Chapter 1

General introduction
Introduction

Despite the fact that neck pain is a very common musculoskeletal disorder, there is still no convincing evidence regarding the most effective treatment. This is an unsatisfactory state-of-affairs in an era of evidence-based practice, with a growing demand for transparency in medical practice and the translation of scientific findings to clinical practice. In order to establish an optimal management strategy for neck pain certain questions need to be answered, for example: How effective are current treatments that claim to use unique methods? Which patient characteristics influence effectiveness? And which variables predict treatment outcome?

This thesis addresses some of these questions. This thesis presents a study that compared the efficacy and cost-effectiveness of one specific School of Manual Therapy, Manual Therapy Utrecht (MTU). Chapter 2 describes the design of a randomized clinical trial on the efficacy of MTU compared to physical therapy. Chapter 3 presents the methods and results of the clinical outcomes of the trial, and chapter 4 presents data on cost-effectiveness. One of the challenges when interpreting RCTs is the fact that treatments are very often poorly described. Therefore, chapter 5 in this thesis focuses on how manual therapy, or more precisely, Spinal Manipulative Therapy (SMT), should be described in scientific articles in order to inform clinicians about the content of the treatment. In chapter 5 we present a Delphi study among experts in the field of SMT, which aimed to reach a consensus on items to be included in RCT reporting related to SMT. As mentioned above, an important question is which variables predict treatment outcome. In chapter 6 we focus on the predictive value for treatment success of various psychosocial variables, such as expectancy, credibility, health locus of control and fear avoidance beliefs, when added to well-known demographic and clinical variables. Chapter 7 includes explorative research on the subgrouping of patients with neck pain based on RCTs conducted in the Netherlands. In the current chapter, the main questions are briefly introduced.

Epidemiology

Impact of neck pain

The physical, psychological and socioeconomic impact of neck pain is considerable. According to the Global Burden of Disease 2015 Study, neck pain is the fourth most common condition worldwide regarding the number of years lived with disability, only ranking behind back pain, depression, and arthralgias\(^1\). The costs and constraints associated with neck complaints are enormous. In United States, the estimated costs in 2011 for treatment and loss of income were 5.7% of the gross national product ($871 billion), with back and neck problems accounting for 291 million registered absenteeism days in 2013. The total costs related to neck pain in the Netherlands were estimated to be approximately €668 million in 1996. Direct medical costs amounted to €160 million (23% of the total costs related to neck complaints)\(^2\). In 2007, the cost of low back pain and neck pain in men was 401 million euros and women 554 million euros\(^3\). This corresponds to 1.28% of total health costs in the Netherlands\(^1\). A substantial proportion of people with neck pain will not consult health professionals\(^4\). Nevertheless, neck pain is an important reason for work disability\(^5\) and the high incidence of neck pain in primary care leads to substantial healthcare expenditures\(^5,10\).

Prevalence

Approximately 14-71% of adults experience neck pain at some point in their life (14% in a cohort of 16 years and older in the United Kingdom\(^11\) and 71% in a 55-year-old Finnish population\(^12\)). The 1-year prevalence rate for neck pain in adults ranges from 16 to 75% (16% in a cross-sectional population-based study in Norway\(^13\) and 75% in Saskatchewan adults\(^14\)), as reviewed by Fejer\(^15\). Neck pain is experienced by people of all ages, including children and adolescents\(^16\) and increases with age, peaking in the age range of 39-49\(^16\). It is more common in women than men (approximately 3:2)\(^16-17\).
Course

Neck pain usually follows an episodic course over a person’s lifetime. In the majority of episodes, neck pain does not seriously interfere with normal activities. However, while chronic neck problems occur less often (2-11%) than acute or subacute symptoms, chronic problems result in high healthcare costs and long-term disability. For both patients and society, it is important to prevent someone reaching the chronic phase (longer than 12 weeks). Neck pain is often accompanied by other comorbidities such as headache, back pain, arthralgias, and depression.

One specific School of Manual Therapy: Manual Therapy Utrecht

Manual therapy is one of the most commonly applied treatments for neck pain, but there are various ‘schools’ in manual therapy. Manual Therapy according to the Utrecht School (MTU) differs from other forms of manual therapy in terms of patient assessment and therapeutic approaches.

G. van der Bijl DO (1909-1977) is the founder of the Manual Therapy according to the Utrecht school, also known as the ‘egg-shell method’. He has extensively studied concepts, ideas and methods in the fields of anatomy, kinesiology, chiropractic and osteopathy. After empirical and theoretical research, he developed his own vision of human functioning and movement and on treatment of complaints of the movement system. Van der Bijl chose to approach the complexity of the individual human movement function in a model, and he was of the opinion that human functioning can be understood in an individual function model using mechanical laws and axioms. The ambition of the human body to optimal equilibrium situations plays an important role in his vision. He explained his theoretical model in ‘Alpha to Omega’, originally published in the Nederlands Tijdschrift voor Fysiotherapie.

Theoretical model

MTU is based on ‘Patho-Functional Morphology’. In the English medical literature this term is generally replaced by the term ‘Mechanobiology’. Van der Meulen and Huiskes described this concept. The central paradigm of skeletal mechanobiology is that mechanical forces modulate morphological and structural fitness of the skeletal tissues (bone, cartilage, ligament and tendon). The phrase ‘form follows function’ encapsulates this concept, and means that forces (biophysical stimuli) govern how bone shape (e.g. of the joint surface) is determined.

The following principles and basic ideas are based on de Cock (1996) and summarized by Leopold who gave an overview of the theoretical foundations of MTU. In short, MTU applies a functional morphological approach to complaints of the musculoskeletal system, wherein the following elements are key:

1. Firstly, MTU assumes a relationship between the form (e.g. articular curvature) and (movement) function (e.g. the joints). This relationship implies that the (normal) asymmetrical location of centres of gravity is in relation to the asymmetry of form and movement functions. As an expression of the asymmetrical position of these centres of gravity, it is postulated that a preference exists for certain movements and postures, because these postures or movements are accompanied by the lowest energy consumption.

2. As a second theoretical foundation, MTU interprets changes of the morphological structure of tissues (which are often described as ‘pathological’ in the medical literature) as adaptations to changing (movement) functions. This assumption implies the existence of individuality and asymmetry of form and posture stereotype in people (this asymmetry is considered “natural” and not an expression of pathology). Following this line of reasoning, complaints related to the musculoskeletal system are approached as patho-functional morphology (mechanobiology), which means that complaints are not seen as aspects of pathological forms that cause symptoms, but that symptoms of the motion system are primarily caused by disordered (joint) functions.

3. Thirdly, MTU applies treatment techniques that are aimed at changing (movement) function. It is assumed hereby that joint movements do not occur in isolation, but that movement happens in conjunction with other joints and parts of the body (in that sense one can speak of a totality of movement pattern). Based on the location of the mass of various parts of the body, a model is developed of individual movement. The treatment is based on this model, and not on an interpretation of (possible) pathology, disorders or complaints. This model is determined through the interpretation of eight habitual gestures and movements that are used to analyse the position of the sub-masses. These include overhand throwing, kicking a ball, thumb cross, crossing arm, digging and sliding. In addition there is a determination of the dominant eye and the phorie of the eyes (by using
a Maddox glass to differentiate an endo or exo phorie of the eyes as preference). These are supposed to be associated with preferable location of the centre of gravity of the cervical part of the body and its rotation. Measurements to determine preferred movements have proven to be reliable in studies (Kappa 0.8-1)\textsuperscript{26}. Palpation is not considered to be a reliable or suitable diagnostic tool in the MTU patient assessment.

Immobilization or (micro-) trauma of the joints can cause changes in the original configuration of the joint collagen fibres. As a result, the positioning of the axis of rotation in joints can change, causing symptoms of pain and/or impairments in mobility of joint functions. Impairments in muscle function may follow as a result. It is assumed that altered joint function, resulting from the changed axis of rotation, leads to compensatory changes in movements elsewhere in the motion chain. Therefore, the joint(s) or region responsible for the patient’s symptoms may not necessarily be the source of the initial changes that took place.

**Patient assessment in MTU and comparison with other MT forms**

General assessment in MTU includes medical history, symptoms, red flags, and indications for treatment by the therapist. In addition, specific tests are used to evaluate the individual preferences of movement of the patient and facilitate interpretation of individual asymmetry in form, posture and movement\textsuperscript{27}. The normal asymmetry and variability of human form and movement function have been described\textsuperscript{28-30}. These studies showed that left-right asymmetries in joint form and functions are common. These asymmetries of joints also lead to asymmetrical movement functions that are also regarded as being normal in healthy movement. Examples of assessment items in MTU are (preferred) hand clasping, (preferred) arm folding, and dominance of arm, leg and eye. The purpose is to determine the direction and position of movement axes for all joints. Although the tests in MTU on which the treatment is based have a high reliability (Kappa 0.8-1)\textsuperscript{26}, the validity of the tests has not been demonstrated.

In general, other manual therapies, as described by Veen et al., are directed primarily at a patient’s complaints, particularly the main complaint\textsuperscript{31,32}. The diagnostic examination typical of other forms of manual therapy focuses on joint function, stability, movement patterns, range of movement, and the severity of disorders\textsuperscript{33}. To diagnose a patient’s complaints, manual examination tests by palpation of passive accessory and passive intervertebral movements are generally used in other MT forms for assessment of mechanical dysfunction of the cervical spine\textsuperscript{34}. The results yield information on tenderness (pain), restricted intersegmental motion (stiffness), and spasm (muscle tension)\textsuperscript{33,33}. Test results are also used as clinical indicators for the application of manual therapy\textsuperscript{34}. Research shows strong evidence for only poor to fair inter- and intra-examiner reliability of the intersegmental and general overall movement testing\textsuperscript{33-38}. Despite these shortcomings, therapists consider end-feel of joint movement or, to a lesser extent, provocation of patient pain as decisive in diagnostic conclusions. Overall, an examiners’ discipline, level of experience, consensus on procedure used, training just before the study, or use of asymptomatic subjects do not improve reliability\textsuperscript{39}.

**Therapeutic process**

In publications by van der Bijl, de Graaf, de Ridder\textsuperscript{40}, van der Bijl\textsuperscript{41} and de Cock\textsuperscript{42}, optimal joint function and joint dysfunction were coupled with the location of axes of motion in joints, according to the insights of Oonk\textsuperscript{43}, and later by Riezebos\textsuperscript{44,45} and Faber\textsuperscript{46}.

In optimal joint function, the position of the axis of motion should be such that a full range of motion is achieved (without excessive effort or tissue damage), whereby the entire surface on both articular cartilage partners is used. The reaction force is therefore always directed perpendicular/right-angled to the contact point\textsuperscript{46}, and the variable position of the axis of movement is still appropriate to the shape of the joint and to the shape of the periarticular tissue. In joint dysfunction, the axis of movement is represented as not being optimally positioned. Limitations of motion, tissue damage, pain on movement and overloading of muscle and tendon system are possible consequences.

The goal of therapy is described as “optimization of joint movement by matching the position of the axis of movement to the shape of the individual joint”, and the performance of certain repetitive passive joint movements aims to influence the position of the axis of movement.
Characteristics of currently used treatment techniques are:
- Passive treatment techniques applied to joints that are three-dimensional and with angular position changes.
- Treatment techniques that aim to optimize the positioning of motion axes in the treated joints, as described in published investigations.
- Joint movements are performed and repeated with low power within the physiological limits of movement of the joint.
- All joints of the body are treated regardless patient’s complaints.

During treatment, the position of the patient can vary depending on the direction of movement in the joint; sitting, supine and side-lying are the most common. The therapist performs repeated passive accessory joint movements with low velocity and intensity, and high accuracy. The rhythm of the movement is slow (approximately 30 cycles/min.) and the movements are repeated about six times. Treatment is, in general, painless. The direction of the joint movements (and axes) is determined by the analysis of the patient’s movement preferences. Movements are performed in a combination of rolling and sliding, or rocking and gliding (or swinging and sliding) of the joint. Movements are performed over the entire range of motion within the physiological range of motion of joints, whereby the curvature of the articular surface is followed. During this process, the physiological range of motion of the joint is carefully respected, and traction or high-velocity movements are not used.

Although much research on manual therapeutic interventions has been conducted to date, investigation of the efficacy and cost-effectiveness of MTU is both desirable and timely.

Translation to clinical practice

In the reporting of most RCTs, considerable attention is paid to the methodological design of the study and the results, and very little attention to the diagnostic and therapeutic process. As authors typically only are allowed by journal editors to use about 3000 words for a scientific article, the intervention is often characterized in only a few sentences. If articles are published, it is important that based on the description within the article a translation to clinical practice is possible. Likewise, it is important in systematic reviews that results are pooled of studies that are clinically homogeneous. In order to do this, a detailed description of the interventions is essential. In order to improve the description of studies, numerous reporting guidelines have been published such as the CONSORT Statement for RCTs, and the CLEAR NPT for non-pharmacological trials. Recently the Template for Intervention Description and Replication (TIDieR) checklist and guide was developed which is endorsed by journals. Descriptions are often intervention-specific, but a reporting guideline for Spinal Manipulative Therapy (SMT) interventions has yet to become available. We will describe the development of a consensus statement on items to be included in RCT reporting related to SMT.

Psychosocial variables in patients with neck pain

In addition to the intervention-specific factors, there are also many other (prognostic) factors that may influence outcomes. Prognostic factors that play a role in neck pain include age, back pain comorbidity, duration of symptoms, previous complaints, pain, functioning, and mental health. The clinical effectiveness of a treatment can be influenced by these prognostic factors in several ways. Besides biomechanical and neurophysiological mechanisms, psychological factors may also play a role. A model that takes these factors into account is the biopsychosocial disease model, in which biological, psychological and social dimensions interact. This model focuses on the complex reciprocal relationships between domains that cannot be separated into individual independent components. Psychological and social factors appear to be consistently associated with the onset and persistence of neck pain and probably play a role in the transition from acute to chronic pain and the limitation of functioning.

Research on the value of psychosocial aspects for outcomes in the treatment of neck pain is important. This may improve the advice offered to patients and treatment can be better tailored to individual patient characteristics. In the present study, as a secondary analysis, it is assumed that a number of constructs are of interest and affect the results of neck pain treatment. These include the patients’
outcome expectations, the locus of control and fear avoidance beliefs. This thesis will examine whether these factors have added value in addition to known (prognostic) variables usually assessed in a clinical setting.

Patients with neck pain are often referred by a general practitioner to manual therapy or physical therapy. However, there is no conclusive evidence that there is a clear distinction between the effectiveness of these interventions. It is assumed that psychological constructs such as outcome expectations, health locus of control and fear avoidance beliefs play a role as prognostic factors in the treatment of neck pain with MTU and PT, and that patient categories differ in their response to treatment with MTU and PT, respectively.

Categorizing prognostic risk profiles in patients

It is still an open question whether providing generalized treatment (‘one size fits all’) to groups of patients with neck complaints is efficient and effective. In order to increase the efficacy and cost-effectiveness of neck pain treatments, an appropriate match between patient characteristics and specific treatments is sought. For low back pain, a screening instrument (the STarT Back Tool) was developed that included nine yes/no questions to be completed by the patient within two minutes, whereby a distinction can be made between low, medium and high-risk profiles for prognostic indicators relevant to initial decision making. Stratified treatments were developed for the different profiles. In a RCT in which one arm received the stratified treatment, and the other arm usual care, the stratified treatment was statistically significantly more effective in reducing levels of disability. A similar tool for neck pain is not yet available. Using data from three RCTs conducted in the Netherlands (by Vonk et al., Pool et al., and Groeneweg et al.), an initial exploration will compile a questionnaire in accordance with SBT, with the same constructs, but based on questions used in instruments from these RCTs. We will then assess whether different risk profiles can be distinguished for non-specific neck pain and whether these profiles differ in outcome success. This may be a first step towards categorization of neck pain patients, after which a stratified treatment can be applied so that in the future patients can be treated more (cost) effectively.

General objectives of this thesis

- To determine the efficacy and cost-effectiveness of manual therapy according to the Utrecht School (MTU) in patients with sub-acute and chronic neck pain, compared to physical therapy (PT).
- To investigate which items should be included in the description of SMT reporting guideline, based on expert consensus.
- To study the added value of psychosocial variables above and beyond patient characteristics and clinical symptoms, and determine whether there are identifiable subgroups of patients in which one intervention is more effective.
- To ascertain whether patients with neck pain can be categorized to low-, medium- or high-risk profiles, and whether these profiles differ in terms of recovery.
REFERENCES


42 Cock DJ. Begrippen van manuele therapie, Systeem Van der Bijl. Utrecht: De Tijdstroom; 1996.


