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# **Prospective Cohort Study of Patients With Neck Pain in a Manual Therapy Setting: Design and Baseline Measures**

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## Abstract

### Objectives

The purpose of this study was to describe the design and baseline measurements of a prospective multicenter cohort study in patients with neck pain treated by Dutch manual therapists. Objectives of the study were to determine which patients seek help from a manual therapist, to describe usual care manual therapy in patients with neck pain, to examine the occurrence of nonserious adverse events after treatment, to describe predictors of adverse events, and to determine whether the occurrence of nonserious adverse events affect outcome after manual therapy care.

### Methods

During a 3-month inclusion period, consecutive patients aged between 18 and 80 years presenting with neck pain in manual therapy practices in The Netherlands were included in the study. Baseline questionnaires included the Numeric Rating Scale, Neck Disability Index (NDI), Neck Bournemouth Questionnaire, Fear Avoidance Beliefs Questionnaire (FABQ), and Patient Expectancy List. Within the treatment episode, manual therapist clinical reasoning and applied interventions were registered and patients reported on adverse events. At the end of the treatment episode and at 12-month follow-up, pain intensity (Numeric Rating Scale), functional outcomes (NDI, Neck Bournemouth Questionnaire), personal factors (FABQ), and global perceived effect were measured.

### Results

During the 3-month inclusion period, 263 participating manual therapists collected data on 1193 patients with neck pain. Most patients (69.4%) were female. The mean age was 44.7 ( $\pm 13.7$ ) years. The NDI showed overall mild disability (mean score 26%). Mean scores in pain intensity were moderate (4.8), and there was low risk of prolonged disability owing to personal factors (FABQ).

### Conclusion

This study provides information on baseline characteristics of patients visiting manual therapists for neck pain. In The Netherlands, patients seeking care of manual therapists are comparable to patients in other countries regarding demographics and neck pain characteristics

## Introduction

Neck pain is a common complaint in the general population. The 12-month prevalence estimates range from 30% to 50% in the general population and rises with increasing age.<sup>1, 2, 3</sup> Women are affected almost twice as often as men. Neck pain is considered nonspecific neck pain when no conclusive evidence of specific pathology can be found.<sup>4</sup> A review showed that the prognosis of neck pain is worse than recently recognized. Without treatment or with minimal treatment, acute idiopathic neck pain shows a rapid decrease in the intensity of pain by 45% and neck pain-related disability by 43% during the first 6.5 weeks, without further improvement at 12 months.<sup>5</sup>

In The Netherlands, about 40% of patients with persistent neck pain visit their general medical practitioner (GP). General practitioners refer 1% of patients with neck pain to a medical specialist, and 51% of the patients with neck pain to a physiotherapist or manual therapist (MT).<sup>6</sup> In The Netherlands, manual therapy is regarded as a specialty within physiotherapy. Manual therapists often apply both spinal manipulation and mobilization. Data on usual care manual therapy and percentages on cervical spine manipulation techniques applied in The Netherlands are lacking.

Manual therapy, including thrust and non-thrust interventions, is one of the conservative interventions that is associated with reducing neck pain and headache.<sup>7, 8, 9</sup> Combining cervical manipulation and mobilization with exercise is more effective than manipulation and mobilization alone.<sup>10</sup> Furthermore, there is preliminary evidence of reduced costs favoring manual therapy in acute, subacute, and chronic neck pain compared with physiotherapy and GP care.<sup>11, 12</sup>

Nonserious adverse events (AEs) and serious AEs of spinal manipulation are reported in the literature.<sup>13</sup> Prospective cohort studies demonstrate that nonserious adverse events such as headache, stiffness, aggravation of complaints, radiating discomfort, and fatigue are common and benign.<sup>14, 15, 16</sup> An accurate risk estimate for the more serious adverse events has been difficult to obtain, but serious AEs such as vertebrobasilar arterial stroke or death after manipulative treatment are very rare or may not have a true association.<sup>17, 18, 19</sup> Currently, the application of cervical manipulation in the upper cervical spine is a matter of debate because the question is raised whether the benefits of manipulative treatment outweigh the potential

risks.<sup>16, 20, 21, 22, 23, 24</sup> Cervical mobilization techniques show equal benefits compared with manipulative treatment; however, AE after cervical mobilization techniques are unknown.<sup>25</sup>

An Australian study showed that many patients who seek care from MTs have high pain intensity, disability, and recurrent neck pain and concomitant symptoms as headache, irradiating arm pain, and low back pain.<sup>26</sup> However, data are lacking on which patients seek care from the MTs in The Netherlands.

To address these issues, we describe the design and baseline values of a prospective cohort study with the following aims: (1) to determine the patient characteristics of patients who seek help from a manual therapist, (2) to describe usual care manual therapy in patients with neck pain, (3) to examine the occurrence of nonserious AEs after treatment, (4) to describe predictors of AEs, and (5) to determine whether the occurrence of nonserious AEs affect outcome after manual therapy care.

## Methods

### Design

The present study was a prospective cohort study with 12-month follow-up in the manual therapy setting in the Netherlands. This study was approved by the Medical Ethical Committee of the Erasmus Medical Centre Rotterdam.

### Study Population

#### Manual Therapists

All manual therapists (MTs) participating in this study were licensed MTs and registered by the Royal Dutch Society for Physical Therapy. They all work in a primary or secondary health-care setting and follow a 2-year course in manual therapy to achieve a master's degree. To achieve this degree, participation in the study was obligatory. Before the study, all participants followed a 2-day course on the protocol of the study. The MTs were responsible for recruitment of patients in their own work setting. At baseline, the characteristics of the MT (age, sex, years of experience, work setting, and additional educational qualifications) were assessed using a web-based questionnaire.

#### Patients

To reduce selection bias, each MT participating in this study was asked to include 5 consecutive patients with neck pain presenting in their clinical practice. Describing usual care neck pain requires broad inclusion criteria. Every patient with nonspecific neck pain, aged between 18 and 80 years, and able to read and write Dutch was eligible for participation. Neck pain was defined as pain in the area between the occiput and spine of the scapulae ([Fig 1](#)).<sup>29</sup> Excluded were all patients with known specific causes of neck pain (eg, known vascular or neurologic disorders, neoplasms, rheumatic conditions). All patients received information on the study and signed an informed consent form

During the recruitment period, all patients with neck pain who may have been eligible but refused to participate (for whatever reason) or were supernumerary because the MT already included 5

patients were registered and information on age and sex was collected. This information was used to check the representativeness of the study group.

At the first consultation, MTs registered patients' demographic characteristics, comorbidity, use of medication, and whether they entered their practice by referral or by direct access.

## Questionnaires

### Patients

Patients filled out a baseline questionnaire, including questions on patient characteristics (eg, age, sex, marital status, work, smoking, sports); the onset, cause, and course of neck pain; concomitant symptoms; and use of medication. Patients scored the average severity of their neck pain on a numerical rating scale (NRS) ranging from 0 (no pain) to 10 (unbearable pain), and completed the Neck Disability Index (NDI), the Neck Bournemouth Questionnaire (NBQ), and the Fear Avoidance Beliefs Questionnaire (FABQ). Pain scores on the NRS were considered low from 1 to 4, moderate when  $\geq 4$  to 7, and high from  $\geq 7$  to 10.<sup>30</sup> The NDI is a 10-item disability questionnaire with questions on pain intensity (neck pain, headache), work-related activities (work, lifting, and concentration), and non-work-related activities (personal care, reading, driving car or bike, sleeping, and recreation).<sup>31</sup> For each item, patients scored the degree of disability from 0 (no limitation) to 5 (major limitation). The scores for all items were summed and converted to 100% scores. Scores were interpreted as follows: 0% to 9%: no disability, 10% to 29%: mild disability, 30% to 49%: moderate disability, 50% to 69%: severe disability, and  $>70\%$ : complete disability.

Both the NDI and NRS have fair to moderate test-retest reliability in patients with nonspecific neck pain. Both instruments also show adequate responsiveness in this patient population.<sup>32</sup> The NDI is the most widely used and most strongly validated instrument for assessing self-rated disability in patients with neck pain.<sup>33, 34</sup> The NBQ covers the salient dimensions of the biopsychosocial model of pain; is quick and easy to complete; and is reliable, valid, and responsive to clinically significant change in patients with nonspecific neck pain.<sup>35, 36, 37</sup> The English version of the NBQ was translated into Dutch and back-translated according to established guidelines.<sup>37</sup> The total score may range from 0 to 70 and must be interpreted using the NDI benchmarks.<sup>38</sup> Fear avoidance was measured using the FABQ for neck pain.<sup>39, 40</sup> The FABQ is a 16-item list with 4 items on fear avoidance in physical activities (FABQ-PA) (range 0-24 points) and 7 items on fear avoidance in work situations (FABQ-W) (range 0-42 points). Total FABQ scores range from 0 to 96, with higher scores indicative of a high self-assessed level of fear avoidance beliefs. Cutoff scores for prolonged disability in patients with neck pain are total FABQ 48 (range 0-96), FABQ-W 18 (range 0-42), and FABQ-PA 15 points (range 0-24).<sup>40</sup> The FABQ has good predictive validity.<sup>40</sup> The FABQ-PA and FABQ-W subscales

have substantial test-retest reliability and internal consistency is high.<sup>41</sup> Patients' treatment expectancies were measured with the Patient Expectancies List (PEL). The PEL is an instrument with 3 questions on the expected recovery due to the total treatment, due to manipulations, and due to exercise, followed by a question on the strength of the persuasion of the given answer. The questionnaire aims to give an indication about patients' expectancies regarding treatment effects.<sup>42</sup> The PEL was scored on a 5-point Likert scale ranging from "much better" to "much worse." Descriptive analysis was performed.

Within 3 weeks after the period in which information was gathered, a telephone call was made to remind the patient to return the questionnaires. [Figure 2](#) shows the design and timeline of the study.

### Manual Therapists

After the first consultation, treatment goals were registered and MTs were asked to estimate patients' suitability for manual therapy treatment, and the chance of developing chronicity (on a 6-point Likert scale). Detailed information of treatment was recorded on standardized forms to prevent information bias and to gain insight into the black box of usual care manual therapy: treatment goals, treatment modalities, compliance, treatment period, total number of treatment sessions, and reasons for terminating treatment are registered in a text box.

### Patients

After every therapy session and at the end of the treatment episode, all patients filled out a questionnaire concerning side effects and AEs: the Adverse Effects Questionnaire.<sup>14, 16, 43</sup> This consists of 14 items regarding symptoms thought to be associated with AE, measured on an 10-point scale: (1) aggravation of complaints in treated area, (2) radiating pain to an upper extremity, (3) headache, (4) stiffness in the treated area, (5) tiredness, (6) dizziness or lightheadedness, (7) nausea, (8) ringing in the ears, (9) confusion or disorientation, (10) cramps, (11) blurred vision, (12) weakness in the limbs, (13) vomiting, and (14) any other symptom not defined by any of the previous categories. Patients can give up to 14 answers, which will all be analyzed separately. Besides intensity, duration of AE and moment of occurrence were registered. The questionnaire has been previously used in the University of California, Los Angeles neck study. No psychometric properties are known.<sup>44</sup>

## Follow-up

At the end of the treatment episode, patients filled out a short-term follow-up questionnaire, which consisted of the pain intensity NRS, NDI, NBQ, and FABQ; in addition, recovery was assessed using the Global Perceived Effect (GPE) questionnaire.<sup>44</sup> The GPE was scored on a 7-point Likert scale ranging from “total recovery” to “worse than ever.” A priori recovery was defined as “completely recovered” or “much improved,” as reported by the patient. Being a single question, it is easy and quick to administer and the results are seemingly simple to interpret. Test–retest reliability of GPE is excellent.<sup>45</sup>

The long-term follow-up questionnaire was sent to the patients 12 months after inclusion and consisted of the Adverse Effects Questionnaire and GPE questionnaires, together with questionnaires concerning pain (NRS), functional outcomes (NDI, NBQ), personal factors (FABQ), and recovery (GPE). Two questions on other treatments during follow-up and possible recurrences of neck pain were added. All patients received prepaid envelopes to return the questionnaires to the researchers (without any involvement from the MT) after the treatment episode and at the 12-month follow-up.

[Figure 2](#) presents the design and timeline of the study design.

## Analysis

Descriptive statistics (IBM SPSS Statistics for Windows, version 23.0) (IBM Corp, Armonk, New York) were used to present baseline characteristics of patients and MTs.

## Results

### Study Population

#### Manual Therapists

Of the 287 MTs eligible to participate, 263 joined the study and enrolled patients during the recruitment period. Reasons for nonparticipation given by 24 MTs were pregnancy (n = 2), working in a rehabilitation center (n = 2), working in a foreign country (n = 2), study delay/missed study deadline (n = 16), and stopped studying (n=2). Most of the MTs are male, aged  $\geq 40$  years, with about 20 years of working experience.

Characteristics of the MTs are presented in [Table 1](#)



## Patients

During the recruitment period, 1193 patients with neck pain provided baseline measurements and participated in the study. Another 2618 patients with neck pain were not enrolled but provided data on age and sex and were used to check the representativeness of the study group. Main reasons for non-enrollment were that the MT already included 5 consecutive patients or patients were not interested in participating. Patient characteristics are presented in [Table 2](#).

The participants were similar to the group of nonparticipants concerning age and sex. The most important findings are that participants were predominantly female and have neck pain  $\geq 12$  weeks, mostly recurrent. Most patients had 1 or more concomitant complaints. Almost all patients in this study had a high expectation regarding recovery as a result of manual therapy treatment, especially spinal manipulation.

Baseline scores are presented in [Table 3](#). The most important findings were that patients score an overall mild disability with moderate pain, moderate impairments, activity limitations, and restrictions in participation owing to neck pain. Regarding the cutoff points known in a neck pain population, 1 in 3 patients were at risk of prolonged disability and high risk of sick leave owing to their fear avoidance beliefs and neck pain.<sup>40</sup>

## Discussion

The current study reports the design and baseline measurements of a prospective cohort study of patients with neck pain in the Netherlands. One of the main goals of the ANIMO (Amersfoort Nek Onderzoek in de manueeltherapie Master) study was to gain insight into the black box of usual care manual therapy and its adverse events in patients with neck pain. The study cohort seems representative of a Dutch population because the enrolled participants do not differ from the non-enrolled.

### Characteristics of Patients

The large proportion of female participants in our study is in accordance with reported prevalence rates of neck pain.<sup>22, 46</sup> The mean age and proportion of female participants reported in the current study were similar to other cohort studies and randomized controlled trials.<sup>16, 26, 47, 48, 49</sup> Compared with similar studies, patients in our study reported concomitant complaints in accordance with literature: headache (62.1%), low back pain (40.1%), and radiating arm pain (41.9%).<sup>16, 26, 47, 48</sup> The high percentage of patients reporting concomitant headache is important

because headache is identified as a predictor of persistent neck pain, especially when accompanied by irradiating pain or recurrent neck pain.<sup>50</sup>

The large number of patients with recurrent neck pain in our study (66.9%) is comparable with similar studies.<sup>16, 48, 50</sup>

### Baseline Scores

Disability (NDI) and pain scores (NRS) were similar compared to another cohort of patients with neck pain in The Netherlands. A GP cohort study with patients with acute neck pain found average baseline pain scores that were higher than ours; this might be explained by the short duration of the complaints, as the GP cohort only included patients with acute neck pain.<sup>47</sup>

The FABQ has previously been used in patients with neck pain, but never in a manual therapy cohort of this extent. In our study, about 1 in 3 patients are at risk of prolonged disability and high risk of sick leave owing to their fear avoidance beliefs and neck pain.<sup>40</sup> The results of the current cohort are similar to other studies.<sup>40, 49, 51</sup> The high risk of prolonged disability and work incapacity (sick leave) is of importance because it plays an important role in the socioeconomic impact of neck pain. Early identification of patients at risk of prolonged work incapacity is essential to implement appropriate treatment modalities.<sup>51, 52</sup>

The NBQ was chosen because it is known that several psychosocial factors are prognostic of outcome, and the NBQ takes into account the biopsychosocial model of illness.<sup>37, 53</sup> In our study, scores on the NBQ were moderate, which is in accordance with another cohort of patients with neck pain.<sup>54</sup>

Data on patient expectancies in MT treatment have not previously been reported in The Netherlands. Surprisingly, almost all patients expected spinal manipulation to be effective for their neck pain (97.8%). Ninety-nine percent of patients expected to recover from their complaints by the total treatment. In a recent cohort study (n = 140), a high proportion of patients (75%) expected manipulation (out of all possible manual therapy modalities) to significantly improve neck pain.<sup>27</sup> However, in that study massage scored higher than spinal manipulations in expectancies (87%). Massage was not assessed in our study. Exercises scored a lower expectancy (54%) compared to our study (87%).<sup>27</sup> A high score on expectancies could be based on a positive effect by prior manual therapy treatment; however, only 31% of patients previously received manual therapy. The current study demonstrated a high score (97.8%) in expectancies regarding the effect of manual therapy on their neck pain. These results might have had a strong influence on outcome in this cohort of patients with neck pain.<sup>27</sup>

### Health Care Provider Beliefs

The health care provider belief of the MTs in the current study—regarding patients being suitable for spinal manipulation—was high (73.3%). This is the first time this expectation of MTs was reported in the literature. Health care provider beliefs are highly associated with the belief of a patient.<sup>28</sup> Maybe this is why almost 100% of the patients were expecting a positive result from the treatment.

The result at the end of treatment and 12-month follow-up should determine whether or not those patients selected by MT as suitable for manipulation had the outcomes expected.

### Limitations

Regarding the inclusion of patients, although we aimed at consecutive sampling, we were unable to control whether the MTs indeed invited the first 5 consecutive patients to participate in the study. Consequently, there might have been selection bias. However, considering the reasons MTs mentioned for submitting less than 5 patients (working part time, work setting provides few patients with neck pain, sick leave, and maternity leave) and considering that the MTs were aware of the descriptive goal of this study, it is unlikely that our sample is biased. Since the psychometric qualities of the PEL were not yet evaluated, we have to be careful in interpreting the results regarding patient expectancies. This study is limited in generalizability to the borders of the Netherlands.

### Conclusion

In the Netherlands, patients seeking care of MTs are comparable to patients in other countries regarding demographics and neck pain characteristics. The most important findings are that participants were predominantly female and have neck pain  $\geq 12$  weeks, mostly recurrent. About 1 in 3 patients are at risk of prolonged disability and high risk of sick leave due to fear avoidance. Patients have high expectations regarding spinal manipulation as an effective treatment modality for their neck pain.

### Funding Sources and Conflicts of Interest

No funding sources or conflicts of interest were reported for this study.

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