4 to 12 weeks a transition from acute to chronic neck complaints takes place. It has been hypothesized that psychological and social factors play an important role in this transition. With this in mind, it is a challenge to study the effectiveness of an intervention which focuses specifically on these psychological and social factors. In the study, described in this thesis, we compare a behavioural graded activity programme with manual therapy. The latter, despite the lack of strong evidence, is the most effective therapy for neck pain so far.

The evaluation of the quality of clinical tests and the study of the applicability of questionnaires used in the clinical setting is also an objective of this thesis.

## **2. An update**

In Chapter 2, we discuss the benefit of evidence based medicine in general, and its role in the treatment of neck pain. Although much evidence for conservative therapy for neck pain is inconclusive, manipulative therapy and/or mobilization in combination with exercise seem to have the most promising results. Additionally, manipulative therapy would appear to be more cost-effective than physical therapy or standard medical care (as administered by the general practitioner).

### **3. Study protocol**

The design of a randomized clinical trial comparing a behavioral graded activity programme with manual therapy for patients with non-specific sub-acute neck pain is described in Chapter 3. The behavioral graded activity programme is a time-contingent approach with an increase in activities from baseline towards pre-determined goals. This protocol was developed in cooperation with experts in the field of behavioral medicine. Manual therapy consists mainly of specific spinal mobilisation techniques and exercises. Patients were included in the study when non-specific neck pain persisted more than 4 weeks but no longer than 12 weeks; aged between 18 to 65 years; when they were referred by the general practitioner.

Primary outcomes included global perceived effect, pain intensity and functional disability. Secondary outcomes included various psychological characteristics, such as kinesiophobia, somatisation and distress.

Patients completed questionnaires at baseline, 6, 12, 26 and 52 weeks after randomisation.

### **4. Effectiveness**

In Chapter 4 the effectiveness of a behavioural graded activity (BGA) programme compared to manual therapy (MT) is described. 35 general practitioners recruited 146 patients with sub-acute non-specific neck pain. Patients were allocated to either the BGA group (n=71) or the MT group (n=75). Overall, the multilevel analysis showed a marginally but statistically significant difference on the outcome disability, mean difference for Neck Disability Index= 2.42 (95% CI: 0.52-4.32), and at 52 weeks, on the outcome pain, mean difference on the NRS = 0.99 (95% CI; 0.15-1.83), both differences are in favour of the BGA programme.

The analysis did not show a significant effect on all other outcomes. The success rates at 52 weeks, based on the GPE were 89.4% for the BGA programme and 86.5% for MT.

We encountered numerous practical problems such as a poor compliance of the physical therapists to perform the BGA protocol. Based on this trial it can be concluded that there are only marginal, but not clinically relevant, differences between a BGA programme and MT.

## **5. Prognostic factors**

An increasing amount of attention is being paid to psychological factors in the development and maintenance of pain and disability. Furthermore, psychological and social factors are possibly involved in the transition from acute to chronic neck pain.

In Chapter 5 a prospective study is described. The aim is to assess whether psychological factors are prognostic indicators of the short and long term outcome. 146 patients with non-specific sub-acute neck pain are included.

Multilevel analyses showed very diverse results on the outcomes perceived recovery, pain and functional disability. Only 'fear of movement' turned out to be consistently and significantly present in the univariable analysis for all outcomes at both follow-up measurements. Also for the short term In the multivariable analyses fear of movement turned out to be a prognostic factor for the outcomes pain and disability.

We conclude that we were unable to identify a core set of prognostic psychological factors that predict the short and long term outcome of sub-acute neck pain. Further prognostic study are recommended.

## **6. Reproducibility**

In Chapter 6 the inter-examiner reproducibility of physical examination of the cervical spine was assessed. Two physiotherapists independently judged the general mobility and the inter-segmental mobility (segments C0-T2) of the cervical spine. Furthermore, the provoked pain score of the patients during each test was recorded. Despite the use of a standardised protocol to assess general mobility and inter-segmental mobility of the cervical spine it is difficult to achieve reasonable agreement and reliability between two examiners. Agreement for general mobility shows kappa values between 0.05 and 0.61, and for the inter-segmental mobility it shows kappa values between -0.09 and 0.63. Likewise, the patients are not able to score the same level of provoked pain in two assessments with an interval of 15 minutes. The ICC's varied between 0.36 and 0.71 for general mobility and between 0.22 and 0.80 for inter-segmental mobility.

We conclude that despite the use of a standardised protocol to assess general mobility and inter-segmental mobility of the

cervical spine it is difficult to achieve reasonable agreement and reliability between two examiners.

## **7. Reproducibility of the range of motion**

An assessment of the intra-rater and inter-rater reproducibility of the measurement of active Range of Motion (ROM) in patients with neck pain using the Cybex Electronic Digital Inclinator-320 (EDI-320), is described in Chapter 7.

In an outpatient clinic in a primary care setting 32 patients with at least 2 weeks of pain and/or stiffness in the neck were randomly assessed. In a test-retest design with blinded raters a standardized measurement protocol was used to test cervical flexion-extension, lateral flexion and rotation.

In general, the intra-rater reproducibility and the inter-rater reproducibility were good. Reliability showed an Intraclass Correlation Coefficient of 0.93 or more for intra-rater reliability and 0.89 or more for inter-rater reliability. The 95% limits of agreement for intra-rater agreement, expressing the range of the differences between two ratings were  $-2.5 \pm 11.1^\circ$  for flexion-extension,  $-0.1 \pm 10.4^\circ$  for lateral flexion and  $-5.9 \pm 13.5^\circ$  for rotation. For inter-rater agreement the limits of agreement were  $3.3 \pm 17.0^\circ$  for flexion-extension,  $0.5 \pm 17.0^\circ$  for lateral flexion and  $-1.3 \pm 24.6^\circ$  for rotation. In general we conclude that the intra-rater reproducibility and the inter-rater reproducibility was good.

## **8. Qualitative research**

During the performance of the randomised clinical trial problems were encountered by the patients filling in questionnaires. The aim of the study described in Chapter 8 is to elicit these problems. Patients understanding and interpretation of the wording used in test items of the Tampa Scale of Kinesiophobia (TSK) are evaluated using a qualitative method: the Three-Step Test Interview (TSTI), which is an observational technique that aims to discover problems with self reported questionnaires. The TSTI consists of three phases: 1) concurrent think aloud; 2) a retrospective interview; 3) a semi structured interview. Through the TSTI data are collected with regards to the thoughts or

considerations of respondents while completing a questionnaire like the TSK

The TSK was developed to measure fear of movement in patients suffering from low back pain. The TSK is being increasingly used for other pain conditions. In the analysis, each transcribed interview was divided into three segments. The thoughts and considerations were then analysed and categorised per item.

During the TSTI two problems were identified. One concerned the meaning of specific words used, like "dangerous" and "injury". The other problem was that several implicit assumptions within some items make it difficult for respondents to answer these items.

It was concluded that in the development and validation of questionnaires like the TSK, not only quantitative psychometric properties are important, but also qualitative research has an important contribution to enhance applicability.

## **9. Qualitative research methodology**

Psychometric analyses, such as factor analysis, internal consistency and construct validity, are well known and frequently applied methods in the development of health related patient reported outcomes. These statistical indexes shed hardly any light on how respondents interpret individual items, or on the meaning of their responses. In the study described in Chapter 9, the Pain Coping and Cognition List (PCCL), a quantitatively validated psychological questionnaire developed for chronic pain, has been subjected to a qualitative research method: the Three Step Test Interview (TSTI), similar as described in chapter 8. Six different types of problems were distinguished: long complicated formulations, composite questions, irrelevant questions, lacking frame of reference, problematic words, and wrongly interpreted questions. This study illustrates that quantitative methods have an added value when developing self reported questionnaires because problems were highlighted that can not be identified using quantitative methods only. Therefore, we recommend that a full qualitative study should be an integral part of the development of questionnaires.

## **10. Minimal Clinically Important Change (MCIC)**

In Chapter 10 the minimal clinically important change (MCIC) on the Neck Disability Index (NDI) and the Numeric Rating Scale (NRS) for pain in patients with neck pain was assessed. Both measurement instruments are frequently used in research and clinical practice, but it is still unknown which changes are clinically relevant.

The MCIC was estimated with two different methods, both integrating an anchor-based and distribution-based approach: the minimal detectable change (MDC) and the optimal cut-off point of the ROC curve. The study population consisted of 183 patients with non-specific neck pain. The results show an MDC of 10,5 points for the NDI (scale range 0- 50) and 4,3 points for the NRS (scale range 0-10), and optimal cut-off points of the ROC curve of 3.5 for the NDI and 2.5 for the NRS.

The estimated MCIC should be used as an indication for relevant changes in clinical practice. It was concluded that, using the optimal cut-off point of the ROC curve is a good choice, while false positives and false negatives are equally weighted.

## **11. General Discussion**

In Chapter 11 the main findings of this thesis are summarized and reflected on. Challenges, practical and methodological issues of research are discussed in more detail. This chapter concludes with the clinical relevance for policymakers, physical and manual therapists as well as general practitioners, and recommendations for future research are made.