

A COMPARISON OF TWO
MANUAL PHYSIOTHERAPY
PROTOCOLS FOR PATIENTS
WITH NECK PAIN

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DECLARATION

I, Martin Louis Elvey, declare that this research report is my own work. It is being submitted for the degree of Master of Science (Physiotherapy) at the University of the Witwatersrand, Johannesburg, South Africa. It has not been submitted before for any degree or examination at this or any other university.

Signed

On this fifth day of December 2005

DEDICATION

מה רבו מעשיך יה

ABSTRACT

Thoracic mobilisation is a popular modality employed by physiotherapists as part of the management of neck pain, despite the lack of evidence as to its benefits. A randomised control trial was conducted to compare manual physiotherapy to the cervical and thoracic regions and manual therapy to the cervical spine alone for the treatment of neck pain. The Spielberger State Anxiety Inventory (STAI) was used to assess anxiety change due to the intervention. The Memorial Pain Assessment Card (MPAC) was used to assess pain change through the intervention. A treatment effects questionnaire (TAQ) was constructed to assess other effects of the treatment protocols. Results showed no difference between the groups for anxiety reduction, although within the groups there was a highly significant reduction in anxiety ($p < 0.0001$). Pain reduction was marginally significantly reduced in the experimental group in comparison to the control group ($p = 0.08$) although the CI was very broad. Within group tests for the MPAC showed a highly significant reduction in pain from either intervention ($p < 0.0001$).

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GLOSSARY

The Biopsychosocial Model: A model of illness and health proposing that physical, emotional and social factors are potentially influential in health outcomes.

Cartesian Theory: Theories accredited to the works of Rene Descartes

Manual Physiotherapy: A specialisation within physiotherapy where the therapist specialises in passive manual techniques including mobilisation and manipulation

Chapter 1

1 INTRODUCTION

1.1. **Introduction**

Physiotherapy clinical decision-making has, until recently, been based primarily on each practitioner's experience and instinct of "what works." In recent years, the physiotherapy profession has made, and continues to make, an effort to validate the techniques that physiotherapists use on an experiential basis, as effective in the management of neuromusculoskeletal pathology.

The Philadelphia panel of 2001, as well as other reviewers (Gross et al, 2002; Hoving et al, 2001) after a systematic review of the available literature, concluded that there was little or no good quality evidence for practice of many physiotherapeutic modalities in the treatment of neck pain. They listed TENS, thermotherapy, massage, electrotherapy, therapeutic exercises or combinations of the above as all insufficiently proven to be effective. It is therefore incumbent on physiotherapy clinicians to subject their techniques to scientific scrutiny, in order to direct the practice of the profession away from anecdote towards evidence-based, effective practice.

Massage and soft tissue mobilisation techniques, particularly, are not well represented in the literature. Some of the problems affecting the quality of available research into massage therapy, in general, were expounded by Menard (2002). She notes that with regard to the study of massage techniques, standardisation of methods is not representative of the practice of massage therapy. Effects of manual therapy techniques could vary depending on the application of the technique. Menard (2002) lists alterations in speed or timing, rhythm and pressure as possible factors that may affect the outcome of a particular massage modality. Gross et al (2002) concluded furthermore in their Cochrane review of the management of neck pain, that the multimodal practice of physiotherapy is more effective than single modalities. Menard (2002) also quoted a survey of the National Certification Board for Therapeutic Massage and Bodywork that found that practitioners of massage therapy typically combine more than one discipline in any given treatment.

In physiotherapy treatment, evidence-based clinical reasoning implies that every modality selected is specifically chosen to affect a certain response, be it reduction of pain, muscle spasm, relaxation, warmth etc. It follows then, that each individual therapist decides which modality to use and in what manner, in order to achieve a particular desired outcome. This type of individualised treatment protocol is representative of the practice of physical techniques. It also makes the

standardisation of physiotherapy in general, and massage, in particular, as not representative of the practice of the profession (Menard, 2002).

Levin et al (1997) reported on the findings of a board convened to examine effective methods of studying these multimodal, personalised types of treatment protocols. They concluded that complex interventions, such as the above techniques, which include individualised treatment, can be studied by looking at the effects of the whole system of care, rather than breaking it down into component parts. Menard (2002) stated that this approach avoids narrowness of the conventional biomedical model, while still remaining scientifically sound. This also allows greater ability to generalise the results, as being representative of the practice of the technique. Menard (2002) went further to conclude that this method also has greater value ethically, as the personal boundaries of each subject are respected.

Physiotherapy management of cervical pain is a multimodal treatment technique, where each physiotherapist carries out a treatment protocol based on their own clinical reasoning of “what works”. South African physiotherapists commonly combine mobilisation of the thoracic vertebral and soft tissue structures with cervical treatment modalities in the treatment of neck pain (personal interviews). Cleland et al (2005) showed a significant immediate reduction of neck pain in

response to thoracic manipulation ($p < 0.001$). It was therefore postulated that thoracic myofascial and joint mobilisation provides extra benefits in the treatment of neck pain, specifically in the area of pain relief. This modality includes deep massage and myofascial release techniques applied to the soft tissues of the thoracic region as well as central and unilateral postero-lateral mobilisations as described by Maitland (1988) to the thoracic vertebrae.

As part of the personal interview with South African manipulative physiotherapists, they were also asked to list other possible benefits of the thoracic mobilisation in the treatment of neck pain. They listed various perceived benefits to this technique. These included pain reduction, increased mobility, feelings of relaxation and warmth and confidence with the treatment as some of the benefits. They felt that the personality of the therapist and other advice given to the patient during treatment play a minimal role in the whole treatment experience of the patient. It was postulated that these effects would be extra benefits of the thoracic mobilisation, not experienced through treatment to the cervical spine only.

The individual's experience of pain is both mental and physical. Linton (2000) reviewed the literature on the involvement of anxiety in neck pain. He concluded that anxiety plays a role in the experience of neck pain, not only in chronic cases,

but even in the acute phase. Gallagher (2005) concluded that while the initial experience of pain is essentially nociceptive, environmental and emotional effects adjust the experience of the pain. He lists anxiety as one of these confounding factors. Interestingly, no literature could be found that assessed the causative role of anxiety in neck pain.

Lawvere (2002) performed a pilot study in which he showed significant reduction of anxiety in a group of ovarian cancer patients in response to Swedish massage ($p < 0.006$). It was postulated that physiotherapy for the neck, with or without thoracic mobilisation, similarly affects not only the physical aspects of neck pain, but also the anxiety component.

The modality studied in this research initiative will broaden the scope of evidence-based modalities available to physiotherapists in clinical practice especially in the field of manual therapy. This study also highlights the positive role of the physiotherapist in short-term reduction in anxiety through physical treatment methods. Furthermore, this study provides some information of the role of anxiety in neck pain.

1.2. **Research Question**

Does cervical and thoracic manual physiotherapy relieve pain and anxiety more than manual physiotherapy to the cervical region alone, in patients with neck pain?

1.3. **Aim**

To determine if cervical and thoracic manual physiotherapy relieves pain and anxiety more than manual physiotherapy to the cervical region alone, in patients with neck pain.

1.4. **Objectives:**

Primary:

- 1 To compare manual physiotherapy to the cervical and thoracic regions to manual therapy to the cervical region alone, in terms of anxiety reduction.
- 2 To compare manual physiotherapy to the cervical and thoracic regions to manual therapy to the cervical region alone, in terms of pain reduction.
- 3 To assess changes in anxiety and pain levels through manual therapy within the groups.

Secondary:

- 4 To compare manual physiotherapy to the cervical and thoracic regions to manual therapy to the cervical region alone, in terms of treatment effects singled out as unique effects of thoracic mobilisation by South African manual physiotherapists.

Chapter 2

2 LITERATURE REVIEW

2.1. **Introduction**

In this chapter the biopsychosocial understanding of illness is explained. This provides a perspective on the role of pain and anxiety in all pain, and particularly in cases of neck pain. Physiotherapy management of neck pain is examined. In addition, the involvement of the thoracic vertebral region with the cervical region is considered. This provides a perspective on the rationale for this study. Finally, the measuring tools are described.

2.2. **The Biopsychosocial Model of Illness**

Evidence-based medicine has placed a spotlight on traditional methods of illness management. This examination has revealed inadequacies in some current treatment methods resulting in an increased emphasis in research on treatment outcomes (Main et al, 2000).

René Descartes (1596-1650), a French philosopher and scientist (World Book, 2002), is arguably the father of the modern biomedical approach to medicine (Sullivan, 2001). Within his theories, he distinguished between the physical, observable world and the mental, moral and spiritual world (Sullivan, 2001). His

theories have become known as Cartesian theory. Cartesian theory assigns physical pain to physical causes, while ignoring the affective side of the pain experience (Sullivan, 2001; Brody, 1990).

The modern biomedical model of illness or disease, in keeping with Cartesian theory, is based on Rudolph Virchow's (1821-1902) concept of "cellular pathology". Virchow proposed a direct link between the signs and symptoms of illness (Main et al, 2000). Hence, all symptoms of disease had a direct, identifiable cause in the body. Virchow's theory ignored the emotional components in pain and his theory ultimately led to a conceptual divorce of mind and body in medicine, where illness was confined to the body and psychology was left for other professions.

However, researchers in the latter half of the twentieth century demonstrated the intertwined roles of mind and body in the experience of disease. Main et al (2000) summarised the deductions of twenty years of research into low back pain into three central points which emphasize the role of psychosocial factors in chronic pain conditions:

1. There exists only a weak association of severity of pain to self-reported disability.

2. The level of disability can be explained by both biomedical and psychosocial factors.
3. Psychological factors are more important than physical signs in predictions of future disability.

This evidence for the role of psychosocial factors in health care necessitated a reassessment of the definitions of illness to include other factors other than simply biomedical disease concepts. The biopsychosocial model of disease and management represented the new order in health care. This model proposes that numerous factors are potentially influential in health outcomes. Careful assessment of biomedical, psychological and social systems is required in order to determine their respective roles in the process of a disease. Some cases will require multilevel intervention, while others will only require intervention at one particular level (Brody, 1990).

2.3. **Pain in the Mind and Body**

The modern world distinguishes between physical pain and mental pain. Mental pain is related to emotional stressors e.g. divorce or death, whereas physical pain is related to physical injury (Sullivan, 2001). The criterion that determines whether pain is mental or physical is the cause. Sullivan (2001), in a scholarly paper, questioned this causal concept that there exists “purely physical pain without

psychological or moral elements”, as well as the idea of “purely mental pain [solely] dominated by psychological or moral elements.” (Sullivan, 2001)

Physical Pain

Damage to the body usually results in pain. The pain is perceived to arise from the area of damage. The natural response to painful stimuli applied to a body part is withdrawal or protection of the part. The automatic reaction to injury of a part is “location-specific pain behaviour” (Sullivan, 2001). Many treatment regimes for pain are directed to the site of injury or the affected body part. All of these responses are not applicable to mental, emotional pain. Observing these natural, normal responses to pain stimuli supports the notion that the cause defines physical pain. According to Sullivan (2001), Descartes (1596-1650) acknowledged that the pain message was registered by the spirit; however the pain itself still remained a physical concept where physical causes were responsible.

Cartesian theory states that the peripheral pain receptor, the nociceptor, is the origin of the pain message. It transmits this pain message via specific, pain-mediated, afferent neural pathways into the spinal cord. Once in the spinal cord, the impulse travels via specific tracts to the cerebral cortex to register the injury and resultant pain (Sullivan, 2001).

This theory, according to Sullivan (2001), makes two incorrect assumptions:

- 1 The amount of pain experienced is proportional to the amount of tissue damage.
- 2 Neural activity with regard to pain travels only in one direction, to the pain centre of the brain (Sullivan, 2001).

In consideration of the concept of single-direction travel of a pain stimulus, Sullivan (2001) described the recent discovery of a complex descending physiological system of pain modulation. The presence of a descending system of pain modulation can explain the variable relationship of pain experience versus tissue damage. Neurones from the brain stem project into the spinal cord and produce nociceptive inhibition and analgesia at the site of the dorsal horn. Endogenous opiates and biogenic amines are the neurotransmitters in this system. On the opposite side of the scale, descending mechanisms have also been implicated in sensitisation of the neural tissues, causing hyperalgesia and allodynia. Inflammatory sensitisation of nociceptors, as well as sensitised nociceptive pathways due to excessive stimulation and subsequent irritation produces increased pain effects that are independent of the amount of tissue damage (Sullivan, 2001).

It is therefore clear that there is a complex system of analysis, interpretation and modulation along the whole nociceptive pathway. “There is no easy demarcation between the mind and the body when it comes to pain perception.” (Sullivan, 2001)

Mental Pain

Descartes (1596-1650) did consider that, notwithstanding the body pain mechanisms, understanding was necessary for pain experience. He claimed that pain is only felt once it is perceived in the mind (Sullivan, 2001; Main et al, 2000). Pain is, by definition, a personal, subjective experience, which makes it a mental phenomenon.

The theories of Ludwig Wittgenstein (1889-1951), an Austrian philosopher (World Book, 2002), propose a philosophy of Linguistic Analysis. Wittgenstein maintained that the meaning of a term in language is dependant on the public attachment of meaning to the term. He maintained that pain sensation alone is not enough to account for pain experience, that “pain words gain meaning as extensions of natural pain expressions (such as ‘ouch!’)” (Sullivan, 2001). Pain is differentiated from other sensations by characteristic expressions and is inherently connected with behaviour responses (such as flexor withdrawal). A pain sensation is often categorised in terms of possible behaviour responses,

suggesting an interdependence of the sensory system with the motor system. Neurophysiological research has demonstrated a strong link between pain sensation and a sense of danger. Pain experience, just like many other sensations, is modified, analysed and interpreted right through the nervous system, involving multiple areas of the brain, all interdependent in their determination of the pain response (Sullivan, 2001).

Acute psychiatric disorders such as depression and panic disorder are related to physical symptoms, especially pain. A strong correlation of depression and anxiety to the number of chronic pain conditions has also been shown (Sullivan, 2001).

2.4. **Biopsychosocial factors in acute pain**

The role of psychosocial issues in chronic pain is well established (Gallagher, 2005; Sullivan, 2001), however the role of psychosocial concepts involved in acute pain is less clear. Gallagher (2005), in a review of the evidence for various biopsychosocial management strategies in the treatment of chronic pain, conceded that acute pain is usually a subject of an initial pathophysiological, nociceptive cause, possibly independent of psychosocial issues. Linton (2001), however, in a review of psychological risk factors in neck and back pain, cites numerous papers that indicate the important role of psychosocial issues even in acute pain.

2.5. **Pain and anxiety**

Among the various psychological affects involved in pain sensation, depression and anxiety play the largest role (Sullivan, 2001; Linton, 2000; Visscher et al, 2001). This is certainly true for chronic pain states but Linton (2000) also found prevalence of anxiety in acute neck and back pain cases. He found 11 studies published between 1985 and 1998 that indicate a relationship between stress, distress and anxiety and neck or back pain. He found mixed results for personality factors. He noted, however, that the overall quality of reviewed studies was poor which highlights the need for good quality studies in this area.

Many authors record anxiety as part of the holistic experience of specifically neck pain (Linton, 2000; Van der Windt et al, 2002; Wenzel et al, 2002). Van der Windt et al (2002) found a significant correlation between neck and upper limb pain and symptoms of psychological distress more so for depression than anxiety ($p < 0.001$). Macfarlane et al (2000) found that health anxiety showed only a weak, non-significant relationship with onset of forearm symptoms. Wenzel et al (2002) studied whiplash disorders in a Norwegian population. They found a significant relationship between anxiety and depression and whiplash disorders sustained more than two years prior to the study ($p < 0.05$). When they controlled their data for pain and headache, the association for depression disappeared totally, while

the relationship to anxiety, although reduced, was still significant ($p < 0.05$). The authors concluded that chronic pain played a larger role in the symptoms experienced in this group than the actual incident of injury, particularly with regard to depression, but also to anxiety.

2.6. **Management of Neck Pain**

Prevalence

Evidence for the physiotherapeutic management of cervical pain syndromes in the literature has attracted much attention in recent years. This is due to the high incidence of neck pain and its economic consequences. Some researchers report a point prevalence of between 10 to 15% (Hoving et al, 2002). Côté et al (1998) found that 67.7% of a North American sample population had suffered with neck pain at some stage in the past, while 22.2% of the sample had neck pain on the day of the study. Hoving et al (2001) found a point prevalence of 9 – 22% for neck pain. No literature could be found with regard to causes of neck pain.

On assessment of the economical impact of neck pain, Borghouts et al (1999), reported the substantive costs of neck pain both with regard to direct (hospital, medical and paramedical care) and indirect costs (absenteeism and disability). Paramedical care, including physiotherapy, accounted for 84% of the direct costs, a significantly larger portion than other management strategies.

Physiotherapy Management of Neck Pain

Notwithstanding the considerable role physiotherapy plays in the management of neck pain, the existing evidence for physiotherapy and manual therapy in cervical pain management is generally of a poor standard (Gross et al, 2002; Hoving et al, 2001; Philadelphia panel, 2001). A Cochrane review of neck pain management states that:

“There is an ongoing lack of clear evidence regarding the effectiveness of manual therapies.” (Gross et al, 2002)

These researchers (Gross et al, 2002; Hoving, 2001; Philadelphia panel, 2001) report poor study design, lack of control groups, lack of randomisation, no blinding and small groups as a few of the problems of existing studies. They highlight the need for high quality studies in the area of manual therapy in the treatment of neck pain.

Gross et al (2001) and Hoving et al (2001) both note that most interventions in physiotherapy are characterised by a combination of active and passive components. Gross et al (2001) in a Cochrane review of the literature on manual therapy for neck pain, show from the available evidence, that multimodal treatment, as is employed in physiotherapy, is more effective in managing neck pain than manipulation alone or mobilisation alone. They note that analgesics or

anti-inflammatory medication are often used as part of the multimodal treatment, but that their effect in the multimodal combination is unclear.

In a randomised control trial on neck and back pain management, Koes et al (1992) showed good results for physiotherapy and especially manual physiotherapy in controlling neck pain. Hoving et al (2002) examined the distinction between physiotherapy and manual therapy in a randomised control trial comparing these two management methods and continued care by the general practitioner in neck pain patients. They limited the physiotherapy group practitioners to passive treatments such as massage, heat or interferential currents and active components being exercise therapies. These physiotherapists were restricted from performing any manipulative techniques on their patients. The manual physiotherapists treated their patients according to the manual therapy protocol as defined by the International Federation of Orthopaedic Manipulative Therapies (IFOMT). They record Manual Physiotherapy as a specialisation within physiotherapy where the therapist specialises in passive manual techniques including mobilisation and manipulation (Hoving et al, 2002). All patients were thus treated according to the limitations of each particular group. Notwithstanding the general restrictions on treatment modalities, all treatments were nevertheless applied according to individual evaluations by the therapists or doctors. At seven weeks, the manual therapy group showed a significant

improvement when compared to the general practitioner group ($p < 0.05$). The physiotherapy group also showed a higher, although not significant, success rate when compared to general medical management. Manual therapy showed a significantly higher success rate than the physiotherapy group ($p < 0.05$). On other outcome measures, manual therapy consistently outperformed physiotherapy, although not all the differences were significant (Hoving, 2002).

Biopsychosocial Management of Neck Pain

Karjalainen et al (2001) performed a Cochrane review of the relevant literature to ascertain effectiveness of biopsychosocial management strategies in the management of neck and shoulder conditions. The trials had to include a multidisciplinary approach where subjects were evaluated by a physician and also consulted either a psychologist or social worker. They found only two studies examining this issue, both of which were considered to be of poor methodological quality. Both studies showed no difference between a biopsychosocial management approach and conventional treatment with regards to neck and shoulder pain management. They stressed the need for more research in this area, specifically emphasizing the lack of intention-to-treat analyses in the available studies.

No literature could be found that examined the effect of physiotherapy or manual physiotherapy on the biopsychosocial factors associated with neck pain. Lawvere

(2002) performed a pilot study to examine effects of Swedish massage on the anxiety associated with ovarian cancer. The Swedish massage to the back and neck significantly reduced the anxiety of the subjects ($p < 0.006$).

2.7. **The Thoracic Spine and Neck Pain**

There is a biomechanical, anatomical and neural relationship between the thoracic spine and the cervical spine. No literature could be found ascertaining the effects of thoracic manual therapy, neither on thoracic nor cervical pain. Cleland et al (2005) studied the effects of thoracic manipulation (thrust techniques) in treatment of pain in the region of the cervico-thoracic junction. They postulated that disturbances in joint mobility of the thoracic spinal region are an underlying contributor to neck disorders. They demonstrated a significant immediate reduction in pain when compared to placebo manipulation ($p < 0.001$). Vincenzino et al (2001) also demonstrated that manipulation or mobilisation at sites remote to the site of pain, including mobilisation of the thoracic region, can induce immediate hypoalgesia in area of the pain. No literature could be found that describes the process by which manipulation or mobilisation helps pain.

Curves of the Vertebral Column

Development of the curves of the vertebral column begins as early as seven weeks in utero. The thoracic and pelvic curves are the primary curves. Both are concave anteriorly. Functional muscle activity leads to the development of the secondary curves, being the cervical and lumbar curves. Formation of the

thoracic kyphosis is due to increased posterior vertebral body height in the developing foetus and young child, continuing into adulthood (Gray, 1995). The cervical lordosis develops later as a result of the child's efforts to hold the head upright (Crouch, 1965).

Poor posture affects the whole vertebral column, and since the cervical spine is the most mobile region of the vertebral column (Galley and Forster, 1987), it thus follows that changes of thoracic kyphosis (either increased or decreased curvature) alters the angle and muscle activity of the neck region.

Erector Spinae muscles

The erector spinae muscle group lies in a groove on the side of the vertebral column. *Iliocostalis cervicus* and *longissimus cervicus* muscles are actively involved in cervical movement, while the rest of the group principally extends the vertebral column. Both of these muscles arise in the thoracic region, the main attachments being on the ribs, lateral to the vertebral column and insert onto the cervical vertebra (Gray H, 1995). *Trapezius* and *Levator scapulae* muscles are superficial muscles of the back, involved in scapular control (Gray H, 1995), and as such do not form part of the thoracic mobilisation technique.

Neural Connections

The spinal cord and meninges are contents of the thoracic vertebral canal, while the sympathetic trunk lies adjacent to the thoracic vertebral region. The upper region of the sympathetic trunk gives rise to the cervical part of the sympathetic system (Gray H, 1995). Indeed, no literature could be found that showed that thoracic mobilisation affects these structures. Furthermore, no literature could be found showing that reduced thoracic dural tension affects spinal cord mobility in the neck region or that mobilisation of the sympathetic trunk affects sympathetic outflow.

2.8. Measuring Tools

2.8.1. The Spielberger state and trait anxiety inventory

The Spielberger state and trait anxiety inventory (Spielberger 1976) is used widely as a measuring tool to assess anxiety (Scott et al, 2005). There are two divisions to the questionnaire, aimed at the trait and state modes of anxiety. The Spielberger state anxiety inventory has been used to assess the phenomenological aspects of anxiety and has been shown to be sensitive to transient anxiety linked to a situation perceived as threatening (Spielberger, 1976)). The questionnaire has high validity and reliability (Scott et al, 2005). The questionnaire is self-administered in two to five minutes. It contains 20 statements arranged in a Likert-scale that encourage the subject to describe feelings at any particular moment. Minimum score is twenty and maximum is eighty, where higher score indicates higher

anxiety. Pagano et al (2004) found a mean control group score of 35.13 (± 12.11) in a study comparing anxiety in fibromyalgia patients to a control group, while Nakamura et al (2002) found a mean level of 39 (± 8.9) in a study looking at anxiety in normal human subjects. Hale and Raglan (2002) divided an exercise population into high and low anxiety groups using a society norm of 39 as the point of change. Lawvere (2002) used the questionnaire in a study into the effects of Swedish massage on anxiety in cancer patients. Scott et al (2005) used the STAI to assess the anxiety level in subjects with chronic whiplash associated disorder, idiopathic neck pain subjects and pain-free subjects.

2.8.2. The Memorial pain assessment card

The Memorial pain assessment card (MPAC) was developed to assess the relative potency of analgesic drugs in cancer treatment (Fishman, 1987). It consists of an A4 sheet of card folded in half. The card contains eight pain intensity indicators and three visual analogue scales (VAS). It was found to have good validity and reliability for cancer patients (Fishman et al, 1987). It was found to be equivalent to longer, more complex pain measurement tools (Fishman, 1987) and effective in assessing pain in cognitively impaired elderly people (Ferrell et al, 1995). Lawvere (2002) found it to be sensitive to change in pain state through Swedish massage. The card was simple, inexpensive and self-administered within 1 minute. All visual analogue scales were measured in millimetres (i.e. maximum score for

each VAS was 100). Each of the pain intensity indicators was allocated a value from 10 for the mildest descriptor to 80 for the most severe descriptor.

2.9. **Summary**

The modern understanding of illness and healing lies in the realm of the biopsychosocial approach to health and sickness. Pain, in particular, is subject to both physical and emotional components, as described above. Of the emotional side of neck pain, anxiety and depression are common complaints, both in the acute and chronic phase. Anxiety, in particular may have a role in the cause of neck pain, although this is not clear in the literature.

As regards physiotherapy for neck pain, manual therapy is well supported in the literature as being effective in the management of neck pain, but there is no evidence regarding the effect on the emotional aspects of the condition. No literature could be found to comment on the efficacy of thoracic mobilisation in conjunction with cervical manual physiotherapy in the treatment of cervical pain. A rationale of support for this treatment modality may lie in the anatomical, neural and biomechanical structures present in the thoracic region.

Chapter 3

3 METHODS

3.1. **Introduction**

This chapter encompasses the methodology employed in this study. Study design, ethical clearance, sample size and selection including inclusion and exclusion criteria are elucidated. The procedure followed in the collection of data is described. The treatment effects questionnaire, used to encapsulate the patients' experience of physiotherapy treatment, is described both with regard to the format of the questionnaire as well as to its construction and formulation. Finally, the statistical analysis is described.

3.2. **Study Design**

This was randomised control trial that compared manual physiotherapy to the cervical and thoracic spines versus manual physiotherapy to the cervical spine only, for patients with neck pain.

3.3. **Ethical Clearance**

Ethical Clearance was obtained from the Human Research Ethics Committee at the University of the Witwatersrand, Protocol Number 40432 (Appendix G).

3.4. **Sample**

3.4.1. **Subjects**

A sample of convenience was drawn from one private physiotherapy practice in the greater metropolitan area of Johannesburg.

3.4.2. **Sample size**

A sample size of 23 subjects per group was necessary for a one-sided interval with alpha of 0.05 and power of 90%. See Statistical Considerations, section 5.1 for method.

3.4.3. **Inclusion Criteria**

These were:

- ❖ Non-specific neck pain with or without neurological signs.
- ❖ 45 – 75 years of age.
- ❖ No physiotherapy treatment administered in the last six months.

3.4.4. **Exclusion Criteria**

These were:

- ❖ Open sores or eczema in the thoracic region.

- ❖ Any “red flag” symptoms (fractures, infections, tumours, osteoporosis)

3.5. **Treatment Effects Questionnaire (TEQ) (Appendix F)**

This questionnaire was constructed according to the opinions expressed by the focus group of manipulative physiotherapists. They were asked to describe their perceptions of the effect of thoracic mobilisation in treatment of neck pain. They expressed ten positive effects of treatment of the thoracic region when treating neck pain. These effects were ratified by the group of patients as true effects. The questionnaire consisted of each of these treatment effects as a statement connected to a Likert scale. The scale was rated from one to four, where lower scores implied agreement with the focus groups as being a positive benefit of treatment.

The questionnaire was piloted prior to the study, in order to establish validity and reliability. Validity was established in consultation with a focus group of six manipulative physiotherapists and a group of five patients with chronic neck pain, all of whom were familiar with the treatment method. Reliability was then established by five patients who completed the questionnaire on two different days within one week. 90% correlation of results was shown.

3.6. **Procedure**

Forty seven envelopes containing information sheets and questionnaires were numbered from 1-47. The envelopes were randomly assigned, using a computer-generated set of random numbers, to one of 2 groups, where E was the experimental group and C was the control group. Allocation to respective groups was concealed from the researcher until all initial questionnaires had been completed.

Initially, the research assistant enquired from prospective subjects regarding willingness to enter into the study as well as exclusion criteria. On verbal consent, subjects were handed an information sheet (Appendix A) and consent form (Appendix B). Once the consent form was signed, subjects were assigned a sealed envelope by the research assistant. In addition to the two separate smaller envelopes containing “before treatment” and “after treatment” questionnaires, the envelope contained the subject number as well as group allocation.

The participants then completed questionnaires contained in the “before treatment” envelope:

- ❖ The demographic questionnaire (Appendix C)

- ❖ The Spielberger state anxiety inventory for adults. (STAI) (Spielberger et al., 1983) (Appendix D)
- ❖ The Memorial pain assessment card. (Fishman et al., 1987) (Appendix E)

Both of the above questionnaires were not piloted because the study was carried out in a private physiotherapy practice, where the subjects were generally on a high socio-economic level all with English as home language. Subsequent to completion of the “before treatment” envelope, this envelope was inserted into the larger envelope and concealed from the researcher. Subjects were then interviewed and evaluated by the researcher according to the Maitland protocol for neck assessment. A diagnosis was made by the researcher based on the assessment. Subjects were assigned to one of five mechanical neck disorder groups as reported in Gross et al (2002):

- ❖ Mechanical neck disorder (MND)
- ❖ Mechanical neck disorder with radicular signs and symptoms (NDR)
- ❖ Neck disorder with headache of cervical origin (NDH)
- ❖ Neck disorder associated with whiplash (WAD)
- ❖ Neck disorder associated with degenerative change (DC)

All treatments were administered by the researcher after diagnosis had been made and treatment had been planned.

3.6.1. Control Group Subjects

Manual therapy to the cervical spine consisted of manual spinal mobilisation techniques, myofascial release techniques to the cervical musculature, cervical stretches and neural tissue mobilisation. The multimodal nature of this treatment is in keeping with the multimodal method of physiotherapy as described in the literature review (Gross et al, 2002). Treatments were adapted to each specific case but all treatments contained the above components.

3.6.2. Experimental Group Subjects

In addition to the cervical spine treatment as described above, this group of subjects received a further modality consisting of manual therapy to the thoracic region of the back. This modality included deep massage and myofascial release of the thoracic musculature as well as thoracic vertebral joint mobilisation. The above mobilisation took approximately five minutes and was applied prior to other treatment modalities.

After the treatment, subjects left the treatment area and completed the questionnaires contained in the “after treatment” envelope in the presence of the research assistant and away from the researcher. They consisted of:

- ❖ The Spielberger state anxiety inventory (a second time).
(Spielberger et al., 1983) (Appendix D)
- ❖ Memorial pain assessment card (a second time). (Fishman et al.,
1987) (Appendix E)
- ❖ Treatment Effects Questionnaire (TEQ). (Appendix F).

All questionnaires were replaced into the envelope, which was then sealed by the research assistant until data capture commenced.

3.7. **Blinding of researcher**

All questionnaires were anonymous. Consent was obtained prior to admission to the study. All questionnaires were self-administered with guidance from the research assistant where necessary. The physiotherapist (researcher) had to be aware of the relevant group to which the subject was allocated, but this was only revealed after the initial completion of questionnaires and subsequent sealing of questionnaires in the envelope. The researcher was therefore blinded to the content of the abovementioned questionnaires as well as to the content of the questionnaires completed after

treatment. All questionnaires were sealed in an envelope and were only opened at the time of data capture.

3.8. **Statistical Considerations**

3.8.1. Sample Size

Sample size was determined using one-sided intervals where alpha was 0.05 and power was 90%. 23 subjects per group were required to show equivalence between the two treatment protocols with respect to mean anxiety score.

3.8.2. Statistical Analysis

This study was powered as an equivalence trial comparing standard and experimental treatment with respect to the Spielberger State Anxiety Inventory.

Spielberger State Anxiety Inventory (STAI)

The data analysis comprised a comparison between the two groups with respect to mean post-treatment anxiety scores, using a Student's two-sided independent t-test. Equivalence of the two protocols was shown if the confidence interval for the difference in mean post-treatment anxiety scores fell within ten points (i.e. the confidence interval lay within the range of -10 to 10).

Groups were compared further with regard to mean post-treatment anxiety scores on analysis of covariance with the pre-treatment STAI mean score as the covariate.

Within groups pre- and post-treatment STAI scores were also compared using the Student's paired t-test in order to test the efficacy of the individual interventions.

Memorial Pain Assessment Card (MPAC)

Post-treatment scores for the Memorial Pain Assessment Card (MPAC) were similarly analysed with a Student's two-sided independent t-test, in order to assess equivalence of the two interventions. Since the study was primarily powered on the STAI, equivalence would be shown if the confidence interval for the difference of the mean post-treatment MPAC scores fell within ten points (i.e. from -10 to 10). If both values exceed zero (0), the experimental intervention would be shown to be superior the standard protocol.

An analysis of covariance was performed on the post-treatment pain scores using pre-treatment MPAC scores as covariate.

Within groups pre- and post-treatment MPAC scores were also compared using the Student's paired t-test in order to assess the efficacy of the individual interventions.

Treatment Effects Questionnaire (TEQ)

Individual items on the Treatment Effects Questionnaire were compared between the groups using a Fisher's Exact test.

Chapter 4

4 RESULTS

The results of the study are presented below in table format, with a brief description of the contents of the table. Some points of interest in the results are highlighted.

4.1. **Demographic Data**

The total population of this study was 47 subjects. One subject neglected to complete the questionnaires correctly and so was excluded from the study. The groups thus consisted of 23 per group. The participant group is illustrated in tables 4.1, 4.2 and 4.3. Some of the data from the demographics questionnaire was not included in statistical analysis because that information was for diagnostic and treatment reasons only.

4.1.1. Gender

The proportion of males and females is illustrated in table 4.1.

Table 4.1: Gender distribution between groups

	<u>Male</u>	<u>Female</u>	<u>p-value</u>
<u>Control (n=23)</u>	8 (34.78%)	15 (65.22%)	p=0.139
<u>Experimental (n=23)</u>	13 (56.52%)	10 (43.48%)	
<u>Total (n=46)</u>	21 (45.65%)	25 (54.35%)	

The groups do not differ significantly with respect to gender distribution.

4.1.2. Age

Subjects ranged in age from 45 to 75 years. Mean age according to group is illustrated in table 4.2.

Table 4.2: Age Distribution between the groups

	<u>Mean age ($\pm$S.D)</u>	<u>95% CI</u>	<u>p-value</u>
<u>Control (n=23)</u>	55.65 ($\pm$ 7.92)	-5.87- 3.00	p=0.52
<u>Experimental (n=23)</u>	57.09 ($\pm$ 6.98)		
<u>Total (n=46)</u>	56.40($\pm$ 7.42)		

The groups did not differ significantly in terms of age distribution ($p=0.52$).

The 95% CI indicates equivalence of the two groups with regard to age.

4.1.3. Diagnostic Groups

Subjects were classified into categories according to diagnosis as reported in Gross et al (2002). The number of subjects per diagnostic groups is illustrated in table 4.3.

Table 4.3: Diagnostic grouping of subjects according to Gross et al (2002)

<u>Category</u>	<u>MND</u>	<u>DC</u>	<u>NDH</u>	<u>WAD</u>	<u>NDR</u>
<u>Control</u> <u>(n=23)</u>	4 (17.39%)	11 (47.38%)	0 (0.00%)	3 (13.04%)	5 (21.74%)
<u>Experimental</u> <u>(n=23)</u>	7 (30.43%)	8 (34.78%)	4 (17.39%)	0 (0.00%)	4 (17.39%)
<u>Total (n=46)</u>	11 (23.91%)	19 (41.30%)	4 (8.70%)	3 (6.52%)	9 (19.57%)

Key: MND Mechanical neck disorder
DC Degenerative change
NDH Neck disorder with headache
WAD Whiplash-associated disorder
NDR Neck disorder with radicular signs

30 of the 46 subjects (65.21%) fell into the degenerative change or the mechanical neck disorder categories. This suggests a high prevalence of these two types of cervical conditions in the population above 45 years of age.

4.2. Spielberger State Anxiety Inventory

4.2.1. Comparison of post-treatment anxiety scores

The two groups were compared with regard to post-treatment STAI scores by means of a two-sided student's t-test. Results are presented in table 4.4.

Table 4.4: Post-treatment anxiety levels

	<u>Mean ($\pm$ SD)</u>	<u>95% CI</u>	<u>Difference:</u> <u>95% CI</u>	<u>p-value</u>
<u>Control (n=23)</u>	31.87 ($\pm$ 7.39)	28.67-35.07	-5.70- 5.09	p=0.91
<u>Experimental (n=23)</u>	32.17 ($\pm$ 10.50)	27.63-36.72		

The confidence interval of -5.70 – 5.09 indicates that the two protocols are equivalent in terms of the effect of the interventions.

4.2.2. Comparison of post-treatment anxiety scores adjusted for baseline anxiety score

The groups were also compared in an analysis of covariance in terms of post-treatment anxiety score with baseline anxiety score as covariate. Table 4.5 illustrates the adjusted mean post-treatment anxiety scores generated with a covariate score of 40.13.

Table 4.5: Post-treatment anxiety change adjusted for baseline means

	<u>Mean ($\pm$ SD)</u>	<u>90% CI</u>	<u>p-value</u>
<u>Control (n=23)</u>	32.12 ($\pm$ 6.94)	29.69-34.56	p=0.92
<u>Experimental (n=23)</u>	31.92 ($\pm$ 6.94)	29.49-34.36	

Table 4.5 illustrates that adjusted anxiety scores were not significantly different between the groups, when adjusted for baseline mean anxiety score. Both groups, however, indicate a reduction in anxiety from the pre-treatment baseline mean of 40.13.

4.2.3. Comparison between pre-and post-treatment STAI scores within groups

The within groups mean anxiety change was assessed through a paired student's t-test. Results are illustrated in table 4.6.

Table 4.6: Comparison of pre-and post-treatment scores within the groups

	<u>Mean ($\pm$SD)</u>		<u>95% CI</u>	<u>p-value</u>
	<u>Pre-treatment</u>	<u>Post-treatment</u>		
<u>Control</u>	39.61($\pm$ 10.23)	31.87($\pm$ 7.39)	(3.46-12.02)	p=0.0011
<u>Experimental</u>	40.65($\pm$ 14.12)	32.17($\pm$ 10.50)	(4.67-12.29)	p=0.0001

Both groups showed highly significant decreases in anxiety post treatment. As shown previously, effects of intervention between the groups do not differ significantly, with regard to anxiety change. Hence the effect of intervention on anxiety scores is independent of thoracic mobilisation as part of the treatment protocol.

4.3. **Memorial Pain Assessment Card**

4.3.1. Comparison of post-treatment pain scores

Post-treatment MPAC scores were compared between the groups by means of a two-sided student's t-test. Results are illustrated in table 4.7.

Table 4.7: Pain scores on the MPAC post-treatment

<u>Group</u>	<u>Mean</u>	<u>95% CI</u>	<u>Difference</u>	<u>p-value</u>
<u>Control (n=23)</u>	137.70 ($\pm$ 52.91)	114.82-160.57	-3.33- 60.28	p=0.08
<u>Experimental (n=23)</u>	109.22 ($\pm$ 54.12)	85.81-132.62		

The experimental group mean MPAC scores were marginally significant when compared to the control group in terms of pain reduction. However a large confidence interval was recorded.

4.3.2. Comparison of post-treatment MPAC scores adjusted for baseline pain scores

The groups were also compared in an analysis of covariance in terms of post-treatment MPAC scores with baseline pain score as covariate. Table 4.8 illustrates the adjusted mean post-treatment pain scores generated with a covariate score of 215.96.

Table 4.8: Post-treatment pain change adjusted for baseline means

<u>Group</u>	<u>Mean ($\pm$SD)</u>	<u>90% CI</u>	<u>p-value</u>
<u>Control (n=23)</u>	134.49 ($\pm$ 52.0)	116.05-152.94	p=0.17
<u>Experimental (n=23)</u>	112.42 ($\pm$ 52.0)	93.98-130.86	

Table 4.8 illustrates that adjusted MPAC scores were not significantly different between the groups, when adjusted for baseline mean pain score. Both groups, however, indicate a reduction in pain from the pre-treatment baseline mean of 215.96

4.3.3. Comparison between pre-and post-treatment MPCA scores within groups

The within groups mean pain change was assessed through a paired student's t-test. Results are illustrated in table 4.9.

Table 4.9: Comparison of pre-and post-treatment scores within the groups

	<u>Mean ($\pm$SD)</u>		<u>95% CI</u>	<u>p-value</u>
	<u>Pre-treatment</u>	<u>Post-treatment</u>		
<u>Control</u>	229.26($\pm$ 57.69)	137.70($\pm$ 52.91)	(59.93-123.20)	p=<0.0001
<u>Experimental</u>	202.65($\pm$ 65.96)	109.22($\pm$ 54.12)	(64.88-121.99)	p=<0.0001

Both groups showed highly significant decreases in pain post-treatment.

4.4. Treatment Effects Questionnaire

Groups were compared with respect to individual items using Fisher's Exact test.

4.4.1. Statement 1: I feel more mobile

Groups were compared with regard to responses regarding increased mobility.

Results are illustrated in table 4.10.

Table 4.10: Comparison of groups regarding mobility increase

<u>Group</u>	<u>Control</u> <u>(n=23)</u>	<u>Experimental</u> <u>(n=23)</u>	<u>Total</u> <u>(n=46)</u>	<u>p-value</u>
<u>Very much so</u>	9 (39.13%)	11 (47.83%)	20 (43.48%)	p=0.53
<u>Moderately so</u>	9 (39.13%)	10 (43.48%)	19 (41.30%)	
<u>Somewhat</u>	5 (21.74%)	2 (8.70%)	7 (15.22%)	
<u>Not at all</u>	0 (0.00%)	0 (0.00%)	0 (0.00%)	

The groups did not differ with regard to increased mobility. Hence, thoracic mobilisations do not increase mobility more than treatment to the cervical region only.

4.4.2. Statement 2: I feel less pain

Groups were compared regarding reported pain decrease. Results are presented in table 4.11.

Table 4.11: Comparison of groups with regard to pain relief

<u>Group</u>	<u>Control</u> <u>(n=23)</u>	<u>Experimental</u> <u>(n=23)</u>	<u>Total</u> <u>(n=46)</u>	<u>p-value</u>
<u>Very much so</u>	6 (26.09%)	11 (47.83%)	17 (36.96%)	p=0.36
<u>Moderately so</u>	9 (39.13%)	8 (34.78%)	17 (36.96%)	
<u>Somewhat</u>	7 (30.43%)	4 (17.39%)	11 (23.91%)	
<u>Not at all</u>	1 (4.35%)	0 (0.00%)	1 (2.17%)	

Groups did not differ with regard to pain relief. Hence, there is no difference between the protocols regarding pain relief. This is simply a statement of whether or not the pain has reduced. It does not assess quality or amount of pain reduction.

4.4.3. Statement 3: I feel confident with the treatment

Groups were compared regarding confidence with the treatment. Results are presented in table 4.12.

Table 4.12: Comparison of groups regarding confidence with the treatment

<u>Group</u>	<u>Control</u> <u>(n=23)</u>	<u>Experimental</u> <u>(n=23)</u>	<u>Total</u> <u>(n=46)</u>	<u>p-value</u>
<u>Very much so</u>	15 (65.22%)	17 (73.91%)	32 (69.57%)	p=0.65
<u>Moderately so</u>	6 (26.09%)	6 (26.09%)	12 (26.09%)	
<u>Somewhat</u>	2 (8.70%)	0 (0.00%)	2 (4.35%)	
<u>Not at all</u>	0 (0.00%)	0 (0.00%)	0 (0.00%)	

There was no difference between the groups, hence subjects felt confident with either protocol.

4.4.4. Statement 4: I feel warm

Groups were compared regarding reported feelings of pleasant warmth. Results are presented in table 4.13.

Table 4.13: Comparison of groups regarding feelings of warmth

<u>Group</u>	<u>Control</u> <u>(n=23)</u>	<u>Experimental</u> <u>(n=23)</u>	<u>Total</u> <u>(n=46)</u>	<u>p-value</u>
<u>Very much so</u>	10 (43.48%)	10 (43.48%)	20 (43.48%)	p=1.000
<u>Moderately so</u>	10 (43.48%)	10 (43.48%)	20 (43.48%)	
<u>Somewhat</u>	2 (8.70%)	3 (13.04%)	5 (10.87%)	
<u>Not at all</u>	1 (4.35%)	0 (0.00%)	1 (2.17%)	

Groups were identical, implying that there is no extra benefit of thoracic mobilisation, with regard to feeling pleasantly warm.

4.4.5. Statement 5: I feel more relaxed

Groups were compared regarding reported feelings of relaxation. Results are presented in table 4.14.

Table 4.14: Comparison of groups with regard to feeling relaxed after treatment

<u>Group</u>	<u>Control</u> <u>(n=23)</u>	<u>Experimental</u> <u>(n=23)</u>	<u>Total (n=46)</u>	<u>p-value</u>
<u>Very much so</u>	11 (47.83%)	14 (60.87%)	25 (54.35%)	p=0.69
<u>Moderately so</u>	9 (39.13%)	7 (30.43%)	16 (34.78%)	
<u>Somewhat</u>	3 (13.04%)	2 (8.70%)	5 (10.87%)	
<u>Not at all</u>	0 (0.00%)	0 (0.00%)	0 (0.00%)	

The groups do not differ with regard to feeling more relaxed after treatment.

Hence, thoracic mobilisation does not lead to increased feelings of relaxation.

4.4.6. Statement 6: I can breathe deeper

Groups were compared regarding a reported increased ability to breathe deeply.

Results are presented in table 4.15.

Table 4.15: Comparison of groups with regard to depth of breathing

<u>Group</u>	<u>Control</u> <u>(n=23)</u>	<u>Experimental</u> <u>(n=23)</u>	<u>Total (n=46)</u>	<u>p-value</u>
<u>Very much so</u>	8 (34.78%)	8 (34.78%)	16 (34.78%)	p=0.66
<u>Moderately so</u>	9 (39.13%)	11 (47.83%)	20 (43.48%)	
<u>Somewhat</u>	5 (21.74%)	2 (8.70%)	7 (15.22%)	
<u>Not at all</u>	1 (4.35%)	2 (8.70%)	3 (6.52%)	

The groups do not differ in terms of increased feelings of being able to breathe deeper.

4.4.7. Statement 7: The treatment is not on target

Groups were compared regarding feelings that treatment was not directed at the correct area. Results are presented in table 4.16.

Table 4.16: Comparison of groups regarding application of the treatment

	<u>Control</u> <u>(n=23)</u>	<u>Experimental</u> <u>(n=23)</u>	<u>Total</u> <u>(n=46)</u>	<u>p-value</u>
<u>Not at all</u>	20 (86.96	22 (95.65%)	42 (91.30%)	p=0.74
<u>Somewhat</u>	0 (0.00%)	0 (0.00%)	0 (0.00%)	
<u>Moderately so</u>	2 (8.70%)	0 (0.00%)	2 (4.35%)	
<u>Very much so</u>	1 (4.35%)	1 (4.35%)	2 (4.35%)	

90% of the subjects felt that the treatment was on target, with not difference between groups.

4.4.8. Statement 8: I am surprised that it is painful there

Groups were compared regarding subjects feeling pain where they did not expect it to be painful. Results are presented in table 4.17.

Table 4.17: Comparison of groups regarding anticipating other painful areas

	<u>Control</u> (n=23)	<u>Experimental</u> (n=23)	<u>Total</u> (n=46)	<u>p-value</u>
<u>Very much so</u>	2 (8.70%)	8 (34.78%)	10 (21.74%)	p=0.05
<u>Moderately so</u>	3 (13.04%)	2 (8.70%)	5 (10.87%)	
<u>Somewhat</u>	3 (13.04%)	6 (26.09%)	9 (19.57%)	
<u>Not at all</u>	15 (65.22%)	7 (30.43%)	22 (47.83%)	

The p-value is significant (p=0.05) probably due to the experimental group subjects having had treatment to more areas than the control group, hence the increased level of surprise with other painful areas besides pain in the neck region.

4.4.9. Statement 9: The effects are mainly to do with the therapist's personality

Groups were compared regarding opinions on the effect of the therapist's personality. Results are presented in table 4.18.

Table 4.18: Comparison of groups regarding effects of the therapist's personality

<u>Group</u>	<u>Control</u> <u>(n=23)</u>	<u>Experimental</u> <u>(n=23)</u>	<u>Total (n=46)</u>	<u>p-</u> <u>value</u>
<u>Very much so</u>	7 (30.43%)	5 (21.74%)	13 (26.09%)	p=0.18
<u>Moderately so</u>	7 (30.43%)	2 (8.70%)	12 (19.57%)	
<u>Somewhat</u>	4 (17.39%)	8 (34.78%)	9 (26.09%)	
<u>Not at all</u>	5 (21.74%)	8 (34.78%)	12(28.26%)	

Although groups did not differ significantly, 60% of the control group felt that personality played a large role, while 70% of the experimental group felt that treatment played a larger role in the effects of treatment.

4.4.10. Statement 10: Effects are mainly due to the advice/education received

Groups were compared with regard to the effect of advice or education received during the treatment session. Results are presented in table 4.19.

Table 4.19: Comparison of groups with regard to the reported effect of advice

<u>Group</u>	<u>Control</u> <u>(n=23)</u>	<u>Experimental</u> <u>(n=23)</u>	<u>Total (n=46)</u>	<u>p-value</u>
<u>Very much so</u>	9 (39.13%)	9 (39.13%)	18 (26.09%)	0.44
<u>Moderately so</u>	3 (13.04%)	3 (13.04%)	6 (21.74%)	
<u>Somewhat</u>	7 (30.43%)	3 (13.04%)	10 (13.04%)	
<u>Not at all</u>	4 (17.39%)	8 (34.78%)	12 (39.13%)	

The groups did not differ significantly with regard to the effects of advice or education received during the treatment.

Chapter 5

5 DISCUSSION

5.1. **Introduction**

In this chapter, the results of this study are discussed in terms of anxiety and pain. The treatment effects questionnaire and various demographic data are also explored. Support for the findings are presented from the literature where applicable. Problem areas of this study are highlighted and recommendations for future research are made.

5.2. **Anxiety**

In order to assess the anxiety component involved in the neck pain of the subjects of this study prior to treatment, it was necessary to ascertain the normal society score for the STAI. Numerous studies have used various normal scores for this questionnaire. Pagano et al (2004) established a score of $35.13(\pm 12.11)$ for their control group in a study comparing anxiety associated with fibromyalgia in comparison to a control group. Nakamura et al (2002) established a societal mean of $39(\pm 8.9)$ in their study on normal subjects, while Hale et al (2002) divided an exercise population into high and low anxiety groups using a society norm of 39 as the point of change.

Baseline mean anxiety score for the subjects in this study was 40.13, slightly above the cut-off point of Hale et al (2002). This indicates that subjects were not significantly more anxious than a normal group of subjects, suggesting that neck pain does not imply elevated levels of anxiety. On comparison of post-treatment scores with this pre-treatment mean, there was a significant reduction in anxiety post-treatment. One must assume that normal society scores for the STAI includes some element of anxiety, hence the reduction in scores post-treatment highlights the de-stressing nature of neck manual therapy whether the treatment includes thoracic mobilisation or not. This is backed up by the response of subjects to statement 5 on the TEQ: “I feel more relaxed”, where 89.13% of the subjects of both groups reported at least a moderate amount of relaxation post treatment.

The study of Eckberg et al (1994) reviewed in Karjalainen (2001) compared active multidisciplinary management (physical training, education, social interaction and work place visit) to traditional treatment (physiotherapy) for management of neck pain. The results of that study showed that there was no difference between the groups highlighting the benefits of physiotherapy on both a physical and emotional level. Their result is backed up by this study that shows significantly that manual therapy has beneficial effects on anxiety. This result also agrees with that of Lawvere (2002), who showed that Swedish massage reduced anxiety significantly in ovarian cancer patients.

Although the study of Lawvere (2002) was a pilot study, the improvement in anxiety post-massage was highly significant. Lawvere (2002) used a crossover design, where massage group subjects had relaxation time the following day, while the relaxation group of the first day had massage on the second day. He notes that the massage group of the first day, after having shown a 33% reduction in anxiety post-massage, showed a return to original anxiety scores by the second day, that is, there was no residual carryover of anxiety reduction from day to day. Temporal aspects of the anxiety reduction were not assessed in this study.

Wade and Shantall (2003) interviewed three female chronic back pain sufferers in order to define their experience of their pain. These authors expressed the opinion of the participants regarding physiotherapists as: “the physiotherapist was perceived as the one person who truly understood and validated the experience of these participants.” They stated further: “The relief provided by physiotherapy, however temporary, was an important factor in enabling participants to cope.”

Thus, the role of the physiotherapist in the therapist/patient relationship is multifaceted and complex. A possibility for further study could be to compare manual physiotherapy to non-manipulative physiotherapy in terms of effect on anxiety.

There was no significant difference between the groups with regard to anxiety change through treatment to the cervical and thoracic regions or to the cervical

region alone indicating that thoracic mobilisation has no extra effect on anxiety in subjects with neck pain.

This result is in contrast to the view of the South African manipulative physiotherapists' panel, who felt that thoracic mobilisation had extra benefits over cervical treatment alone with regard to relaxation and decreased anxiety.

A possible confounder of the lack of difference between the groups could be due to the large equivalence delta of ten points set in this study. This equivalence delta treats all scores within ten points as equal. A smaller equivalence delta would have been more sensitive to differences between the groups regarding anxiety change between the groups and may yield a different result.

5.3. **Pain**

Within group scores on the MPAC showed highly significant differences between pre- and post-treatment for pain reduction in both groups. This benefit of manual therapy is well documented in the literature (Koes et al, 1992; Hoving et al, 2001; Hoving et al, 2002). Cleland et al (2005) found that thoracic manipulation produced immediate neck pain relief, in agreement with the results of this study, albeit with different modalities.

Marginally significant improvements in pain of the experimental group were recorded between groups. This supports the view of the panel of physiotherapists

who felt that thoracic mobilisation had added benefits in the treatment of neck pain. No literature could be found to substantiate this result although Cleland et al (2005) did show significant neck pain reduction after thoracic thrust manipulation.

The benefits of the MPAC are the ease of use, the speed of use and the easily understood concepts. Fishman et al (1987) found this questionnaire to be comparable to other pain questionnaires. It seemed in this study, that some subjects expressed the reduction in pain from pre- to post-treatment as vast on the visual analogue scales while others were more conservative in their estimation, even though their pain reduction could have been similar in objective terms. It was this that led to the large confidence interval of -3.33-60.28, which compromises the value of the results. This study was powered on the basis on the STAI and was not focussed optimally on the MPAC to allow for this, and hence, this questionnaire was possibly not used to its full effect.

A repeat of this study is recommended employing an improved protocol for the MPAC or using another pain measuring tool with more objective measures to assess the effect of thoracic mobilisation for neck pain more effectively.

5.4. **Other treatment effects**

The treatment effects questionnaire showed no significant differences between the groups for any of the statements. This indicates that these effects are not

necessarily products of the thoracic mobilisation, but rather are products also of cervical treatment alone.

For statement 9, subjects were asked to express opinions on the effect of the physiotherapist's personality in comparison to the effect of the treatment itself. 60.83% of the control group emphasised the effect of the therapist's personality while only 39.17% of the control group felt that the treatment produced the main effect. In the experimental group, 69.56% of the experimental group felt that the treatment played a larger role than the personality of the physiotherapist. Although this difference was not significant ($p=0.18$), as noted previously, the experimental group exhibited marginally significant pain reduction ($p=0.08$) and 70% of the subjects in that group expressed a conviction that the manual therapy treatment brought about the treatment effects. This indicates that the broader treatment method of the experimental group was more convincing regarding the positive effects of manual therapy than the control group.

5.5. **Demographic Results**

5.5.1. Gender

There was no difference between the groups or in the total number of males to females in the study. This is in contrast to the conclusions of Hoving et al (2002), Côté et al (1998) and McGreary et al (2003) who found that neck pain is more

common in women than men. Côté et al (1998) also found that women experience disabling neck pain more frequently than men.

5.5.2. Age

The groups were equivalent in terms of age. Subjects were limited to between 45 and 75 years and the mean age was 56.40 (± 7.42). Hoving et al (2002) quoted studies showing prevalence to be most common at 50 years of age, while Côté et al (1998) showed mild neck pain to be more common between 20-29 years with no difference of prevalence across the age groups for more severe cases.

5.5.3. Diagnostic Categories

Gross et al (2002) reviewed a number of random clinical trials assigning the subjects to five different groups: neck disorder with cervical headache; mechanical neck disorder; mechanical neck disorder with radicular signs; neck disorder associated with whiplash; neck disorder associated with degenerative change. This method of classification can permit investigation into treatment protocol efficacy within different pathology groups. It follows then that randomised control trials should define the sample group in terms of these five diagnostic groups to aid the application of treatment protocols and results into a larger base of evidence-based research.

In this study, the degenerative change group was the most common diagnosis made (40.30%). Twenty four percent of the subjects had mechanical neck pain and a further twenty percent had neck pain with radicular signs. Only 8.70% of the subjects had neck pain with headache and 6.52% had whiplash associated disorder. It was expected that there would be a predominance of degenerative change diagnoses due to the age restriction of 45 years and above of the sample group. Diagnostic predominance may differ extensively in a younger age group. Siivola et al (2002), in a magnetic resonance imaging study of teenage and young adults with and without neck pain, found that the only significant indicator for neck pain in young adults was cervical disc herniation.

Summary

In summary, the effect of cervical and thoracic manual physiotherapy on the anxiety associated with neck pain was shown to be equivalent to manual therapy of the cervical spinal region alone. Pre-treatment anxiety levels were similar to society norms but both protocols showed a highly significant decrease in anxiety post-treatment.

As regards pain relief, the experimental group showed a marginally significant improvement in level of pain in comparison to the control group, although the large confidence interval compromised this result. On within group analysis, both

groups showed highly significant improvement in level of pain. The positive benefits of manual therapy in treatment of neck pain are highlighted.

Treatment effects were equivalent between the groups, showing that thoracic mobilisation produces no extra benefit with regards to the treatment effects over standard cervical manual therapy.

Further clarification of the role of anxiety in neck pain is needed. This is both in the role of anxiety in the causation of neck pain, and the role of neck pain in the causation of anxiety. A comparison of manual physiotherapy to standard physiotherapy with regard to anxiety and pain management is also recommended. Treatment of the thoracic region also needs further investigation with regard to different treatment protocols for cervical and thoracic pain.

Limitations of this study related to the measuring tools. A narrower delta may have been more sensitive to differences between the groups on the STAI. Furthermore, the study was not powered on the MPAC which may possibly also have produced more reliable results in the area of effect of treatment on pain. The performance of a pilot study to assess the validity and reliability of these two measuring tools could have averted these shortcomings. The Treatment effects questionnaire was designed for this study and includes ambiguous and superfluous questions. This tool needs further refinement and adjustment in order to make it a reliable measure of treatment effect.

Chapter 6

6 CONCLUSIONS

- ❖ Manual physiotherapy to the cervical and thoracic regions does not reduce anxiety more than manual therapy to the cervical region only.
- ❖ Manual physiotherapy to the cervical and thoracic regions may possibly reduce pain more effectively than manual therapy to the cervical region only.
- ❖ Manual therapy to both the cervical and thoracic regions or to the cervical region only, reduces anxiety significantly.
- ❖ Manual therapy to both the cervical and thoracic regions or to the cervical region only, reduces pain significantly.
- ❖ There is no difference between manual therapy to the cervical and thoracic regions and manual therapy to the cervical region alone in terms of treatment effects as listed in the Treatment Effects Questionnaire.

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APPENDICES

Appendix A: Information Sheet.

Dear Patient

Hi, thanks for taking the time to read this. My name is Martin Elvey and I am at present conducting a research project as part of the degree of Master of Science in Physiotherapy at the University of the Witwatersrand. The aim of my research is to compare patients' perceptions of different types of neck physiotherapy treatment.

Neck pain is a common condition seen by physiotherapists worldwide. Treatment varies between countries and even individuals, but all the different treatment methods work very well. While this is the case, the medical world is generally more convinced of treatment benefits when the treatment has been studied in a strict, regimented way to prove that the treatment, not chance, causes relief of neck pain. It may be the therapist's personality, or a healing environment, or even just the opportunity to relax that causes the improvement.

Entrance into the study is on an absolutely voluntary basis. It is the choice of all participants whether to join the study or even to withdraw from the study at any stage, without any prejudice to any further treatments. Any patient between 45 and 75, suffering with neck pain is eligible to take part in this study. Also, this should be your first treatment in this episode of pain. All that is required of you is to fill in 2 short questionnaires (taking about 5 minutes in total). Thereafter, I will make an assessment of your neck problem and perform the treatment. After the treatment, there are 3 more short questionnaires to complete (taking about 6 minutes in total) and you're finished. All the information is anonymous and confidential. When all the questionnaires are completed, your envelope containing the questionnaires can be placed in the sealed box on the reception area. The box will only be opened after I have collected enough questionnaires (about 50). You can be sure that I will not know the identity of any of the participants from the questionnaires. So be as honest as you can be, being assured that all information is anonymous and confidential.

There are no risks to this treatment. If you would like any more information, feel free to ask me. There are no extra costs involved as a result of taking part in this study and you are also free to withdraw from the study at any point, without this having any effect on any future treatments in any way.

Thanking you for your time
Martin Elvey, B.Sc. (Physiotherapy)(UCT)

Appendix B: Consent Form

Please sign and date the consent form below as an acknowledgement that you have read the information sheet and agree to be a participant in the study. This also confirms that you understand that you are free to withdraw from the study at any time.

Signature:_____

Date:_____

Appendix C: Demographic Information Form

Place a cross in the correct option

1	Age			
2	Gender	Male	Female	
3	Occurrence of neck pain	First time	Repeated episode	
4	Frequency	Once a year	Monthly	Weekly
5	Allergies to oils	Yes	No	
6	Previous treatment	Yes	No	
7	Effect of previous treatment	Good	Fair	Poor
8	Does your neck feel stiff as well as sore?	Yes	No	
9	Do you also have pain in your upper back?	Yes	No	
10	Do you also have pain in your lower back?	Yes	No	
11	Do you have any numbness?	Yes	No	
12	Does your arm feel lame or weak?	Yes	No	
13	Do you have blurred or altered vision?	Yes	No	
14	Are you feeling dizzy or disorientated?	Yes	No	

Appendix D: Spielberger State Anxiety Inventory

Place a cross in the most correct option		NOT AT ALL	SOME- WHAT	MODERA- TELY SO	VERY MUCH SO
1	I feel calm				
2	I feel secure				
3	I am tense				
4	I feel strained				
5	I feel at ease				
6	I feel upset				
7	I am presently worrying over possible misfortunes				
8	I feel satisfied				
9	I feel frightened				
10	I feel comfortable				
11	I feel self- confident				
12	I feel nervous				
13	I am jittery				
14	I feel indecisive				
15	I am relaxed				
16	I feel content				
17	I am worried				
18	I feel confused				
19	I feel steady				
20	I feel pleasant				

Appendix E: Memorial Pain Assessment Card – Outer View

4

Worst mood |-----| Best mood

Indicate your mood change due to treatment on the line below.

MOOD SCALE

PAIN SCALE

Indicate your pain level after the treatment on the line below.

Least possible pain |-----| Worst possible pain

1

MPAC2

Appendix E: Memorial Pain Assessment Card – Inner View

2

Severe

Mild

Moderate

Weak

No pain

Just noticeable

Strong

Excruciating

Circle the term describing the severity of your pain after treatment most accurately.

PAIN DESCRIPTOR

RELIEF SCALE

Indicate level of pain relief from this treatment on the line below.

NO
relief of pain

|—————|

COMPLETE
relief of pain

3

Appendix F: Treatment Effects Questionnaire

Place a cross in the most correct option		NOT AT ALL	SOME- WHAT	MODER- ATELY SO	VERY MUCH SO
1	I feel more mobile				
2	I feel less pain				
3	I feel more confident with the treatment				
4	I feel warm				
5	I feel relaxed				
6	I am breathing easier/deeper				
7	I feel that the treatment is not on target				
8	I am surprised that it is painful there				
9	Effects are mainly due to the therapist's personality				
10	Effects are mainly due to advice/education received				

Appendix G: Ethical Clearance Certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAU)

R14/49 Elvey

CLEARANCE CERTIFICATE

PROTOCOL NUMBER 40432

PROJECT

A randomised, control trial to compare perceptions of treatment to the cervical and thoracic spine v perceptions of treatment to the cervical spine only, in patients with neck pain.

INVESTIGATORS

Mr. M L Elvey

DEPARTMENT

Physiotherapy

DATE CONSIDERED

04.05.07

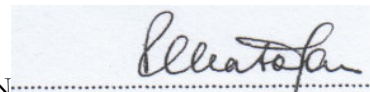
DECISION OF THE COMMITTEE*

Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 04.05.28

CHAIRPERSON



(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor: Dr A Stewart

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and ONE COPY returned to the Secretary at Room 10005, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned 'research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES