SUMMARY

The central theme of this thesis is research into neck pain. Neck pain is a common condition and has a major impact on the patient himself, his social environment and society as a whole. Neck pain has many possible causes and many explanations for why the complaints persist. Consequently, patients and therapists attempt to treat neck pain in as effective manner as possible. The aim of this thesis is to investigate and describe neck pain in broader terms and from a variety of points of view.

Chapter 1. Introduction

Chapter 1 describes the general objectives of this thesis. This chapter also examines the severity of the problem of neck pain, and includes a consideration of the incidence, prevalence and costs associated with neck pain.

In addition, in this chapter Manual Therapy treatment according to the Utrecht School (MTU), as developed and applied by Van der Bijl sr, is described in detail. This treatment occupies a prominent place in this thesis. The theoretical background and rationale of this holistic treatment system are explained and the therapeutic process is described. Furthermore, in order to understand the differences between manual therapies, MTU treatment is compared to other forms of manual therapy.

This chapter also deals with the choices and rationale for the various topics that will be discussed in the subsequent chapters of this thesis.

As already indicated, MTU treatment plays an important role in this thesis. Several treatment methods exist for neck pain and these were often initially developed on purely empirical grounds and may or may not have theoretical support. Although other types of manual therapy have been investigated for effectiveness, no research has yet been conducted into the (cost)effectiveness of MTU treatment. This deficiency was the motivation to investigate differences in the (cost)effectiveness of MTU and physiotherapy. This chapter describes the protocol that served as a starting point for research into the difference in (cost)effectiveness between Manual Therapy Utrecht (MTU) and physiotherapy (PT).

Before commencement of the research, independent research assistants carried out a randomization, classifying blocks by severity of complaint and age. The study participants were patients with neck pain complaints between the ages of 18 and 70 years. The treatment protocols for MTU and physiotherapy are described in detail in the study design. PT consisted of active exercise therapy using PT protocols prepared by the participating physiotherapists. The MTU treatment protocol is a standard protocol and is also comprehensively described in Chapter 1. Similarly, baseline measurements as well as outcome measures are described in the design.

Chapter 2 explains the design of the study, which in chapter 3 is followed by a description of the differing effectiveness of the interventions. Chapter 4 addresses the difference in cost-effectiveness of MTU treatment versus physiotherapy.

Chapter 5 of this thesis describes the development of a guideline for the reporting in published research of manual therapy interventions. The descriptions in scientific publications of applied interventions are today very often inadequate, which makes it difficult to translate a particular intervention to clinical practice. The often poor description of treatment methods was the motivation behind the development of a guideline for the adequate reporting of manual therapeutic interventions in published articles.

Chapter 6 considers psychosocial aspects in patients with neck pain. In addition to the mechanical and biomedical features that are the general focus of therapeutic interventions, psychosocial aspects are also important factors in patients with long-term neck pain. The chapter discusses the rational behind the choices to investigate specific psychosocial variables and whether these variables predict the treatment outcomes of different therapies.

In Chapter 7, a preliminary attempt is made to distinguish prognostic risk profiles in patients with non-specific neck pain. This is a result of research in patients with low back pain for whom a screening instrument, the STarT Back Tool (SBT), was developed. Differentiation based on matching patient variables and aspects of therapy could increase the successful outcome of treatments. Charting risk factors associated with either a poor or good treatment prognosis can help in arriving at a final optimal choice of therapy.

Finally, in Chapter 8 a summary is provided of the main findings of the thesis, points of discussion regarding the various parts of the studies are highlighted and suggestions are made for future research.

Chapter 2. The Research Design

This chapter describes the protocol that served as a starting point for research into the difference in (cost)effectiveness between Manual Therapy Utrecht (MTU) and physiotherapy (PT).

Before commencement of the research, independent research assistants carried out a randomization, classifying blocks by severity of complaint and age. The study participants were patients with neck pain complaints between the ages of 18 and 70 years. The treatment protocols for MTU and physiotherapy are described in detail in the study design. PT consisted of active exercise therapy using PT protocols prepared by the participating physiotherapists. The MTU treatment protocol is a standard protocol and is also comprehensively described in Chapter 1. Similarly, baseline measurements as well as outcome measures are described in the design.

Primary outcome measures were global perceived effect and functioning. The secondary outcome measure relates to the intensity of pain. Finally, prognostic factors in the design are described, as well as the times when measurements were
performed. Patients filled in the questionnaires at the beginning and after 3, 7, 13, 26, 39 and 52 weeks, either digitally or using pen and paper.

Chapter 3. The Effectiveness of Interventions
The implementation and results of randomized research into differences in effectiveness between MTU and PT - conducted in accordance with the design as outlined in Chapter 2 - are described in this chapter.
A total of 181 patients participated (90 in the MTU group and 91 in the PT group). Patients were referred by their GP or included on the basis of self-referral. The research involved 20 research assistants, 17 manual therapists and 27 physiotherapists from 16 practice locations in the Netherlands.
Multilevel analyses of the study, conducted according to the intention-to-treat principle, did not show statistically or clinically relevant differences in effectiveness between the MTU group and the PT group over the period of one year. The number of treatments in the MT group was found to be significantly lower than in the PT group (3 treatments versus 6 over a 7-week period, and 6 treatments versus 10 over a 26-week period).

Chapter 4. Cost-Effectiveness
Chapter 4 describes an analysis of the difference in cost-effectiveness between the MTU group and the PT group.
The analysis considered the intervention costs, healthcare costs and productivity costs. Global perceived effect, functioning and quality-adjusted life-years (QALYs) were used as clinical outcome measures. These outcomes were measured over a period of one year.
At 52 weeks there were no significant differences between the two groups. Although the intervention costs and healthcare costs were lower in the MTU group compared to the PT group, productivity costs were significantly higher in the MTU group. There were also no differences in cost-effectiveness in terms of global perceived effect, functioning or QALY’s.
The overall conclusion of chapters 3 and 4 is that choice of therapy cannot be made based on differences in the effectiveness and/or cost-effectiveness of MTU and PT. This means that patient and/or therapist preference play a major role in the choice of treatment.

Chapter 5. Guideline for the Reporting of Manual Interventions
This chapter describes the development of a new guideline for the reporting of manual therapy interventions in research. The often inadequate description of the investigated treatment methods in scientific publications prompted the development of a guideline for describing Spinal Manipulative Therapy (SMT) as an extension to the CONSolidated Standard of Reporting Trials Statement (CONSORT Statement) and the modified guideline for non-pharmacological trials. An adequate description of manual therapy is, in the case of positive outcomes, clearly necessary for the implementation of the treatment in daily practice. Furthermore, an adequate description of the investigated interventions is an absolute requirement for the assembly of individual study results in systematic reviews.
In a Delphi study with international experts in the field of SMT, online surveys were circulated in order to reach a consensus on a list of criteria for the minimum description of SMT in publications. Before consulting these international experts, a first version of a list of criteria was formulated based on literature research, and then further developed after consultation with experts. This list was subsequently presented to the international experts using the Delphi method. A total of 123 experts from 18 countries participated in the Delphi study, of whom 70% work as clinicians, 93% as researchers, 27% as academics and 14% as magazine editors (this comes to >100% because most experts performed more than two roles). An item was considered relevant if more than 70% of respondents gave a positive answer. After two rounds, consensus was reached on all items, after which a workshop with 18 participants was held to further clarify descriptions of the items and, if necessary, reword them. The workshop was also successful in formulating an example of a satisfactory description of SMT treatment as it should be included in a published article. In round three of Delphi, a final list for a minimum description of SMT was established. The final list covers 24 items in five domains, namely:
1. The rationale of the therapy
2. Description of the intervention
3. Description of the SMT techniques
4. Additional interventions/techniques given to the SMT group
5. Quantitative data

Chapter 6. Psychosocial variables
This chapter describes the study of the influence of psychosocial variables in patients with neck pain, which in the case of musculoskeletal pain are known to
affect the outcome of treatments. This study specifically looked at the influence of the following four psychosocial variables: 1) the treatment outcome expectancy, 2) the treatment credibility, 3) the locus of control, and 4) fear avoidance beliefs. The question is whether these psychosocial variables can predict treatment outcomes, over and above demographic and clinical variables and if a specific treatment (MTU and PT) modifies the treatment outcomes. If so, this could make the choice of treatment more effective.

All four abovementioned psychosocial variables were studied in the participating patients. Treatment success in patients was defined by the outcome measures global perceived effect, functioning and pain. Demographic and clinical variables were obtained (e.g. age, gender, severity of complaint, previous treatments, functioning, pain, overall mental and physical health) by questioning patient’s in daily practice.

Hierarchical logistic regression analysis of the data showed that patient expectations of outcomes have added value in addition to the known demographic and clinical variables. The additional predictive values for outcome success were 6% for pain and 17% for functioning after 7 weeks, and 16% for functioning after 26 weeks. The credibility of treatment, locus of control and fear avoidance beliefs did not have significant added value. There were also no significant interactions between the treatments in the MTU group and the PT group and the psychosocial variables in any model or on any outcome measure.

Chapter 7. Patient Risk Profiles

In this chapter we explored the possibility of distinguishing prognostic risk profiles in patients with non-specific neck pain. The motivation and initiative for this research was provided by the fact that this type of instrument already exists in the case of low back pain and has produced positive results. The goal was therefore to develop an equivalent well-functioning tool for aspecific neck pain.

The STarRT Back Tool (SBT), a screening tool consisting of nine items was prepared and tested for reliability and validity in low back pain. Next, patients with back pain were classified as low, medium or high-risk, given stratified treatments, and outcomes compared with usual care. Stratified treatment proved to be the better option. The following question was whether an analogous questionnaire could distinguish the three profiles in patients with neck pain and whether the profiles related to success after treatment.

Based on data and comparable constructs used in three randomized clinical trials conducted in the Netherlands, questions analogous to those in the SBT were selected. These included questions and statements about co-morbidity (radiating pain and pain in other locations), functioning, fear, depression, pessimistic patient expectations, mood and bothersomeness.

A total of 466 patients were included, resulting in 70.7% with a low, 23.3% with a medium and 6.9% with a high-risk profile. These three risk profiles differed significantly on baseline pain, functioning and mental and physical health. Worse scores on baseline corresponded to higher risk profiles. Using longitudinal regression analysis (generalized estimating equation, GEE), the outcome global perceived effect showed an overall statistically significant difference between risk profiles, measured for each risk profile at 6-9, 26 and 52 weeks, respectively.

The results of this exploratory study provide sufficient justification for the further development of a screening instrument for risk factors in patients with neck pain. Before it can be tested in a larger cohort for predictive value, the next step is to test the screening instrument for psychometric properties.

Chapter 8. General Discussion

Chapter 8 summarizes the most important findings of the thesis. In addition, points of discussion are indicated for the different components of the research, such as practical and technical research aspects. Furthermore, the practical implications are indicated and suggestions are made for future research.