The relative effectiveness of the combination of spinal manipulation and Homoeopathic Simillimum in the treatment of chronic mechanical neck pain.

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Dissertation submitted in partial compliance with the requirements for the Master's degree in technology in Technology: Homoeopathy in the Faculty of Health Sciences at the Durban University of Technology.

I, Kym Belling, do hereby declare that this dissertation represents my own work in concept and execution.

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DEDICATION

This thesis and all the hard work behind it is dedicated to my beautiful blessings, Dudley, Sebastian and Zanna, you mean the absolute world to me. I thank God every day for the three of you and you have made me so happy and proud and I can’t wait to see what our future holds. Thank you for being mine, I adore you with all I am.

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ABSTRACT

Background: According to Picavet and Schouten (2003) the incidence of neck pain is increasing at a greater rate than other spine problems (Hoving *et al.* 2004). Furthermore, chronic neck pain is a substantial burden to society with chronic neck pain being the fourth leading cause of disability worldwide (Hoy *et al.* 2014). Chronic mechanical neck pain (CMNP) has been defined as localised, asymmetrical neck pain with restricted range of motion and dysfunctional musculature (Grieve, 1988).

Treatments for those suffering with chronic pain, which are non-surgical, appear to be the most beneficial for patients according to Haldeman *et al.* (2008). Giles and Müller (1999) have stated that spinal manipulation is the most effective method of treating spinal pain on its own. However, the literature suggests that there is benefit in combining manipulation with an "anti-inflammatory type" drug (Crawford 1988; Oberbaum 1998; Serrentino 2003). Many studies have been successfully conducted on Homoeopathic complexes to treat neck pain (Fisher 1986; Bohmer and Ambrus 1992; Hepburn 2000; Soeken 2004) however no study has yet to been carried out on the combination of Homoeopathic Simillimum (single remedy) and spinal manipulation for CMNP.

Objective: The aim of this study was to determine if spinal manipulation and Homoeopathic Simillimum in combination are more relatively effective than spinal manipulation alone in the treatment of chronic mechanical neck pain.

Methodology: This study was a randomised, blinded placebo controlled quantitative trial with a comparative clinical trial design. Thirty consenting participants with CMNP who met the inclusion criteria were randomly distributed between two treatment groups. Group A received spinal manipulation as well as Homoeopathic Simillimum and group B received spinal manipulation with placebo medication. Each participant received three treatments over a period of a week; with subjective and objective readings taken at every consultation. The subjective tools included the Numerical Pain Rating Scale and Canadian Memorial College of Chiropractic Neck Disability Index. Objective tools included the Algometer and CROM-II Goniometer. All data captured

was analysed using SPSS version 24.0. Inferential and non-parametric analysis of the data were also be performed.

Results: The results showed that no statistically significant differences were observed between the two groups in terms of subjective and objective measurements. However, there were statistically significant improvements seen in both groups equally in terms of ANOVA subjective and objective measurements i.e. both groups showed improvement.

Conclusion: The results of this study concluded that no statistical or clinically significant changes were noticed between the groups and therefore the Homoeopathic Simillimum added no statistical significant improvements in those who received it over those participants who received placebo in the treatment of chronic mechanical neck pain.

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LIST OF ABBREVIATIONS

% - Percentage

> - Greater than

< - Less than

AHPCSA - Allied Health Professions Council of South Africa

CMCC - Canadian Memorial Chiropractic College

CMNP - Chronic mechanical neck pain

CROM - Cervical range of motion

DUT - Durban University of Technology

Group A - Cervical spine manipulation and Homoeopathic Simillimum group

Group B – Cervical spine manipulation and placebo group

M.Tech - Masters of Technology

n - Number of participants in group

N - Total number of participants

NDI - Neck Disability Index

NRS - Numerical Pain Rating Scale

NSAIDs - Non-Steroidal Anti-Inflammatory Drugs

p - Refers to p-value, which is the statistical significance of the data

ROM - Range of motion

SMT – Spinal manipulative therapy

Std - Standard

DEFINITION OF TERMS

Centesimal: The first scale that Hahnemann developed during the early years of Homoeopathy is the centesimal scale. As its name would suggest, it has a 1:100 dilution ratio (Vithoulkas 2004).

Convenience sampling: A method that removes bias from the selection of participants, whereby any participant who fulfils the study criteria and is be able to be compliant during the study period, is accepted into the sample group (Dirckx 2001).

Double-blind: A study conducted with neither the researcher nor participants knowing which participants are in the control group (i.e. placebo group). This is to prevent bias in recording results (Dirckx 2001).

Fixation: The state whereby an articulation has become temporarily immobilized in a position that it may normally occupy during any phase of physiological movement (Haldeman 1992).

Homoeopathy: A system of therapy developed by Samuel Hahnemann based on the "law of infinitesimal doses" and *similia similibus curantur* (likes are cured by likes) (Dirckx 2001).

Infinitesimal dose: The idea that much smaller doses of the drug are needed to bring about a reaction in the diseased body, as Homoeopathy is based on the paradigm of healing that the patient brings about the cure after remedies stimulate the patient's curative powers (De Schepper 2006).

Law of Similars: The fundamental tenet of Homoeopathy that states that a substance which causes a set of symptoms in a healthy person acts as a curative medicine when given to sick people who have its similar symptoms (Cummings and Ullman 1997). Furthermore, the Law of Similars states that the Simillimum is the remedy that most clearly matches the symptoms of the patient and that produces the greatest benefit (Reichenberg-Ullman and Ullman 2000).

Manipulation: A passive manual manoeuver during which the three joint complex is suddenly carried beyond the normal physiological range of movement without exceeding the boundaries of anatomical integrity, with the object of restoring mobility to restricted areas (Schafer and Faye 1990).

Materia medica: A book that includes individual Homoeopathic remedies and their indications (Reichenberg-Ullman and Ullman 2000).

Mechanical neck pain: Mechanical neck pain is a complaint of neck pain, headaches and limited range of motion. The pain is described as a dull aching discomfort in the posterior neck that sometimes radiates to the shoulder or mid back regions (Windsor 2004).

Placebo: An inert compound identical in appearance to material being tested in experimental research, which may or may not be known to the physician and/or patient, administered to distinguish between drug action and suggestive effect of the material under study (Dirckx 2001).

Plussed potency: Remedies given in water when frequent repetition is required (Vithoulkas 2004). It is based on the ability of potentised water to transmit its potency to unmedicated water (Gray 2000).

Potency: The strength of a Homoeopathic medicine, as determined by the number of serial dilutions and successions (Reichenberg-Ullman and Ullman 2000).

Potentization: The process of serial dilution and succussion of a solution, thereby increasing its effectiveness as a Homoeopathic remedy when prescribed according to the Similia Principle (Gray 2000).

Randomisation: Assignment of the subjects of experimental research to groups by chance (Dirckx 2001).

Repertory: A book or software programme of remedy drug pictures classified with reference to symptoms, developed to organise the vast amount of information of materia medica (Kayne 2006).

Simillimum: The Homoeopathic medicine prescribed according to the Law of Similars that most clearly matches the symptoms of the patient and that produces the greatest benefit (Reichenberg-Ullman and Ullman 2000).

Succussion: The systematic and repeated shaking of a Homoeopathic medicine after each serial dilution (Reichenberg-Ullman and Ullman 2000).

CHAPTER ONE

INTRODUCTION

1.1 INTRODUCTION

In a study by Carroll *et al*. (2008) found most individuals will suffer from neck pain at some point during the course of their lives. The incidence of neck pain is growing at a greater rate than other spinal conditions (Picavet and Schouten 2003; Dennison and Leal 2011; Vincent *et al.* 2012). With that said, mechanical neck pain is a common complaint and is associated with headaches, limited range of motion and a myofascial component (Windsor 2004; Bennet 2007; Ge *et al.* 2011). Common allopathic medications used to conventionally treat musculoskeletal disorders are non-steroidal anti-inflammatory drugs (NSAIDs) or opioids. However, the chronicity of the complaint usually requires medication for a substantial length of time, which can lead to adverse drug reactions (Weiner and Ernst 2004). Therefore patients often pursue other forms of Complementary treatments to reduce pain and improve their quality of life when suffering with chronic mechanical neck pain (CMNP).

A form of treatment for mechanical neck pain is spinal manipulation, the effects of which may include pain relief, reduction in disability and an increase in the active range of movement (Lee *et al*. 1995; Tsolakis 2001; Gross *et al*. 2007; Miller *et al*. 2010). In addition to this, Kohlbeck *et al*. (2005) showed that medication-assisted manipulation appears to offer some patients increased improvement in pain and disability however further investigation is needed.

With the above in mind, Homoeopathy is a curative system of medicine as it restores the patient to health and balance, both mentally and physically (Eizayaga 1991). Homoeopathy is also considerably cheaper than conventional medicine, making it a desirable alternative to allopathic medication (Ullman 1991). The Tunbridge Wells Homeopathic Hospital conducted a survey in 2000, and musculoskeletal conditions were the second highest diagnostic group treated at the hospital, accounting for 13% of its patients (Clover 2000). According to De Schepper (2000) the pain and inflammation associated with musculoskeletal disorders, especially in cervical conditions, is dramatically reduced by Homoeopathic Simillimum. However Simillimum treatment has never been researched with regard to CMNP and neither has the combination of spinal manipulation and Homoeopathic Simillimum.

1.2 THE STATEMENT OF THE PROBLEM

The purpose and primary goal of this study was to investigate, via a randomised, double blinded, comparative, placebo controlled quantitative clinical trial, whether spinal manipulation and Homoeopathic Simillimum in combination are more effective than spinal manipulation and placebo in the treatment of CMNP.

1.3 AIMS, OBJECTIVES AND HYPOTHESES

The aim of this study was to determine if spinal manipulation and Homoeopathic Simillimum in combination are more effective than spinal manipulation alone in the treatment of CMNP. The specific objectives of this study were:

1.3.1 The first objective and hypothesis

1.3.1.1 The first objective

To compare spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by means of the Numerical Pain Rating Scale (NRS).

1.3.1.2 The first null hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show no greater reduction in pain on the NRS than the spinal manipulation and placebo group.

1.3.1.3 The first alternative hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show greater reduction in pain on the NRS than the spinal manipulation and placebo group.

1.3.2 The second objective and hypothesis

1.3.2.1 The second objective

To compare spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by means of the Canadian Memorial Chiropractic College (CMCC) Neck Disability Index (NDI) questionnaire.

1.3.2.2 The second null hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show no greater improvement on the CMCC NDI than the spinal manipulation and placebo group.

1.3.2.3 The second alternative hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show greater improvement on the CMCC NDI than the spinal manipulation and placebo group.

1.3.3 The third objective and hypothesis

1.3.3.1 The third objective

To compare spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by using an Algometer, to measure participants' pain threshold.

1.3.3.2 The third null hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show no greater reduction in pain on the Algometer than the spinal manipulation and placebo group.

1.3.3.3 The third alternative hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show greater reduction in pain on the Algometer than the spinal manipulation and placebo group.

1.3.4 The fourth objective and hypothesis

1.3.4.1 The fourth objective

To compare spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by using a cervical range of motion (CROM) Goniometer to measure cervical spine range of motion.

1.3.4.2 The fourth null hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show no greater improvement on the CROM-II Goniometer than the spinal manipulation and placebo group.

1.3.4.3 The fourth alternative hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show greater improvement on the CROM-II Goniometer than the spinal manipulation and placebo group.

1.4 RATIONALE OF THE STUDY

- Mechanical neck disorders are common as well as disabling, (Fejer, Kyvik and Hartvigsen 2006; Slabbert 2010; Muchna 2011) and a large section of health-care costs can be attributed to visits to health-care providers (Waalen and Waalen 1993; Linton, Hellsing and Hallden 1998; Skargren, Carlsson and Oberg 1998, Korthals-de Bos *et al.* 2003). If a combination of effective treatments can be administered over a shorter period of time, requiring fewer amounts of visits, costs can be curbed by patients. Furthermore, for maximum patient benefit, multiple treatment methods need to be investigated to see which

renders the most effective solution as well as to add to the body of literature (Korthals-de Bos *et al*. 2003; Kohlbeck *et al*. 2005).

- Giles and Müller (1999) show that spinal manipulation is the most effective method of treating spinal pain on its own. Furthermore the spinal manipulation has been shown to be an effective force necessary to facilitate the restoration of cervical movement (Schafer and Faye 1990). Manual therapies have individually proven their effectiveness within the realm of treatment of mechanical neck pain however the added benefit of a combination of multiple therapy types and comparison needs to be investigated further (Miller *et al*. 2010).

- A survey conducted by the Tunbridge Wells Homeopathic Hospital lists musculoskeletal as the second highest condition group treated, accounting for 13% of its patients surveyed (Clover 2000). According to De Schepper (2006) the pain and inflammation associated with musculoskeletal disorders especially in cervical conditions is dramatically reduced by Homoeopathic Simillimum as well as time taken for recovery and improvement was diminished and the prognosis was improved. In a study by Zenner and Metelmann (1992) Homoeopathic treatment using Traumeel®S for such conditions as arthosis, myogelosis, sprains, periarthropathia humeroscapularis, epicondylitis, tendovaginitis and others, showed that 78.6% of patients had complete and long-term relief from their complaints or definite long-term improvement when assessing the objective and subjective outcomes.

- In a systematic review by Hoving *et al*. (2004), reviewers found inconclusiveness of effects of manipulation and mobilization in combination with other conservative treatments. Investigation of combination therapies is necessary in multi-faceted conditions like mechanical neck pain such that maximum patient care is administered (Haldeman and Kohlbeck 2002; Dagenais *et al.* 2008). Therefore this study aims to determine if spinal manipulation and Homoeopathic Simillimum in combination are more effective than spinal manipulation and placebo in the treatment of CMNP.

1.5 DELIMITATIONS OF THE STUDY

The limitations of this study are those that could either not be controlled for or were inherent limitations based on the study design and therefore cognisance of these limitations need to be taken.

- The results of this study may not necessarily be applicable to all patients suffering from CMNP through the various stages of the disease process, and therefore generalizations to the condition would be limited.
- The Hawthorne effect (Mouton 1996) should be taken into account with respect to the subjective outcomes, which discusses the participants need to produce results that they believe the researcher wishes to see/hear.

1.6 ASSUMPTIONS OF THE STUDY

- Participants took the medication as prescribed.

- Participants adhered to instructions to abstain from any other treatment for the duration of the study.

1.7 DISCLAIMER

The researcher is a registered Chiropractor (Practise number: 004 000 044 1384 and Registration number: A11087) and was therefore able to conduct this study in terms of performing the spinal manipulation on the participants.

1.8 CONCLUSION OF THE CHAPTER AND WAY FORWARD IN THE DISSERTATION

This chapter has sketched the problem and its setting in order to provide a basis for an overview of the aims, objectives and rationale of this study. Chapter Two highlights the literature surrounding the problem and its setting with particular interest in CMNP, spinal manipulation and Homoeopathic Simillimum. Chapter Three describes the materials and methods used in this study, Chapter Four presents the results obtained and Chapter Five provides for a discussion of the results. Chapter Six draws the final conclusions and recommendations based on the subjective and objective outcomes of this study.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

This chapter investigates the literature related to CMNP, Homoeopathic medicine, spinal manipulation and the general treatment of musculoskeletal conditions of the cervical spine. The anatomy of the neck, as well as the biomechanics will be discussed in detail. Other aspects that will be addressed include the definition of CMNP, method of injury and clinical presentation. Varying treatment methods and their efficacy based on literature will be explored. This will function to illustrate existing treatment options that are available and will highlight the deficiency in the literature with respect to the management protocols of CMNP.

2.2 DISCUSSION OF THE RELATED ANATOMY

2.2.1 Bones of the cervical spine

According to Moore and Dalley (2006), the osseous structures of the cervical spine are made up of seven small vertebral bodies, which are the smallest movable vertebra of the spine. It begins at the base of the skull and ends where the thoracic spine begins. They are divided into atypical (C1 the atlas and C2 the axis) and typical (C3-C7) vertebrae (Bogduk 1999; Windsor *et al*. 2011). The atlas (C1) is ring shaped and does not have a body, with the axis (C2) having a large vertebral body, which contains the dens, that articulates with the atlas. The typical vertebrae (C3-C7) all have vertebral bodies, raised uncinate processes and spinous processes (Gatterman 1990;

Windsor *et al*. 2011).The spinous processes of C3-C6 are short and bifid whereas the spinous process of C7 is significantly longer (Moore and Dalley 2006; Standring 2008).

2.2.2 Joints of the cervical spine

Three different joint articulations exist in the cervical spine which includes zygapopyhseal, uncovertebral and craniovertebral joint articulations (Moore and Dalley 2006; Standrig 2008).

- Zygapopyhseal Joints: also known as facet joints are true diarthrodial joints of the vertebral arches (Moore and Dalley 2006). They are supported by articular cartilage, ligaments, a synovial capsule and muscles (Gatterman 2005; Standrig 2008).
- Uncovertebral Joints: These joints are found at the posterolateral and lateral borders of the interverterbral discs, between the uncinate processes of C3-C6 verterbral bodies and the verterbral bodies above them (Moore and Dalley 2006).
- Craniovertebral Joints: There are two cranioverterbral articulations namely the atlanto-occipital joint and the atlanto-axial articulation (Windsor *et al*. 2011). Atlanto-occipital articulation is between the superior articular facets of C1 and the occipital condyles of the occiput (Moore and Dalley 2006). The atlanto-axial joint has two articulations. The medial joint refers to the odontoid process of C2 and anterior arch of C1. The lateral joint is a gliding joint and refers to the articulation between the inferior facets of C1 and superior facets of C2 (Gatterman 2005; Moore and Dalley 2006; Windsor *et al*. 2011).

2.2.3 Ligaments of the cervical spine

Ligaments within the cervical spine are strong fibrous bands that hold the vertebrae together, they also aid in stabilising the spine, and protecting the discs (Gatterman 2005; Moore and Dalley 2006). There are three key ligaments of the cervical spine, namely: the ligamentum flavum, anterior longitudinal ligament (ALL), and posterior longitudinal ligament (PLL). Both the ALL and PLL are continuous bands that run from the top to the bottom of the spinal column along the vertebral bodies (Gatterman 2005; Standrig 2008) and prevent excessive movement of the vertebral bones. The ligamentum flavum attaches between the lamina of each vertebra. In between the vertebral bodies lie intervertebral discs (Moore and Dalley 2006) which serve as an articulation between adjacent vertebral bodies, unite them and allow for movement to take place at that motion segment (Gatterman 2005). The discs provide flexibility and curvatures to the vertebral column act as shock absorbers and provide strength and weight bearing abilities (Chaitow and Delany 2000; Moore and Dalley 2006). The anterior column consists of the ALL and the anterior two thirds of the vertebral bodies, the annulus fibrous, and the intervertebral discs (Moore and Dalley 2006). The middle column is composed of the PLL and the posterior one third of the vertebral bodies, the annulus fibrosus, and the intervertebral discs. The posterior column is made up of the posterior arches, including the pedicles, transverse processes, articulating facets, laminae, and spinous processes (Moore and Dalley 2006).

2.2.4 Muscles of the cervical spine

The main function of the neck muscles are to produce and guide movement, control posture and balance the head on the neck (Moore and Dalley 2006). The musculature

of the cervical spine can be classified as global muscles or local muscles (Middleditch and Oliver 2005). Local muscles attach directly to the vertebra and are responsible for intersegmental stability and must function independent of the global muscles (O'Sullivan, 2005). The global muscles are responsible for regional stability of the spine (Middleditch and Oliver 2005). The muscles of the neck may also be described as intrinsic (deep) muscles or extrinsic (superficial) muscles (Moore and Dalley 2006). Muscles in the neck are innervated by a high proportion of afferent fibres which makes them more sensitive to pain and changes in position (Bergmann, Peterson and Lawrence 1993). The sub-occipital area, which is the area below the occiput, is a common site for the attachment of neck muscles (Simons, Travell and Simons 1999). This area is therefore a common site of pain due to pulling of the affected muscles on the tenoperiosteal junction (where the tendon of a muscle attaches to the bone) which is a result of the muscle going into spasm (Middleditch and Oliver 2005). Some of the main muscles involved in the development of neck pain (mechanical neck pain in particular) are the trapezius, splenius, levator scapulae and posterior cervical muscles of the neck (Chaitow and Delany 2000).

Muscles are known to work as a channel through which the compensatory effects of the central nervous system are conducted (Liebenson 1996). If a joint is dysfunctional, a muscle or muscle group will react with a spasm or pain (Liebenson 1996; Middleditch and Oliver 2005). The reverse is also true in that if a muscle or group of muscles are affected, a joint may as a result become restricted (Liebenson 1996).

2.2.5 Nerve supply of the cervical spine

The cervical spine consists of eight pairs of spinal nerves that exit via the foramen (Moore and Dalley 2006). They are the largest at C2-C3 and the progressively decrease in size (Windsor *et al.* 2011). The fibrous capsules of the synovial facet joints are innervated by mechanoreceptors (type I, II, and III) (Windsor *et al.* 2011) and located in the deep capsular tissues and may be linked to proprioception of the cervical spine (Windsor 2004). The facet joints are innervated by both the ventral and dorsal rami (Moore and Dalley 2006). C0-C1 and C1-C2 joints are innervated by the ventral rami of the 1st and 2nd cervical spinal nerves, two branches of the 3rd cervical spinal nerve dorsal ramus innervate C2-C3 facet joint, while the remaining cervical facet joints (C3-C4 to C7-T1) are supplied by the dorsal rami medial branches one level above and below the joint (Haldeman 1992; Windsor 2004).

2.2.6 Biomechanics of the cervical spine

Understanding the biomechanical implications of the cervical spine is of importance to understanding the mechanism of injury to the neck (White and Panjabi 1990). The cervical spine is an area that consists of several joints (Moore and Dalley 2006) and can be divided into two anatomically and biomechanically distinct regions, the upper cervical spine, comprising C1 and C2, and the lower cervical spine, incorporating C3 to C7 (Haldeman 1992; Reid 1992). The cervical spine's range of motion is approximately 80 degrees to 90 degrees of flexion, 70 degrees of extension, 20 degrees to 45 degrees of lateral flexion, and up to 90 degrees of rotation to both sides (Swartz, Floyd and Cendoma 2005). In light of the significant range of motion in the cervical spine, the mobility compromises the amount of stability offered by the neck

(Moore and Dalley 2006). It is this feature that makes it prone to injury (Swartz, Floyd and Cendoma 2005).

2.3 CHRONIC MECHANICAL NECK PAIN

2.3.1 Definition of CMNP

Pain within the neck can be caused by abnormal stress and strain on the vertebral column and surrounding structures through poor posture, lifting and sitting habits (Bergmann, Peterson and Lawrence 1993). Gatterman (1998) and Bergmann, Peterson and Lawrence (1993) state that the most common cause of mechanical neck pain is zygophyseal joint locking and muscle strain.

The diagnosis of mechanical neck pain can be made according to the following criteria (Grieve 1988):

a) Local chronic cervical pain with or without arm pain.

b) Juxtaposition of hypo and hypermobile segments of the cervical spine due to spondylitic changes.

c) Asymmetrical neck pain that gets worse as the day progresses and is aggravated by driving, reading etc.

d) Unilateral occipital pain and neck pain.

e) Restricted and painful movements, especially rotation and lateral flexion to the painful side.

f) Prominent trigger points within Levator Scapulae muscle and upper and middle fibres of the Trapezius muscle.

2.3.2 Mechanism of injury of CMNP

According to Strasser (2004) the causes of CMNP include activities and events that influence cervical biomechanics such as extended sitting, repetitive movement, accidents, falls and blows to the body or head, normal aging and every day wear and tear.

The aetiology of mechanical neck pain is poorly understood and mostly multifactorial, including poor posture, depression, anxiety, neck strain and occupational or sporting activities (Binder 2007). Bergmann and Peterson (2002) state that any event or condition (e.g. incorrect posture, ageing, acute injury, congenital or developmental defects) which leads to altered joint mechanics or muscle structure or function, can result in mechanical neck pain.

Risk factors for mechanical neck pain include work that is physically demanding or of a repetitive static nature, those of lower socioeconomic standing, individuals with a history of previous neck trauma and those with co-morbid pathologies. It has also been shown that the incidence of neck pain increases with age and is more common among women (Côté, Cassidy and Carroll 2003).

2.3.3 Clinical features of CMNP

Patients that present with CMNP complain of neck pain, headaches, and limited range of motion. The pain is described as a dull aching discomfort in the posterior neck that may radiate to the shoulder or mid back region (Reid 1992; Windsor 2004).

Clinical features that often are associated with cervical facet pain include tenderness to palpation over the facets or paraspinal muscles, pain with extension and/or rotation, and absent neurological abnormalities (Windsor 2004). Schafer and Faye (1990) also include the presence of asymmetries or misalignments that are observed or palpated statically, abnormalities in range of motion detected through motion palpation, and special orthopaedic tests. Signs of cervical spondylosis, narrowing of the intervertebral foramina, osteophytes, and other degenerative changes are present equally in people with and without neck pain (Windsor 2004). A study by Bogduk and Marsland (1988) attempted to determine if the facet joints in patients without objective neurological signs were the primary source of their neck pain. Those with lower cervical spine pain underwent C5 and C6 medial branch blocks first (using Bupivacaine), if they did not find relief then the adjacent levels were blocked until the pain was relieved. Those that had upper neck pain underwent third occipital nerve blocks, and C3 and C4 if necessary. Fifteen out of twenty four patients had complete relief of their neck pain, and repeat blocks had the same effect. No clinical or radiological features corresponded with the positive responses. This finding suggests that facet joints in the cervical spine can be a significant source of neck pain.

2.3.4 Grading of CMNP

According to Binder (2007), most patients present with “non-specific neck pain” where the signs and symptoms have a postural or mechanical basis. According to Haldeman *et al.* (2008), the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Associated Disorders suggested the following classification system for neck pain:

Grade I: Neck pain with no or minor interference with daily activities

Grade II: Neck pain with major interference on activities of daily living

Grade III: Neck pain with neurological signs and symptoms

Grade IV: Neck pain due to structural pathology

2.3.5 Incidence and Prevalence of neck pain and CMNP

According to Picavet and Schouten (2003) the incidence of neck pain is increasing at a greater rate than other spine problems, gaining personal, social and health costs (Hoving *et al*. 2004). Most individuals will suffer neck pain at some time during the course of their lives (Carroll *et al.* 2008) and the literature has stated that non-steroidal anti-inflammatory drugs (NSAIDS) are the first line of treatment for most types of spinal pain (DiPalma and DiGregorio 1994; Dabbs and Lauretti 1995; Koes *et al.* 1997). According to Zell *et al.* (1989) a Homoeopathic alternative to NSAIDS is Traumeel®S (a commercially available Homoeopathic complex). Furthermore a study by Hepburn (2000) compared the relative efficacy of Traumeel®S against NSAIDS in the treatment of cervical facet syndrome and concluded that there was statistically no difference between the two therapies and therefore it can be concluded that Traumeel®S is a valid alternative to NSAIDS. Spinal manipulation has been shown to have fewer side effects and be more effective than conventional NSAIDS (Dabbs and Lauretti 1995;

Giles and Müller 1999). Therefore this study aims to determine if spinal manipulation and Homoeopathic Simillimum in combination are more effective than spinal manipulation and placebo in the treatment of CMNP.

2.3.6 Treatment options for CMNP

At present, there are varying types of treatment protocols for managing CMNP (Windsor 2004). According to the literature non-steroidal anti-inflammatory drugs (NSAID's) is the first line of conventional treatment for many types of pain, including that of spinal origin (DiPalma and DiGregorio 1994; Dabbs and Lauretti 1995; Koes *et al.* 1997). Other treatment alternatives include other forms of manual therapy including mobilisation, ischaemic compression, dry needling, muscle energy techniques, soft tissue therapy and stretching. Further and more invasive treatment options include ultra-sound therapy; inter-articular facet joint injection; medial branch blocks; percutaneous radiofrequency neurotomy; and surgical intervention such as fusion (Alvarez and Rockwell 2002; Windsor 2004; Rickards 2006; Penas *et al*. 2007; Yap 2007).

Physical modalities and electrical modalities such as Interferential Current, ultrasound and transcutaneous electrical therapy are generally used as supplementary adjuncts, as they aid in controlling muscle pain and spasm (Yap 2007). Spinal manipulation has also proven to aid in myofascial release (Mense, Simmons and Russell 2000; Hong 2006).

The effectiveness of these aforementioned treatment protocols is not fully recognised even though many different methods have been stated in the literature (Esenyel *et al*. 2007; Annaswamy *et al.* 2011).

2.4 HOMOEOPATHY IN CMNP

2.4.1 Homoeopathy Theory

The word Homoeopathy is derived from '*homoio',* which means similar, and '*pathos'*, meaning suffering (Gray, 2000). Therefore the word lends itself to the Law of Cure, as laid down by the German physician and founder of Homoeopathy, Samuel Hahnemann (Vithoulkas 1987). Hahnemann authored this defining principle known as '*Similia Similibus curanter'* or *'Like Cures Like'* (Mathur, 1998), and it is on this which prescriptions are based (Swayne, 1998).

The Simillimum is a single-remedy Homoeopathic prescription administered at a time to the patient; the purpose of which is to improve the patient's condition, if not cure the present disorder. '*Like Cures Like'* is based on the principle that a substance, once ingested, produces certain symptoms in healthy people, analogous to that which it can cure in the sick (De Schepper, 2001). The medicine is then selected for its "similarity" to the totality (physical and psychological symptoms) of a person's presenting complaint (Ullman, 1991). These Simillimum remedies are used to stimulate the innate healing response of the human being by influencing the energetic, live giving force of a person known as the Vital Force (Carlston and Micozzi 2003).

2.4.1.1 Vital Force

The entire concept of health and healing, according to Homoeopathy, is based on the life giving principle of the Vital Force. This is the energy impulse or influence within the body. The role of Homoeopathy is to reduce the patient's susceptibility to external and

internal factors, by strengthening the Vital Force. This is done through administering Homoeopathic remedies, which in turn stimulates the Vital Force (De Schepper 2006).

2.4.1.2 The Law of Similars

This is the principle which states that a substance, which produces certain symptoms in healthy people, can cure the same symptoms in those who are ill. In order to cure gently, rapidly and permanently in each case, one must choose that medicine which can arouse a similar suffering to the one it is supposed to cure (De Schepper 2006).

2.4.1.3 Infinitesimal Dose

Hahnemann noted that ordinary doses of medicines acted much too powerfully, and caused great aggravation of symptoms before the cure took place (Cook 2000). He then by degrees reduced his doses until he could get the curative effect without aggravating. The infinitesimal dose is based on the idea that much smaller doses of a drug are needed to bring about a reaction in the body, as Homoeopathy is based on the paradigm of healing that the patient brings about the cure after remedies stimulate the patient's curative powers.

Homoeopathic remedies are prepared by a controlled process of successive dilutions alternating with succussions (shaking in a prescribed manner). These may be continued to the point where there are no more molecules of the original substance in the solution. Each stage of dilution and succussion produces a different Homoeopathic potency. Low potencies are lesser dilutions, and higher potencies are greater dilutions (Cook 2000). The Arndt-Schultz law states that small doses of drugs encourage life, large doses of drugs impede life activity, and very large doses of drugs destroy life. Kotschau repeated this work and produced the biphasic response curve, which

effectively validates the law of the infinitesimal dose (Wilcher 1996). The potency is selected according to the clarity of the case and the state of the patient's vital force (De Schepper 2006).

2.4.1.4 Totality of Symptoms

The totality of symptoms is a comprehensive picture of the whole person (Reichenberg-Ullman and Ullman 2000). The role of the Homoeopath is to find the totality of symptoms through careful, thorough case taking. This involves taking into account mental, emotional and physical states of the patient in their current state (De Schepper 2006).

2.4.1.5 Homoeopathic Simillimum

Simillimum arises from the fundamental principle of Homoeopathy, which states that '*Like Cure Like'* (Vithoulkas 1986). The physician must find the remedy that is most similar to the totality of symptoms. This remedy is known as the Simillimum and should cover the case on all levels; mental, emotional and physical. Homoeopathic provings are conducted to determine the symptoms elicited by various substances on healthy people. Treating with Homoeopathic Simillimum is the basis of classical Homoeopathy. This also brings in the classical Homoeopathic concept of the administration of single, simple medicines, as emphasised by Hahnemann in Aphorism 273 (O"Reilly 2001: 246): *"In no case is it necessary to employ more than a single simple medicinal substance at one time with a patient."*

According to Swayne (1998) the Homoeopathic approach involves an exceptionally complete and detailed description of the patient, the illness and its evolution. This is because the Homoeopath inevitably seeks to select a single remedy out of a vast

number of potential Homoeopathic medicines (Carlston and Micozzi 2003). Furthermore, there are over 3000 Homoeopathic medicines with specific clinical indications and with a repertoire of multifarious symptomatology (Swayne, 1998).

In recent times, many Homoeopathic treatments are done in a complex or combination form however Vithoulkas (1980) states that remedies were proven singly in separate, carefully conducted provings and there is no literature or research to ascertain how they would act on a person in a group or complex. Likewise Hahnemann (2011) stated in Aphorisms 274, 286 and 287, that it is wrong to prescribe complexes when simple means will suffice, thus advocating Simillimum prescription as the ultimate and only means of prescription. In light of all the above, as pertaining to Homoeopathic Simillimum treatment, it must be emphasized that there are various methods of prescribing for patients (Bloch 2002). Regardless of the methodology used, the ultimate aim of the Homoeopathic enquiry and analysis is to arrive at the Simillimum (Bloch 2002).

A detailed case history is vital to arrive at the Simillimum as each person has a characteristic or unique symptom or presentation, which has to be identified and differentiated from common symptoms associated with the condition. A detailed case history was taken for every participant in this study and a Simillimum was selected. The researcher was unaware of which participants received Simillimum and which received placebo in order to be a fully blinded.

2.4.1.6 Placebo Effect

Placebo refers to a medical treatment, which has no specific medicinal activity and is just a ‘blank’. Placebo effect dates back to Hippocrates who observed that certain gravely ill people seemed to recover through sheer “contentment”. Placebo accounts

much of the benefit people get from anti-depressants and all the benefit from antibiotics taken for viral infections, which are not affected by the drugs (Grady 2004).

For the purpose of this trial, placebo was used as a control group, to determine the relative effectiveness of the treatment groups. Therefore all participants received medicines which looked, smelled and tasted the same and in this way one can see if it was truly the Homoeopathic medicines which caused a change within the participant or just the concept of taking in a medicine.

2.4.2 Homoeopathy in Musculoskeletal conditions

According to Townhill (2009), common medications used to conventionally treat musculoskeletal disorders such as arthritic pain are non-steroidal anti-inflammatory drugs (NSAID's) or analgesics. However, whilst these drugs may mask the pain experienced by patients, the chronicity of the complaint usually requires medication for a long period of time, which often leads to antagonistic drug reactions (Weiner and Ernst 2004). Thus patients often seek other forms of Complementary and Alternative treatments to improve their quality of life. This move to alternative treatment is illustrated by the patient benefit survey, conducted at the Department of Homeopathic Medicine in Liverpool, where the largest diagnostic group treated were for musculoskeletal conditions, representing 261 of the 1100 completed questionnaires (23.7%) (Richardson 2001). A similar survey conducted by the Tunbridge Wells Homeopathic Hospital also lists musculoskeletal conditions as the second highest diagnostic group treated, accounting for 13% of its patients surveyed (Clover 2000).

Soeken (2004) who examines systematic reviews of Complementary therapies for arthritis related pain cites one review of Homoeopathy and rheumatic disease by Jonas, Linde & Ramirez (2000). This review included six trials using either random assignment or double-blinding. Three trials were on rheumatoid arthritis (RA) and another three trials on osteoarthritis (OA), fibromyalgia, and myalgia. Soeken (2004) states that the meta-analysis of these trials shows Homoeopathy to be twice as effective as placebo although the number of studies is small to reach a definitive conclusion.

Long & Ernst (2001) conducted a systematic review on the Homoeopathic treatment of OA. In this, four randomised controlled trials met the inclusion criteria and were described to be of high average methodological quality, with two of the studies giving a positive result in the efficacy of Homoeopathic treatment in OA. Overall this review concluded that the research data shows Homoeopathy to be more effective than placebo, but that the small number of studies again prevents firm conclusions being drawn (Weiner and Ernst 2004).

Gibson *et al.* (1980) conducted a double-blind randomised controlled trial that compared 23 people with RA on anti-inflammatory drugs and individualised Homoeopathic treatment to 23 people with RA on anti-inflammatory drugs and placebo for a three month period. This research found that there was a significant improvement in subjective pain, articular index, stiffness and grip strength in those patients receiving Homoeopathic remedies (Gibson *et al.* 1980) compared to the placebo group.

Bell *et al*. (2004) used individualised Homoeopathy in a double-blind randomised controlled trial to assess the efficacy of Homoeopathic treatment for fibromyalgia. Bell *et al.* (2004: 577) state, “Fifty three people completed the treatment protocol.

Participants on active treatment showed significantly greater improvements in tender point count and tender point pain, quality of life, global health and a trend towards less depression compared with those on placebo".

Fischer (1986) conducted a double-blind, placebo controlled trial using one of three remedies (*Arnica montana, Bryonia alba or Rhus toxidendrum*) in a 6c potency to treat the symptoms of fibrositis, with measurements on pain, the number of tender spots and sleep. These remedies were selected as they were thought to cover the symptom picture of fibrositis in most cases. Each patient was also scored on how well they fitted the prescribed remedy. Fischer (1986) concluded that Homoeopathy produced a statistically significant improvement, but only when the prescribed remedy was well indicated.

Furthermore a Homoeopathic alternative to NSAID's is Traumeel®S, it fulfils all the criteria for a locally acting therapeutic medication (Zell *et al.* 1989). In a study by Zenner and Metelmann (1992) Homoeopathic treatment using Traumeel®S for various musculoskeletal conditions showed that 78.6% of patients had complete and long-term relief from complaints.

As one can see from the above literature, Homoeopathy is being used frequently in musculoskeletal conditions, however there is still not much literature on the efficacy of Homoeopathy in neck pain, and CMNP in specific.

2.5 CHIROPRACTIC IN CMNP

2.5.1 Chiropractic theory

Haldeman (1992:137) defines spinal manipulative therapy as “all procedures where the hands are used to mobilise, adjust, stimulate or otherwise influence the spinal and paraspinal tissues with the aim of influencing the patient’s health”. Chiropractors seek out areas in the cervical spine that have decreased movement that are associated with neck pain using palpation. Once found, the affected joint/s are treated via manipulation to release the joint and restore movement. The chiropractic adjustment is an effective way of providing the force necessary to facilitate the restoration of this movement (Schafer and Faye 1990). Cassidy *et al.* (1992) describes the adjustment as a high velocity, low amplitude thrust directed beyond the passive range of motion of the spine and associated with an audible ‘’crack‟ caused by the cavitation of the underlying facet joint. Sandoz (1976) states that a chiropractic adjustment is a passive manual manoeuvre during which the three-joint-complex (intervertebral disc and facet joints) is suddenly carried beyond the normal physiological range of movement without exceeding the boundaries of anatomical integrity. The term “manipulation‟ can be used ambiguously in manual therapy to mean passive movement of any kind (Bourdillon and Day 1992). For the purpose of this study manipulation will be defined as articular manipulation characterized by a dynamic thrust of high velocity, low amplitude and specific direction over specific contact points located through motion palpation (Bergmann and Peterson 2002).

The application of manipulative therapy is based on the evaluation and integrity of the neuromuscular skeletal system and the presence or absence of joint dysfunction (Bergmann and Peterson 2002). Bergmann and Peterson (2002) modified the

acronym PARTS from Bourdillon and Day (1992) to identify five diagnostic criteria for the identification of joint dysfunction. These five signs and symptoms are indicative of joint dysfunction:

P – Pain and tenderness produced by palpation of the bony and soft tissue elements.

A – Localized or at multiple levels, noted through observation, static palpation or x-rays.

R – Range of motion which included active, passive and accessory movement felt through motion palpation or x-rays.

T – Tone, texture and temperature abnormalities, soft tissue changes observed through palpation or instrumentation.

S – Special tests, e.g. Kemps test.

The therapeutic effect of manipulation, as explained by Curl (1994), works through two mechanisms. Firstly, the mechanical effect which causes mechanoreceptor stimulation, muscle spindle stretching and the breaking down of joint adhesions which results in an increase in active as well as passive joint motion. Secondly, manipulation causes stimulation of the autonomic nervous system resulting in reflex inhibition of pain and muscle hypertonicity.

The effectiveness of the manipulation is hypothesised to work according to several different theories (Bergmann and Peterson 2002):

a) Mechanical

The high velocity low amplitude manipulation causes rapid separation of two joint surfaces (cavitation) resulting in stretching of the periarticular tissues, thereby

releasing intra- and extra-articular adhesions. The cavitation also stimulates joint nociceptors and mechanoreceptors which in turn stimulate the golgi tendon organs, resulting in somatic afferent receptor activity. The combination of these events rather than the cavitation is what makes manipulation effective in breaking the pain cycle, resulting in a decrease in pain and muscle spasm and an increase in joint mobility and soft tissue flexibility (Bergmann and Peterson 2002). Manipulation maintains tissue extensibility by stimulating the repair of the articular soft tissue and cartilage as well as by preventing excessive fibrosis formation, atrophy and degeneration.

b) Analgesic

It has been hypothesised that the force of manipulation activates both the deep and superficial mechanoreceptors, proprioceptors and nociceptors, resulting in strong afferent impulses to the spinal cord, inhibiting central pain transmission. Korr (1986) theorized that manipulation also releases endogenous opioids (enkephalis and endorphins) which decreased pain sensation. The placebo effect should also be considered as a consultation with a skilled and concerned practitioner may have an analgesic effect.

c) Neurobiological

Manipulation has the ability to affect both local and distant somatic and visceral tissues by restoring normal joint mechanics resulting in cessation of altered neurogenic reflexes associated with joint dysfunction (Bergmann and Peterson 2002).

d) Circulatory

There are two theories surrounding the effects of manipulation on circulation. Firstly, that segmental vasoconstriction can occur due to the joint dysfunction altering the

sympathetic tone of that segment, thereby manipulation would remove the irritation and improve the circulation. Secondly, the efficacy of the circulatory system depends on the integrity of the musculoskeletal system as the venous and lymph systems are dependent on body movement and muscular pumping actions. Leach (1994) attributes the greatest clinical effect of manipulative therapy not only to the pure mechanical effect but also to the increased circulation within the joint.

2.5.2 Spinal manipulative therapy for neck pain

Cassidy *et al*. (1992) produced a study in which 100 patients were either given a spinal manipulation or mobilisation technique to treat mechanical neck pain. It was determined that a single manipulation is more effective than mobilisation in decreasing pain in patients with mechanical neck pain, although both treatments did increase range of motion in the neck to similar degrees. A study by Vernon *et al.* (1990) examined the effect of cervical manipulation versus mobilisation on pressure pain threshold in the cervical spine measured five minutes after the intervention. Of the two methods used, manipulation produced significantly higher increases in the pressure pain threshold. Yeomans (1992) assessed the cervical intersegmental mobility before and after manipulative therapy. Two systems of manipulation were utilised in 58 case studies. The results revealed that the post-manipulative mobility is significantly greater than the pre-manipulative data with the exception of the C1 segment of both male and female treatment groups.

In a pilot study (n = 50) by Cassidy *et al*. (1992), assessing the immediate effect of cervical spine manipulation in the treatment of MNP, showed that all planes of range of motion increased and that pain scores had decreased post-treatment. A study (n = 36) by Pikula (1999) on the effect of manipulation in acute unilateral neck pain,

revealed that following a single manipulation ipsilateral to the neck pain, increased ROM and decreased pain intensity. Van Schalkwyk and Parkin-Smith (2000) had similar results in terms of increased range of motion and decreased pain in their study (n = 30) on the efficacy of two different types of manipulation (cervical rotary and lateral break) in the treatment of mechanical neck pain. Both types of manipulation were equally effective. Whittingham and Nilsson (2001) conducted a double-blind randomised controlled trial (n = 105) to study the effect of spinal manipulation on cervical ROM. The authors concluded that after receiving spinal manipulation, active range of motion in the cervical spine increased significantly ($p < 0.0006$).

Vernon *et al*. (1990), in a pilot study (n = 9*)*, showed cervical spinal manipulation to immediately increase pain pressure threshold levels, while a review of the literature by Hurwitz *et al.* (2008), revealed that patients with sub-acute and chronic neck pain showed an improvement in the visual analogue scale when SMT was compared to muscle relaxants or “usual medical care”. Giles and Muller (1999) conducted a prospective, independently assessed pre-intervention and post-intervention pilot study comparing spinal manipulation, acupuncture and non-steroidal anti-inflammatory drugs in the treatment of chronic spinal pain syndromes (neck and back). The results concluded that the manipulation group (n = 36) (after a treatment period of 4 weeks) was the only group that showed a statistically significant improvement (p = < 0.001). More specifically, patients who received neck manipulations had a 25% improvement on the NDI scores and pain reduction according to the visual analogue scale, was 33% for the neck. These studies advocated the use of SMT in the treatment of CMNP. In a retrospective, outcome-based analysis of patients with CMNP, McMorland and Suter (2000) found that, patients under chiropractic management had a statistical significant reduction in their pain-related disability after treatment. These studies advocated the

use of SMT in the treatment of CMNP however there is a need for future research studies as most of these studies were pilot studies with small sample sizes with no placebo group.

Schafer and Faye (1990) hypothesise that SMT restores movement to a fixated joint through the application of a high velocity low amplitude thrust. The sudden stretch of the muscle spindles relaxes the paravertebral musculature and an impulse is sent into the central nervous system (CNS). This has a normalizing effect on the CNS reflexes that maintain abnormal muscle tone. Clinically there will be an increase in range of motion and a decrease in muscle spasm (Lewit 1991).

Manipulation forms the foundation of the chiropractic profession (Bergmann and Peterson 2002). High velocity, low amplitude manipulations are applied to dysfunctional joints. These dysfunctional joints are identified through a diagnostic criteria outlined by Bergmann and Peterson (2002). Studies have shown manipulation to be effective in decreasing pain and increasing range of motion (Cassidy *et al*. 1992; Giles and Muller 1999; Van Schalkwyk and Parkin-Smith 2000; Whittingham and Nilsson 2001) in patients with cervical spine pain. However, due to several contra-indications to high velocity low amplitude manipulation it is important to assess the patient thoroughly in order to evaluate if the patient will benefit from this form of treatment.

2.6 COMBINATION THERAPY IN CMNP

Mechanical neck pain is a common and costly clinical complaint that requires a multi-disciplinary approach (Côté, Cassidy and Carroll 1998; Ferrari and Russell 2003;

Gross *et al*. 2007; Pena 2007). Many practitioners believe that solo-care approaches do not represent best treatment outcomes for patients and therefore combination treatments need to be used (Haldeman and Kohlbeck 2002; Kohlbeck *et al*. 2005; Dagenais *et al*. 2008; Miller *et al*. 2010). Various treatment options exist in both fields of manual and pharmacological therapy (Gross *et al*. 2002; Ferrari and Russell, 2003). Traditional pharmacological treatment involves the use of non-steroidal anti-inflammatory drugs (NSAIDs) or analgesics (Gross *et al*. 2002; Ferrari and Russell 2003). Manual therapy includes manipulation, mobilisation, massage, exercise therapy and the use of modalities (Gross *et al*. 2002; Miller *et al*. 2010).

Various studies have shown the effects of combination therapies in the treatment of neck pain to be superior in pain relief (Hurwitz *et al*. 2008) In a study by Hoving *et al*. (2002) on physical therapy, manual therapy and care by a general practitioner for patients with neck pain, results showed that manual therapies scored consistently in comparison to physical or medicinal treatment. Therefore our aim with this study is to determine if the combination of Homoeopathic Simillimum and spinal manipulation will yield a positive result over physical or pharmacological treatment independently.

2.7 RELIABILITY OF SUBJECTIVE/OBJECTIVE CLINICAL MEASURES USED IN THIS STUDY

2.7.1 Introduction

Assessment in the form of subjective and objective measures was utilised. This includes the use of NRS, CMCC NDI, Algometer and CROM-II Goniometer.

2.7.2 Numerical Pain Rating Scale (Appendix E)

This is a scale in which the patient is asked to rate their perceived level of pain intensity on a numerical scale from zero to ten, with zero being no pain and ten excruciating pain. The patient is asked to give two values a) when pain is at its worst and b) when pain is at its least. The average of these two figures indicated the average pain intensity experienced by the patient. The scale's practicality and validity was shown by Jensen, Karoly and Braver (1986) by comparing it to six other methods of assessing clinical pain intensity. Cleland *et al.* (2008) states that the NRS exhibits fair to 34 moderate test-retest reliability in patients with MNP. According to Mannion *et al.* (2007), the NRS is the preferable tool in the assessment of pain intensity when compared to traditional types of visual analogue scales. This is in keeping with Jensen, Karoly and Braver (1986), who stated that the NRS is superior and simple to administer in either a verbal or written form and the scale does not appear to be associated with age.

2.7.3 CMCC Neck Disability Index (Appendix F)

This index was designed by Vernon and Mior (1991) from the CMCC to fill the need for a measurement tool to measure the effects of neck pain on activities of daily living (Liebenson 1996). A study done by Vernon and Moir (1991) together with Cleland *et al.* (2008) showed that the NDI has a high degree of validity, test-retest reliability and internal consistency. It consists of a questionnaire containing ten sections, each consisting of six options. On completion, scores of each section are added together and multiplied by two in order to get a percentage. This percentage indicates the patient's disability measured at different times during the course of treatment.

2.7.4 Algometer (Appendix G)

In a study by Vaughan, Mclaughlin and Gosling (2007), a total of 300 measurements were collected from an Algometer as it was applied to a force plate at five different pressures. The Algometer was found to be acceptable and consistent. For that reason, Algometer readings were taken by applying the device to the lateral joint complex to assess the participant's pain threshold at the joint (Vaughan, Mclaughlin and Gosling 2007). The Algometer that was utilised by Vaughan, Mclaughlin and Gosling, was the Wagner FDK20 Force Dial (Wagner Instruments, P.O.Box 1217, Greenwich, CT, 06836, USA).

According to Livingston, Bernadi and Carroll (1998), an Algometer is designed to quantify and document levels of tenderness via pressure threshold measurement and pain sensitivity via pain tolerance measurement. In a study done by Fischer (1997), he demonstrated excellent reliability and reproducibility with pressure threshold measurement. Therefore, according to Livingston algometry may be used for objective medico-legal documentation of pain intensity (Livingston, Bernadi and Carroll 1998).

The procedure for taking these measurements was followed as outlined by Livingston, Bernadi and Carroll (1998):

a) Patient was positioned in a relaxed seated position and the area being tested was exposed.

b) The procedure was explained to patient and the patient was asked to say "yes" at the onset of pain.

c) Before starting the screen was cleared to ensure a reading of zero.

d) The area of joint dysfunction was located through palpation and was documented for further testing purposes.

e) The applicator tip was placed on the articular pillar to be tested.

f) Force was applied perpendicular to the skin's surface at a gradually increasing rate until patient acknowledged the onset of pain. At that moment a reading was taken and recorded on Appendix G.

The Algometer used in this clinical trial was the Algometer Commander of JTech Medical Industries.

2.7.5 CROM-II Goniometer (Appendix H)

The Performance Attained Associates Model CROM (3600 Labore Road, Suite 6, St. Paul, MN 55110-41144) is an instrument used to measure active cervical ROM: extension, flexion, right and left rotation. According to Youdas (1991), the CROM showed a high degree of reliability when it was compared to two other types of Goniometers. They reported that good inter- and intra- examiner reliability occurred and that the measurement procedure did not seem to affect the patient's condition. A study done by Tousignant, Duclos and Laflecche (2002), found the CROM to have good validity in terms of measuring flexion, extension and lateral flexion in patients with neck pain.

Procedure as described by Rheault *et al*. (1992):

a) CROM instrument was placed on the bridge of the nose and ears of the patient and fastened at the back of the patient's head with Velcro straps.

b) The patient's chair was then positioned in such a way that the magnetic field was zeroed on the dial meter for the rotational measurement.

c) The correct patient posture was to sit erect with lower back against backrest, mid-back away from the chair, arms hanging freely at the side and feet together on the floor.

d) Calibrated dials to zero before measuring active cervical flexion, extension, right and left rotation, and right and left lateral flexion.

e) Each motion was measured twice and an average reading was recorded.

f) Cervical range of motion was performed in the same order for each patient i.e. flexion, extension, left lateral flexion, right lateral flexion, left rotation, and right rotation.

g) The readings were recorded on Appendix H.

2.8 CONCLUSION

As stated by Haldeman and Kohlbeck in 2002 and Dagenais *et al.* in 2008 an investigation of a combination of therapies is necessary in multi-faceted conditions like mechanical neck pain. As seen above chiropractic treatment has shown to decrease the symptoms of CMNP and according to De Schepper (2000) the pain and inflammation associated with musculoskeletal disorders, especially in cervical conditions, is dramatically reduced by administering a Homoeopathic Simillimum.

However Simillimum treatment has never been researched in regards to this condition and thus it is imperative to undertake this research to grow the field of Homoeopathy as well as a combination of Complementary treatments. At present, literature has not

shown the effectiveness of combination therapy of a chiropractic adjustment in combination with Simillimum versus chiropractic adjustment with placebo in the treatment of CMNP. A study of this nature may be beneficial as a treatment option for the above condition and will add to the body of literature available. Therefore, this study aimed to test this hypothesis by comparing the relative effectiveness of spinal manipulation with the concurrent administration of Simillimum in patients with CMNP and spinal manipulation along with placebo.

CHAPTER THREE

METHODOLOGY

3.1 INTRODUCTION

The aim of this study was to determine if spinal manipulation and Homoeopathic Simillimum in combination are more effective than spinal manipulation and placebo in the treatment of CMNP. This research methodology was approved by Durban University of Technology (DUT) Institutional Research Ethics Committee (IREC) (Appendix K).

3.2 STUDY DESIGN

This research study was designed in the form of a double-blinded, quantitative, randomised, comparative clinical trial (Mouton 1996).

3.3 PARTICIPANTS

3.3.1 Advertising for participant recruitment

Numerous methods of recruiting participants were employed. Advertisements and posters were placed on the notice boards of the DUT Homoeopathic Clinic (Appendix A), around the DUT Berea and City campuses, local universities, gyms, libraries, the local shopping complexes, the local newspaper (for which permission was received) and direct contact with participants. The researcher conducted a telephonic interview to assess the eligibility of the participant for the study in question.

3.3.2 Sampling

Participants were recruited through convenience sampling, the advantage of this method was that it was inexpensive and executed quickly and the disadvantages are that it can lead naturally to sampling error and bias (Ally 2013). The study population included all persons between the ages of 18 and 55 with neck pain living in the Greater Durban area. The sample size was 30 consenting participants, 15 in each of the treatment groups. The sample was recommended by the statistician and reflects the minimum sample required for effects to be noticeable. Each participant was placed randomly, by means of a randomisation table (Appendix J), into one of the two treatment groups to ensure homogeneity in the study (Mouton 1996).

3.3.3 Inclusion and Exclusion criteria

These criteria were chosen to maintain homogeneity (Mouton 1996) within the study population.

Inclusion criteria:

- Only participants between the ages of 18 - 55 years were recruited into the study. This included males and females from all ethnic groups. The age group was a prerequisite to reduce cases that may be caused by degenerative disc or joint disease (Esenyel, Caglar and Aldemir 2000).
- Only cases of CMNP were accepted. This is defined as the onset being longer than two weeks before the start of the trial (Haneline 2005).

- Participants on analgesics were considered after a washout period of three days (Schafer and Faye 1990).
- Only participants who displayed signs and symptoms of mechanical neck pain were recruited into the study. This according to (Schafer and Faye 1990) includes:

    1. Pain or tenderness over osseous and soft tissue areas.

    2. Abnormal range of motion detected actively and passively through motion palpation.

    3. Positive special orthopaedic tests specific to the cervical region of the spine and associated structures (Appendix D).

Exclusion Criteria:

- Participants were excluded if they have neck pain for less than 2 weeks.
- If the participant showed any evidence of the presence of absolute contraindications such as bone infection or spinal tumours (Kirkaldy – Willis 1992).
- If the participant had a history of Rheumatoid Arthritis or any other arthritides.
- Presence of a progressive systemic disease such as TB, Collagen disorders, Multiple Sclerosis, HIV/AIDS infection or any other autoimmune disorders.
- If the participant had received any other form of treatment for neck pain during the duration of the study.

Immediate family members and close friends of the researcher were not accepted into the study to limit investigator bias and the placebo effect (Ally 2013).

3.4 ETHICAL CONSIDERATIONS

The full research procedure was explained to the participant and a Letter of Information and consent (Appendix B) was filled out and all questions were answered. The dosage and instructions on how to take the medication and possible treatment outcomes were also explained to the participants. Both groups of participants received spinal manipulation treatment for the condition however those in the placebo group were offered further Homoeopathic treatment at the end of the study. Furthermore, all information was kept confidential at all times. Participants were issued with a number, meaning that no names or personal identifiers were recorded on any data collected. The DUT IREC procedure for handling and reporting was followed. All medication and consultations was provided free of charge for the duration of the study. The study was cleared by the DUT IREC before commencement (Appendix K).

3.5 CLINICAL ASSESSMENT PROCEDURE

This study was conducted in two phases:

3.5.1 Phase one: the introductory stage

After the telephonic interview with the researcher, a verbal explanation of the study was given to the participant by the researcher at the consultation and any queries regarding the study were addressed. If the participant met the inclusion criteria, an appointment was made at the DUT Homoeopathic Clinic.

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Participants were given a letter of information and consent (Appendix B), providing a detailed explanation on what the research entailed. It was also be explained to them verbally. The participants were also given the opportunity to ask questions and made aware that they may withdraw from the study at any time without prejudicing any further treatment

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A full case history, a physical examination (including vital signs) and a cervical regional examination (Appendix C and D) were then performed.

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The eligible participants were then randomly allocated via a randomisation table (Appendix J) into one of the two treatment groups, group A (spinal manipulation and Simillimum) or group B (spinal manipulation and placebo). The study was blinded to the researcher, and therefore the allocation was done by Dr M Maharaj, an impartial party and the dispensing of medicines was conducted by the specialist technician at the DUT Homoeopathy Day clinic.

3.5.2 Phase two: The test readings and treatment

Following that, the participants were then asked to fill in the Subjective data; which was the NRS for pain and the CMCC NDI (Appendix E and F). The objective data; namely the Algometer and CROM-II Goniometer (Appendix G and H) were then used to assess to the patients pain and range of motion.

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Group A participants were administered given spinal manipulation by the researcher (a qualified and registered chiropractor) as well as the Homoeopathic Simillimum treatment. Group B participants were administered spinal manipulation, by the researcher, and a placebo Homoeopathic medicine. Following the treatment, the next two consultations were booked on day three and seven according to recommendations of Hepburn (2000) and Harpham (2005).

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The first follow-up (consultation two) was conducted three days after the participant's first treatment (Hepburn 2000; Harpham 2005). During this consult, the patient was asked to perceptively describe their progress, inform the researcher of any new symptoms, or loss of a previous symptom. The participant's vital signs were once again examined as well as the cervical orthopaedic regional examination. The subjective and objective tests were then carried out to assess any improvement or worsening of the participants symptoms. Within the Simillimum Group (Group A), the researcher had the opportunity to change the remedy if the need arose.

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In the final consultation (consultation three) five days after the initial treatment, participants were asked to describe their progress and note any new or old symptomatology. The vital signs and cervical orthopaedic testing were once again conducted and subsequently the subjective and objective tests carried out and the data collected.

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The participant was then free to leave as all treatment and data had been collected and was to be analysed. Participants in group B were then also offered Homoeopathic Simillimum treatment (as they had been in the placebo group).

3.6 MEASUREMENT TOOLS

The study incorporated both subjective and objective data mentioned below:

3.6.1 Subjective data

1. NRS (Appendix E) was used to assess the amount of pain that the patient was experiencing and to note if there was a decline in the pain. This subjective pain scale is known as the gold standard with respect to its validity and reliability (Liggins 1982).
2. The CMCC NDI (Appendix F) is a well-researched questionnaire and according to Howel (2011) and Schellingerhout *et al.* (2011) the NDI has shown to have adequate internal consistency, validity and responsiveness. The NDI questionnaire consists of 10 items concerning pain and activities. Each item is scored out of a score of five (with the no disability response given a score of zero). The total score for the questionnaire is out of 50. Higher scores in the questionnaire, represent greater disability (Vernon 2008). At every consult prior to treatment each participant will be allocated a questionnaire to complete. Their progress was monitored over the period of the study.

3.6.2 Objective data

1. Algometer (Appendix G) is a measurement tool that measures pain threshold in an area of tenderness (Fischer 1997). Fischer (1997) stated in his study that pressure threshold measurements with an Algometer to have good reliability and reproducibility. This is supported by Potter, McCarthy and Oldham (2006) who, in their study, found the Algometer to be reliable and valid in measuring a patient's pain. The Algometer that was used was manufactured by Wagner instruments: P.O Box 1217, Greenwich T 06836 USA. The Algometer readings were taken by applying the device to the lateral side of the cervical joint to assess the participant's pain threshold at the joint (Vaughan, Mclaughlin and Gosling 2007) and readings were taken at all three consultations prior to treatment.

2. CROM-II Goniometer (Appendix H) assesses the cervical range of motion and this instrument has shown good intra- and inter-examiner reliability in measuring patient's cervical ranges of motion (Youdas 1991). The CROM has been used in multiple research clinical trials at DUT and has been shown to be effective (Hepburn 2000; Harpham 2005). Readings were taken at all three consultations prior to treatment. The CROM-II Goniometer that was used was manufactured at 3600 Labore Road, Suite 6, St Paul, MN 55110-41144.).

3.7 HOMOEOPATHIC MEDICINES

3.7.1 Preparation of medication and placebo

The medicines utilised during this study were provided by the DUT Homoeopathic Clinic dispensary and were prepared by the DUT Homoeopathic Clinic's specialist technician so as to maintain the blinding of the researcher. Both groups received a 30ml bottle of medication in a 30 plussed potency. The process of preparation of the Homoeopathic remedies involves first making the liquid potency from the mother tincture, then medicating lactose granules with the desired potency and allowing them to dry. The mother tincture was made in accordance to Method 3a of the German Homoeopathic Pharmacopoeia (Benyunes 2005).

Following that 10 granules, of either the remedy-impregnated granules (Appendix L) or the neutral granules (placebo), were placed in a 30ml dropper bottle. 15ml of distilled water was added after which the bottle is swirled to dissolve the granules. 5ml of 96% ethanol (Appendix L) was then added to the bottle once the granules completely dissolved. The bottle was then closed and vigorously shaken 10 times (Benyunes 2005). The medicated granules used above were produced in accordance with method 10 of the German Homoeopathic Pharmacopoeia (Benyunes 2005). The granules underwent triple impregnation, at 1% volume/volume, with the medicating potency in 96% ethanol base. The placebo granules also underwent triple impregnation, at 1% v/v, with 96% ethanol base alone. This rendered the placebo treatment indistinguishable in its appearance and taste from that of the Simillimum treatment. The placebo medication was dispensed in the same manner as the Homoeopathic Simillimum and participants were told to take 10 drops daily after 10 succussions.

3.7.2 Posology

Participants received a 30 plussed potency in a 30ml bottle and were informed to take ten drops after ten succussions, once per day, before meals. The succussions were illustrated to the participant by the researcher as to educate the participant of the posology of the medication they had received.

3.7.3 Explanation of the Simillimum treatment

The Simillimum remedy for each participant was decided by the researcher, in consultation with the clinician on duty, by matching of all the symptoms provided by the participant to the most similar remedy picture, thus finding the closest fit (Vithoulkas 1980). The remedy was arrived at by taking into consideration all the symptoms that distinguish the person as an individual. This includes his family history, past medical history, appetite, thirst, bowel habits, sleep, and temperament, among others, taking special note of any changes on the mental, emotional and physical levels (Sankaran 1997).

The case was repertorised by hand using The Essential Synthesis Homoeopathic repertory (Schroyens 2007) and the Concordant Materia Medica (Vermeulen 2002) was utilised to read up and confirm the Simillimum remedy.

3.8 SPINAL MANIPULATION

Spinal manipulation was administered by the researcher (who is a qualified and registered chiropractor) to participants in both group A and group B. Fixations (areas

of reduced range of motion) were located through motion palpation (Bergmann and Peterson 2002) of the cervical spine and manipulated using the diversified technique, as described by Schafer and Faye (1990) and Bergmann and Peterson (2002). Fixations were manipulated in the direction of the restriction (decreased motion) and to standardize treatment protocol, participants were all manipulated in the supine position using an index contact.

3.9 DATA ANALYSIS

3.9.1 Statistical Analysis

Data was collected by the researcher and inserted into a Microsoft Excel® spreadsheet according to the allocated participant numbers and this was sent to the statistician. All data captured was analysed using SPSS version 24.0. Inferential and non-parametric analysis of the data was performed and this included:

- Descriptive statistics using frequency and cross-tabulation tables and various types of graphs
- Inferential statistics using correlations
- Testing of hypotheses using chi-square tests for nominal data
- Testing of hypotheses using ANOVA (factorial or mixed factorial) (Singh 2015).

3.9.2 Clinical significance

The phrase “clinical significance” is used to describe the change that is assessed as a result of the effect of the clinical implication of a treatment both within and between groups (Ogles *et al.* 2001; Atkins *et al*. 2005). Clinical significance can be positive, negative or insignificant and it allows the results that are interpreted from the study, to

be taken and utilised within a population outside the group that had been studied, which cannot be completed with statistical significance (Fetheney 2010). The reason that clinical significance is employed is to convey the possible uses and practical implications of the treatment and application in clinical practice (Ogles *et al.* 2001 and Fetheney 2010). Two terms that are linked with clinical significance are MDC (Minimal Detectable Change) which is the minimum amount of change that can be detected on an outcome measure and MCID (Minimally Clinically Important Difference) which reflects the changes in results due to the treatment are in fact meaningful to the patient (Cook *et al.* 2006). Therefore, it was noted that clinically significant results play a major role in determining the value of the treatment and the impact it has on patients in terms of their recuperation (Cook *et al*. 2006).

Tabulated below are the clinically significant values for the outcomes in this study:

Table 3.1 Clinically significant values for each test utilised in the study

Test	**Clinically significant value**
NRS	A 1.39 change in the NRS is to be noted for MCID to be met for this parameter and for clinical significance to be reached (Kendrick and Strout 2005).
CMCC NDI	The MCID for the Neck Disability Index is a change of 10.5 for clinical significance to be met (Pool *et al.* 2007).
Algometer	The MCID is an improvement of 1.77kg.cm^2 for this parameter in order for clinical significance to be met (Chesterton *et al.* 2007).

CROM-II Goniometer	No MCID exists for the Goniometer however it has been suggested by Vernon *et al.* (1990) that a 20% change would be seen as clinically significant.

CHAPTER FOUR

RESULTS

4.1 INTRODUCTION

This chapter presents the results and the findings of this study. The data collected from the responses was analysed with SPSS version 24.0. The results will present the descriptive statistics in the form of graphs, cross tabulations and other figures for the quantitative data that was collected. Inferential techniques include the use of correlations and Mann Whitney test values; which are interpreted using the *p* - values.

Primary Data: Data was collected only from those patients who met the research criteria and who participated for the full duration of the research programme. Only subjective and objective readings taken by the researcher were utilised.

Secondary Data: Data was obtained from journal articles, books and any related literature, to obtain information on the procedure, reliability and signs to look for on clinical trials.

4.2 AIMS AND OBJECTIVES

The aim of this study was to determine if spinal manipulation and Homoeopathic Simillimum in combination were more effective than spinal manipulation and placebo in the treatment of CMNP. The specific objectives of this study were:

- To compare the effectiveness of spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by means of the NRS.
- To establish the effectiveness of spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by means of the CMCC NDI questionnaire.

- To compare the effectiveness of spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by using an Algometer, to measure the participant's pain threshold.
- To compare the effectiveness of spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by using a CROM-II Goniometer to measure cervical spine range of motion.

The following results and statistical analyses are presented in this chapter:

1. Demographic data that was collected in the statistical analysis.
2. EFI association to the subjective/objective clinical measures (NRS, CMCC NDI, Algometer and CROM-II Goniometer) as well as inter-group analysis and clinical significance.

4.3 DEMOGRAPHIC DATA

The sample in this study consisted of thirty participants with CMNP. Participants were placed into one of the two treatment groups according to a randomisation table (Appendix J). Group A receiving spinal manipulation and Simillimum and group B receiving spinal manipulation and placebo. Statistically significant differences were not noted with respect to any of the demographic variables between the treatments groups in terms of any of the demographic variables.

4.3.1 Gender

The table below describes the overall gender distribution by group.

Table 4.1 Gender distribution between groups

			Group		Total
			Simillimum	Placebo	
Gender	Male	Count	2	3	5
		% within Group	13.3%	20.0%	16.7%

	Female	Count	13	12	25
		% within Group	86.7%	80.0%	83.3%
Total		Count	15	15	30
		% within Group	100.0%	100.0%	100.0%

As can be seen in the table above, the number of female participants exceeded the male participants, however there were similar numbers of males and females per group (p = 0.624).

4.3.2 Race

The table below indicates the racial composition of the sample.

Table 4.2 Racial distribution between groups

			Group		Total
			Simillimum	Placebo	
Ethnicity	African	Count	0	2	2
		% within Group	0.0%	13.3%	6.7%
	Coloured	Count	1	0	1
		% within Group	6.7%	0.0%	3.3%
	Asian	Count	1	0	1
		% within Group	6.7%	0.0%	3.3%
	White	Count	13	13	26
		% within Group	86.7%	86.7%	86.7%
Total		Count	15	15	30
		% within Group	100.0%	100.0%	100.0%

Overall, the participants were predominately white, however the composition of the groups by race did not differ significantly (p = 0.261).

4.3.3 Age

The table below is a summary of the descriptive statistics for age.

Table 4.3 Mean age of participants between groups

Group		Age
Simillimum	N	15
	Mean	32.8000
	Std. Deviation	8.84146
	Maximum	53.00
	Minimum	18.00
Placebo	N	15
	Mean	36.0000
	Std. Deviation	9.08688
	Maximum	55.00
	Minimum	26.00
Total	N	30
	Mean	34.4000
	Std. Deviation	8.95814
	Maximum	55.00
	Minimum	18.00

As can be seen in the table above, the mean age of the placebo group was slightly higher than the Simillimum group.

4.3.4 Occupation

The table below is a summary of the occupations of the participants in each group.

Table 4.4 Summary of the occupations of the participants

			Group		Total
			Simillimum	Placebo	
Occupation	Admin	Count	0	2	2
		% within Group	0.0%	13.3%	6.7%
	Beautician	Count	0	2	2
		% within Group	0.0%	13.3%	6.7%
	Bookkeeper	Count	0	1	1
		% within Group	0.0%	6.7%	3.3%
	Chiropractor	Count	1	0	1
		% within Group	6.7%	0.0%	3.3%
	Crane driver	Count	0	1	1

		% within Group	0.0%	6.7%	3.3%
	Designer	Count	1	0	1
		% within Group	6.7%	0.0%	3.3%
	Driver	Count	1	0	1
		% within Group	6.7%	0.0%	3.3%
	Engineer	Count	3	1	4
		% within Group	20.0%	6.7%	13.3%
	Financial advisor	Count	1	1	2
		% within Group	6.7%	6.7%	6.7%
	Housewife	Count	2	3	5
		% within Group	13.3%	20.0%	16.7%
	Manager	Count	1	1	2
		% within Group	6.7%	6.7%	6.7%
	Politician	Count	0	2	2
		% within Group	0.0%	13.3%	6.7%
	Sales rep	Count	1	0	1
		% within Group	6.7%	0.0%	3.3%
	Self	Count	0	1	1
		% within Group	0.0%	6.7%	3.3%
	Shipping admin	Count	1	0	1
		% within Group	6.7%	0.0%	3.3%
	Student	Count	3	0	3
		% within Group	20.0%	0.0%	10.0%
Total		Count	15	15	30
		% within Group	100.0%	100.0%	100.0%

As can be seen in the table above, the most common occupations in this study were housewives, engineers and students with no statistical difference between the groups.

4.3.5 Chronicity

The table below is a summary of the descriptive statistics for chronicity of the neck pain.

Table 4.5 Chronicity of condition between both groups

Group		Chronicity (weeks)
Simillimum	N	15
	Mean	119.0667
	Std. Deviation	180.83831
	Maximum	600.00
	Minimum	1.00
Placebo	N	15
	Mean	138.4667
	Std. Deviation	217.85836
	Maximum	600.00
	Minimum	1.00
Total	N	30
	Mean	128.7667
	Std. Deviation	196.97097
	Maximum	600.00
	Minimum	1.00

As can be seen in the table above, the average chronicity (how long the person had the existing condition) of the placebo group was slightly higher than the Simillimum group.

4.4 STATISTICAL ANALYSIS OF THE VARIABLES

The section that follows analyses the mean scoring patterns of the participants per each test or objective (NRS, NDI, Algometer and CROM-II Goniometer).

4.4.1 Numerical Pain Rating Scale

The NRS was utilised to assess the participant's perception of pain and was conducted before treatment at all three visits. The results are shown below for each group.

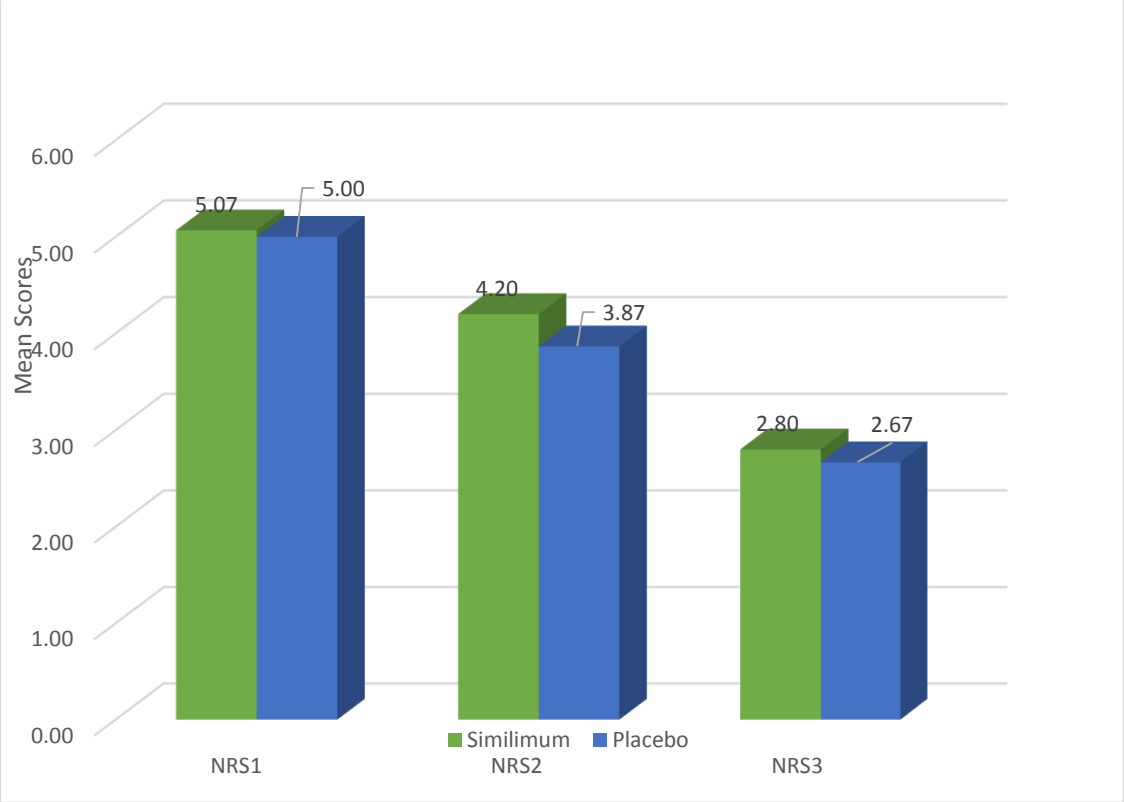


Figure 4.1 Mean scores of NRS in both groups

When observing the patterns in the graph above, the Simillimum group showed higher levels for the NRS with a decreasing trend i.e. the groups total pain was slightly higher to start off with but the pain reduction was more significant than the placebo group.

Table 4.6 Significance of mean values in NRS in both groups

	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)
NRS1	112.500	232.500	0.000	1.000
NRS2	106.500	226.500	-0.253	0.801
NRS3	108.000	228.000	-0.189	0.850

The above Mann Whitney test was done to determine whether the scoring patterns were significantly different per measure. The null hypothesis claims that the mean values are similar. The alternate states that there is a significant difference. None of the significant values (*p* - values) are less than 0.05 (the level of significance), and therefore it implies that the means were similar.

4.4.2 CMCC Neck Disability Index

The NDI was utilised to assess the participant's perception of their pain, movement and quality of living in relation to their neck pain. The test was conducted before treatment at all three visits. The results are shown below for each group.

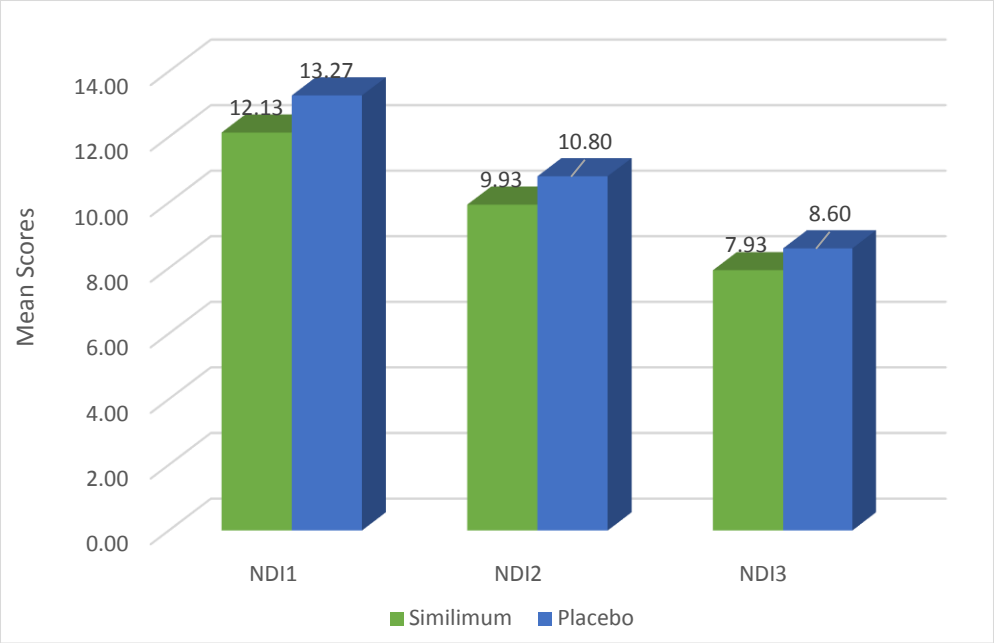


Figure 4.2 Mean scores of NDI in both groups

When observing the patterns in the graph above, the placebo group had higher mean values for NDI, with a decreasing trend and therefore the implication of the trends is that the interventions were more prominent for NDI i.e. the Simillimum group had lower scores for NDI and therefore the Simillimum group may have fared better.

Table 4.7 Significance of mean values in NDI in both groups

	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)
NDI1	94.500	214.500	-0.750	0.453
NDI2	94.500	214.500	-0.751	0.453
NDI3	98.500	218.500	-0.583	0.560

The above Mann Whitney test was done to determine whether the scoring patterns were significantly different per measure. The null hypothesis claims that the mean values are similar. The alternate states that there is a significant difference. None of the significant values (*p* - values) are less than 0.05 (the level of significance), and therefore it implies that the means were similar.

4.4.3 Algometer

The Algometer was utilised to subjectively assess the participant's pain threshold over the neck area. The test was conducted before treatment, three separate points were tested at each session and this test was done at all three sessions. The results are shown below for each group.

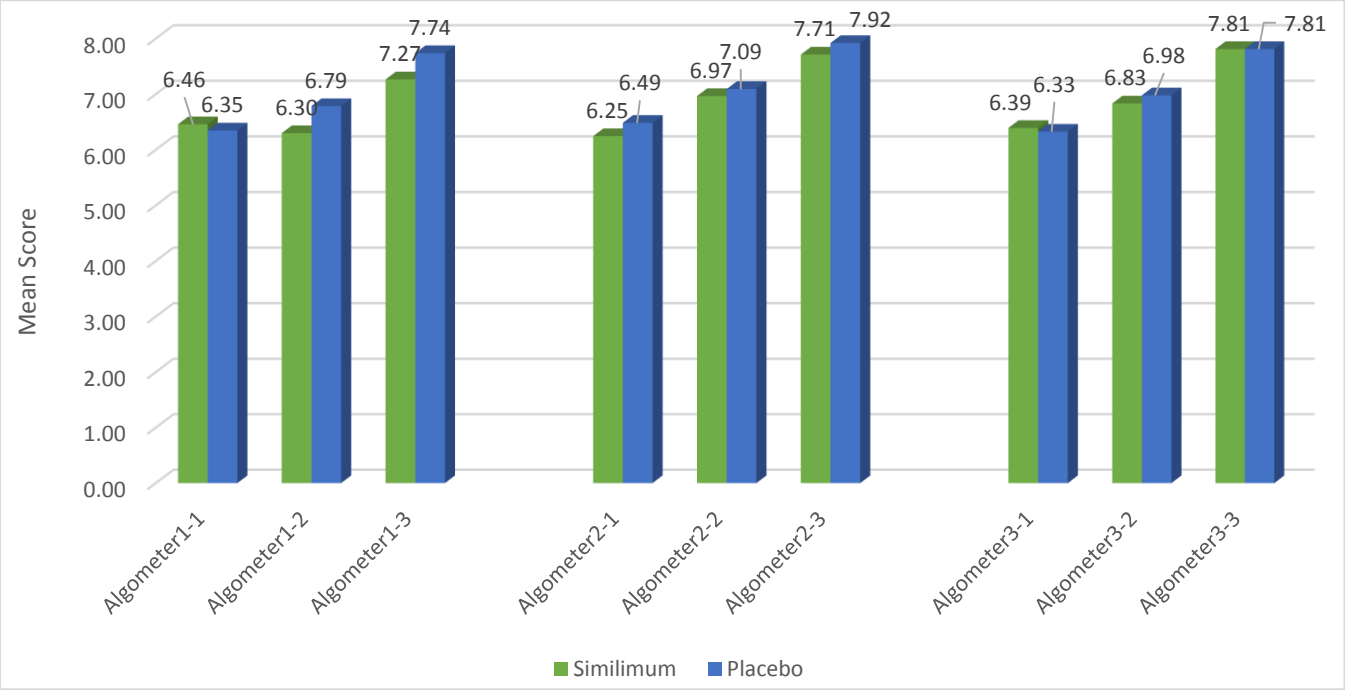


Figure 4.3 Mean scores of Algometer readings in both groups

As can be seen in the graph above, the Algometer mean readings were similar for each group, with an increasing trend in both groups. This suggests both groups of participants were able to tolerate more pain with each treatment session.

Table 4.8 Significance of mean values in Algometer readings in both groups

	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)
Algometer 1-1	110.500	230.500	-0.083	0.934
Algometer 1-2	102.500	222.500	-0.416	0.677
Algometer 1-3	100.000	220.000	-0.519	0.604
Algometer 2-1	104.000	224.000	-0.353	0.724
Algometer 2-2	111.500	231.500	-0.042	0.967
Algometer 2-3	105.500	225.500	-0.291	0.771
Algometer 3-1	111.000	231.000	-0.062	0.950
Algometer 3-2	112.000	232.000	-0.021	0.983
Algometer 3-3	112.500	232.500	0.000	1.000

The above Mann Whitney test was done to determine whether the scoring patterns were significantly different per measure. None of the significant values (*p* - values) are less than 0.05 (the level of significance), it implies that the means were similar and no statistical difference was noted.

4.4.4 CROM-II Goniometer

The CROM-II Goniometer was utilised to subjectively assess the participant's cervical range of motion in flexion, extension, rotation and lateral flexion. The test was conducted before treatment, in each of the mentioned ranges of motion and this test was done at all three sessions. The results are shown below for each movement and group.

4.4.4.1 Flexion

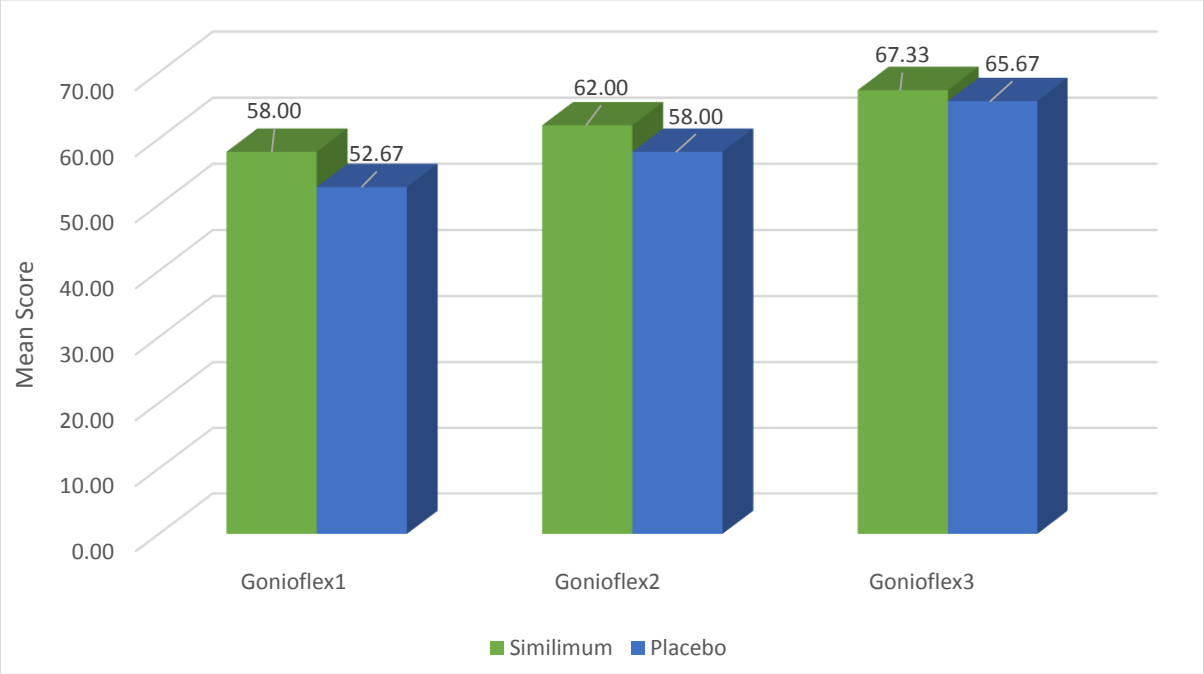


Figure 4.4 Mean scores of flexion in the CROM-II Goniometer readings in both groups

As can be seen in the graph above the flexion readings of the CROM-II Goniometer were similar for each group, with an increasing trend in both groups, this suggests both groups of participants had more range of motion with each treatment session. The values for the Simillimum group are higher however the below test was done to see if it was statistically notable.

Table 4.9 Significance of mean values in flexion in both groups

	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)
Gonioflex1	89.500	209.500	-0.989	0.323
Gonioflex2	93.500	213.500	-0.805	0.421
Gonioflex3	100.000	220.000	-0.528	0.597

The above Mann Whitney test was done to determine whether the scoring patterns were significantly different per measure. None of the significant values (*p* - values)

are less than 0.05 (the level of significance), it implies that the means were similar and no statistical difference was noted.

4.4.4.2 Extension

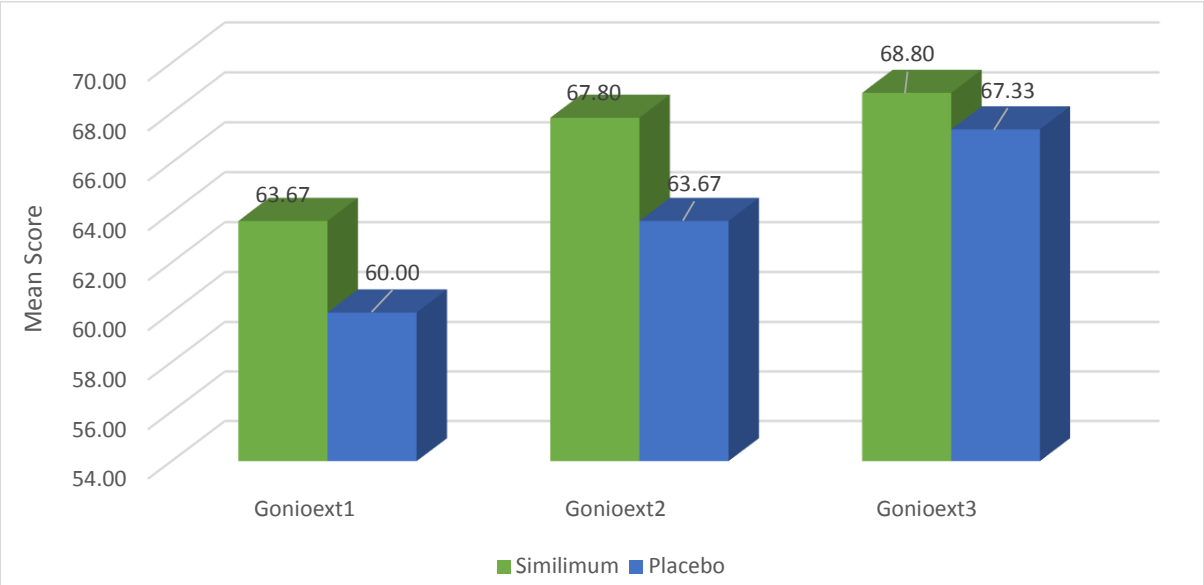


Figure 4.5 Mean scores of extension in the CROM-II Goniometer readings in both groups

As can be seen in the graph above, the average extension readings of the CROM-II Goniometer were higher in the similmum group, however an increasing trend in both groups was noticed, and this suggests both groups of participants had more range of motion with each treatment session. The values for the Simillimum group are higher however the below test was done to see if it was statistically notable.

Table 4.10 Significance of mean values in extension in both groups

	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)
Gonioext1	74.000	194.000	-1.643	0.100
Gonioext2	83.500	203.500	-1.226	0.220
Gonioext3	99.000	219.000	-0.572	0.568

The above Mann Whitney test was done to determine whether the scoring patterns were significantly different per measure. None of the significant values (*p* - values)

are less than 0.05 (the level of significance), it implies that the means were similar and no statistical difference was noted.

4.4.4.3 Rotation

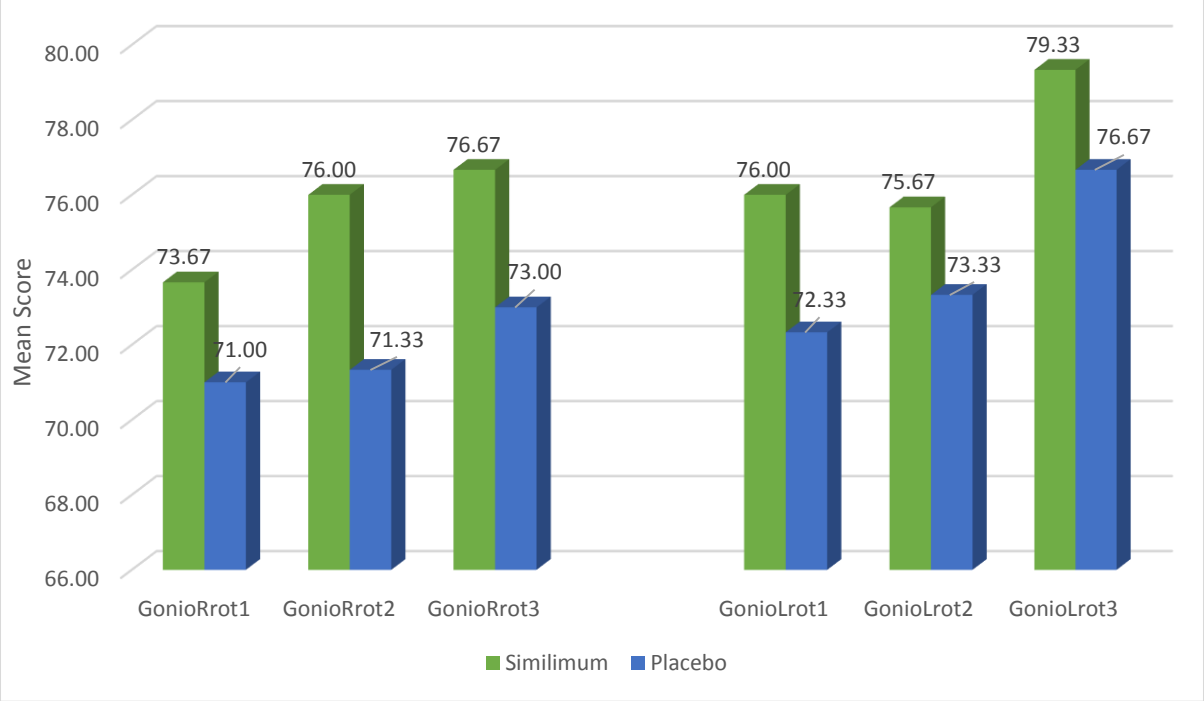


Figure 4.6 Mean scores of rotation in the CROM-II Goniometer readings in both groups

As can be seen in the graph above, the average rotational readings of the CROM-II Goniometer were higher in the similmum group, however an increasing trend in both groups was noticed, and this suggests both groups of participants had more range of motion with each treatment session. The values for the Simillimum group are higher however the below test was done to see if it was statistically notable.

Table 4.11 Significance of mean values in rotation in both groups

	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)
GonioRrot1	67.500	187.500	-2.072	0.038
GonioRrot2	46.500	166.500	-2.918	0.004
GonioRrot3	63.500	183.500	-2.136	0.033

GonioLrot1	67.000	187.000	-2.050	0.040
GonioLrot2	86.000	206.000	-1.155	0.248
GonioLrot3	78.500	198.500	-1.498	0.134

The above Mann Whitney test was done to determine whether the scoring patterns were significantly different per measure. Some of the significant values (*p* - values) are less than 0.05 (the level of significance), and this implies that a statistical difference was observed for CROM-II Goniometer right rotation i.e. the similmum group improved in terms of rotation on the right more so than the placebo group.

4.4.4.4 Lateral flexion

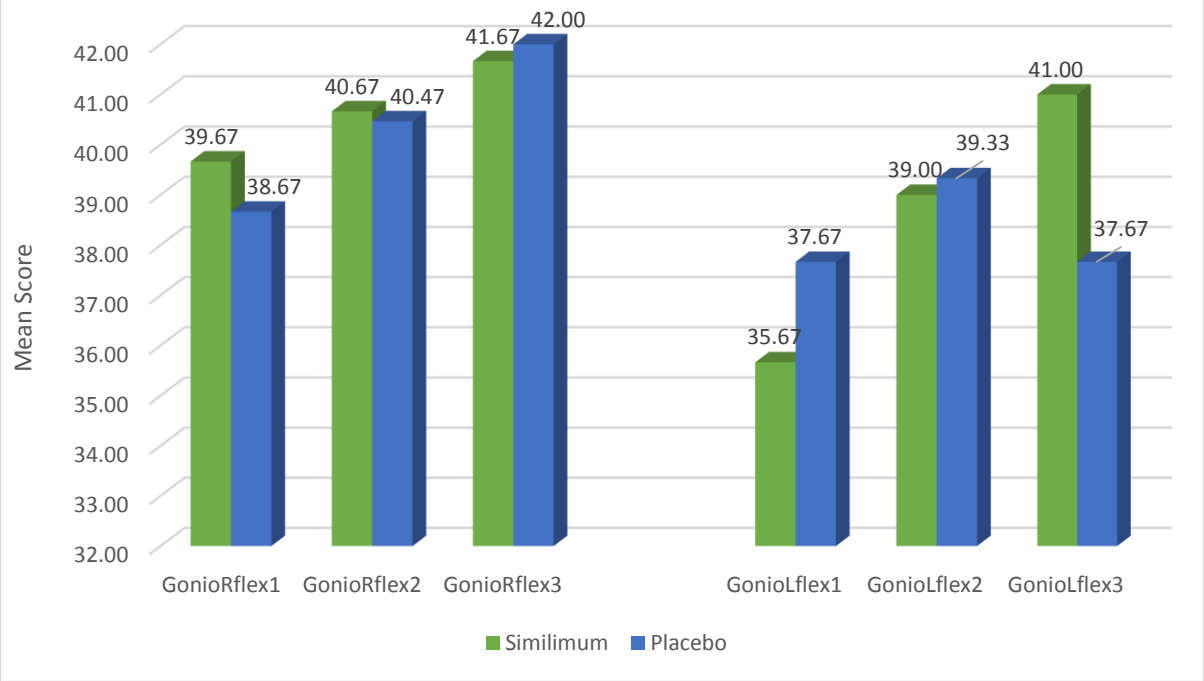


Figure 4.7 Mean scores of lateral flexion in the CROM-II Goniometer readings in both groups

As can be seen in the graph above, the average lateral flexion readings of the CROM-II Goniometer were similar in both groups and an increasing trend in both groups was noticed, and this suggests both groups of participants had more range of motion with each treatment session.

Table 4.12 Significance of mean values in lateral flexion in both groups

	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)
Gonio Rflex1	100.000	220.000	-0.620	0.535
Gonio Rflex2	109.000	229.000	-0.159	0.874
Gonio Rflex3	99.000	219.000	-0.627	0.531
Gonio Lflex1	93.500	213.500	-0.874	0.382
Gonio Lflex2	107.000	227.000	-0.265	0.791
Gonio Lflex3	68.000	188.000	-1.982	0.048

The above Mann Whitney test was done to determine whether the scoring patterns were significantly different per measure. Most of the significant values (*p* - values) are less than 0.05 (the level of significance), it implies that the means were similar and no statistical difference was noted overall. However lateral flexion at the last session was 0.048 which is below 0.05 and therefore significant.

4.4.5 Correlations between variables

Bivariate correlations were also performed on all the data, the results indicated the following patterns: positive values indicate a directly proportional relationship between the variables and a negative value indicates an inverse relationship. All significant relationships are indicated by a * or **.

Table 4.13 Correlation for all variables in the placebo group

		NRS	NDI	Algometer_1	Algometer_2	Algometer_3	Gonio_flex	Gonio_ext	Gonio_Rrot	Gonio_Lrot	Gonio_Rflex	Gonio_Lflex
NRS	Pearson Co	1										
	Sig. (2-tailed)											
	N	15										
NDI	Pearson Co	.824**	1									
	Sig. (2-tailed)	0.000										
	N	15	15									
Algometer_1	Pearson Co	-0.493	-0.431	1								
	Sig. (2-tailed)	0.062	0.109									
	N	15	15	15								
Algometer_2	Pearson Co	-0.467	-0.451	.957**	1							
	Sig. (2-tailed)	0.079	0.092	0.000								
	N	15	15	15	15							
Algometer_3	Pearson Co	-0.354	-0.356	.917**	.907**	1						
	Sig. (2-tailed)	0.195	0.193	0.000	0.000							
	N	15	15	15	15	15						
Gonio_flex	Pearson Co	0.223	0.182	-0.401	-0.410	-0.286	1					
	Sig. (2-tailed)	0.425	0.517	0.139	0.129	0.301						
	N	15	15	15	15	15	15					
Gonio_ext	Pearson Co	-0.306	-0.123	-0.228	-0.243	-0.289	.602*	1				
	Sig. (2-tailed)	0.267	0.663	0.414	0.382	0.296	0.018					
	N	15	15	15	15	15	15	15				
Gonio_Rrot	Pearson Co	-0.145	-0.022	-0.204	-0.232	-0.290	0.134	0.171	1			
	Sig. (2-tailed)	0.607	0.939	0.466	0.405	0.295	0.635	0.542				
	N	15	15	15	15	15	15	15	15			
Gonio_Lrot	Pearson Co	0.468	0.237	-0.032	-0.053	-0.040	0.204	-0.219	0.511	1		
	Sig. (2-tailed)	0.078	0.395	0.909	0.852	0.887	0.466	0.434	0.051			
	N	15	15	15	15	15	15	15	15	15		
Gonio_Rflex	Pearson Co	-0.512	-0.345	0.284	0.129	0.120	0.194	0.339	0.314	0.032	1	
	Sig. (2-tailed)	0.051	0.208	0.305	0.646	0.670	0.488	0.216	0.255	0.910		
	N	15	15	15	15	15	15	15	15	15	15	
Gonio_Lflex	Pearson Co	-0.149	-0.162	0.126	0.002	-0.097	-0.229	-0.189	0.178	0.056	.523*	1
	Sig. (2-tailed)	0.595	0.564	0.654	0.993	0.730	0.411	0.501	0.526	0.842	0.045	
	N	15	15	15	15	15	15	15	15	15	15	15

Table 4.14 Correlation for all variables for the similmum group

		NRS	NDI	Algometer_1	Algometer_2	Algometer_3	Gonio_flex	Gonio_ext	Gonio_Rrot	Gonio_Lrot	Gonio_Rflex	Gonio_Lflex
NRS	arson Correlat	1										
	Sig. (2-tailed)											
	N	15										
NDI	arson Correlat	.599*	1									
	Sig. (2-tailed)	0.018										
	N	15	15									
Algometer_1	arson Correlat	0.128	-0.190	1								
	Sig. (2-tailed)	0.648	0.498									
	N	15	15	15								
Algometer_2	arson Correlat	0.118	-0.135	.954**	1							
	Sig. (2-tailed)	0.675	0.631	0.000								
	N	15	15	15	15							
Algometer_3	arson Correlat	0.232	0.003	.922**	.980**	1						
	Sig. (2-tailed)	0.404	0.993	0.000	0.000							
	N	15	15	15	15	15						
Gonio_flex	arson Correlat	-0.135	-0.067	0.148	0.245	0.216	1					
	Sig. (2-tailed)	0.631	0.812	0.598	0.379	0.439						
	N	15	15	15	15	15	15					
Gonio_ext	arson Correlat	0.057	0.199	0.152	0.174	0.225	.728**	1				
	Sig. (2-tailed)	0.841	0.477	0.588	0.534	0.419	0.002					
	N	15	15	15	15	15	15	15				
Gonio_Rrot	arson Correlat	-0.176	-0.147	0.026	-0.079	-0.100	0.020	0.191	1			
	Sig. (2-tailed)	0.531	0.602	0.928	0.780	0.722	0.944	0.496				
	N	15	15	15	15	15	15	15	15			
Gonio_Lrot	arson Correlat	0.083	-0.077	0.435	0.372	0.389	0.060	0.286	.636*	1		
	Sig. (2-tailed)	0.769	0.786	0.105	0.172	0.152	0.831	0.301	0.011			
	N	15	15	15	15	15	15	15	15	15		
Gonio_Rflex	arson Correlat	0.092	0.110	-0.210	-0.136	-0.083	-0.063	0.084	0.007	0.243	1	
	Sig. (2-tailed)	0.745	0.698	0.452	0.630	0.769	0.822	0.765	0.980	0.382		
	N	15	15	15	15	15	15	15	15	15	15	
Gonio_Lflex	arson Correlat	-0.049	0.153	-0.411	-0.284	-0.192	-0.436	-0.169	0.039	-0.104	0.464	1
	Sig. (2-tailed)	0.863	0.586	0.128	0.305	0.492	0.104	0.548	0.889	0.714	0.082	
	N	15	15	15	15	15	15	15	15	15	15	15

As can be noted in the tables above, the correlation value between NRS and NDI for both Simillimum and placebo was significant and directly proportional. As NRS increased, so did NDI, and vice versa. Although there were some notable values amongst the other data, no solid correlations seemed to exist between Algometer and CROM-II Goniometer readings for both groups.

4.4.6 Multiple Regression

Multiple regression is an extension of simple linear regression. It is used when one wants to predict the value of a variable based on the value of two or more other variables. The variable we want to predict is called the dependent variable. The variables we are using to predict the value of the dependent variable are called the

independent variables. In this study we have only done a multiple regression for the variables we found to be statistically significant, therefore NRS and NDI have been analysed for both placebo and Simillimum groups.

4.4.6.1 Placebo (Dependent variable – NRS)

The three tables below show multiple regression for NRS in the placebo group and the finding will be mentioned below.

Table 4.15 Model summary for multiple regression for NRS in the placebo group

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.913[a]	.834	.535	1.35014

a. Predictors: (Constant), Gonio_Lflex, Algometer_2, Gonio_Lrot, Gonio_ext, Gonio_Rrot, Gonio_Rflex, Gonio_flex, Algometer_3, Algometer_1

Table 4.16 Analysis of variance (ANOVA) for NRS in the placebo group

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	45.768	9	5.085	2.790	.136[b]
	Residual	9.114	5	1.823		
	Total	54.882	14			

a. Dependent Variable: NRS

b. Predictors: (Constant), Gonio_Lflex, Algometer_2, Gonio_Lrot, Gonio_ext, Gonio_Rrot, Gonio_Rflex, Gonio_flex, Algometer_3, Algometer_1

Table 4.17 Coefficients of multiple regression for NRS in the placebo group

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	7.359	12.847		.573	.592
	Algometer_1	-.244	.950	-.270	-.257	.807

	Algometer_2	-.428	.747	-.436	-.573	.591
	Algometer_3	.211	.665	.217	.318	.763
	Gonio_flex	.015	.070	.076	.215	.838
	Gonio_ext	-.027	.100	-.096	-.267	.800
	Gonio_Rrot	-.277	.152	-.495	-1.823	.128
	Gonio_Lrot	.319	.139	.665	2.299	.070
	Gonio_Rflex	-.140	.148	-.318	-.946	.387
	Gonio_Lflex	.064	.156	.124	.413	.696

a. Dependent Variable: NRS

In the model summary table above there was a strong relationship noted between the dependent variable and the independent variables. However in the ANOVA table the *p* - value was greater than 0.05, and it therefore implied that the predictors do not collectively describe the dependent. In the third table of coefficients, none of the independent variables significantly affected the dependent variable. Therefore overall the independent variables do not describe or predict NRS within the placebo group.

4.4.6.2 Placebo (Dependent variable – NDI)

The three tables below show multiple regression for NDI in the placebo group and the finding will be mentioned below.

Table 4.18 Model summary for multiple regression for NDI in the placebo group

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.636[a]	.405	-.666	5.00627

a. Predictors: (Constant), Gonio_Lflex, Algometer_2, Gonio_Lrot, Gonio_ext, Gonio_Rrot, Gonio_Rflex, Gonio_flex, Algometer_3, Algometer_1

Table 4.19 Analysis of variance (ANOVA) for NDI in the placebo group

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	85.336	9	9.482	.378	.903[b]
	Residual	125.314	5	25.063		
	Total	210.650	14			

a. Dependent Variable: NDI
b. Predictors: (Constant), Gonio_Lflex, Algometer_2, Gonio_Lrot, Gonio_ext, Gonio_Rrot, Gonio_Rflex, Gonio_flex, Algometer_3, Algometer_1

Table 4.20 Coefficients of multiple regression for NDI in the placebo group

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	32.393	47.635		.680	.527
	Algometer_1	1.676	3.521	.947	.476	.654
	Algometer_2	-2.084	2.771	-1.084	-.752	.486
	Algometer_3	-.491	2.466	-.257	-.199	.850
	Gonio_flex	.065	.261	.167	.250	.812
	Gonio_ext	-.110	.369	-.202	-.298	.778
	Gonio_Rrot	-.141	.564	-.129	-.250	.812
	Gonio_Lrot	.193	.515	.205	.374	.724
	Gonio_Rflex	-.261	.548	-.303	-.476	.654
	Gonio_Lflex	-.137	.577	-.134	-.237	.822

a. Dependent Variable: NDI

In the model summary table above there was a strong statistical correlation noted between the dependent variable, NDI, and the independent variables, however it was lower than the above NRS. In the ANOVA table the *p* - value was greater than 0.05, and it therefore implied that the predictors do not collectively describe the dependent. In the third table of coefficients, none of the independent variables significantly affected the dependent variable. Therefore overall the independent variables do not describe or predict NDI within the placebo group.

4.4.6.3 Simillimum (Dependent variable – NRS)

The three tables below show multiple regression for NRS in the Simillimum group and the finding will be mentioned below.

Table 4.21 Model summary for multiple regression for NRS in the Simillimum group

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.752[a]	.565	-.218	2.61684

a. Predictors: (Constant), Gonio_Lflex, Gonio_Rrot, Algometer_3, Gonio_ext, Gonio_Rflex, Gonio_flex, Gonio_Lrot, Algometer_1, Algometer_2

Table 4.22 Analysis of variance (ANOVA) for NRS in the Simillimum group

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	44.483	9	4.943	.722	.684[b]
	Residual	34.239	5	6.848		
	Total	78.722	14			

a. Dependent Variable: NRS

b. Predictors: (Constant), Gonio_Lflex, Gonio_Rrot, Algometer_3, Gonio_ext, Gonio_Rflex, Gonio_flex, Gonio_Lrot, Algometer_1, Algometer_2

Table 4.23 Coefficients of multiple regression for NRS in the Simillimum group

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	19.563	22.074		.886	.416
	Algometer_1	-.842	1.927	-.883	-.437	.681
	Algometer_2	-2.974	2.874	-3.053	-1.035	.348
	Algometer_3	4.680	2.363	4.145	1.981	.105
	Gonio_flex	-.100	.160	-.549	-.625	.560
	Gonio_ext	.019	.219	.057	.086	.935
	Gonio_Rrot	.190	.438	.255	.434	.682
	Gonio_Lrot	-.236	.470	-.315	-.502	.637
	Gonio_Rflex	.188	.280	.281	.671	.532
	Gonio_Lflex	-.541	.441	-.885	-1.228	.274

a. Dependent Variable: NRS

Within all three tables above there are no significant variables or statistically significant values seen for NRS in the similmum group.

4.4.6.4 Simillimum (Dependent variable – NDI)

The three tables below show multiple regression for NDI in the Simillimum group and the finding will be mentioned below.

Table 4.24 Model summary for multiple regression for NDI in the Simillimum group

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.831[a]	.690	.133	4.27869

a. Predictors: (Constant), Gonio_Lflex, Gonio_Rrot, Algometer_3, Gonio_ext, Gonio_Rflex, Gonio_flex, Gonio_Lrot, Algometer_1, Algometer_2

Table 4.25 Analysis of variance (ANOVA) for NDI in the Simillimum group

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	203.995	9	22.666	1.238	.428[b]
	Residual	91.536	5	18.307		
	Total	295.531	14			

a. Dependent Variable: NDI

b. Predictors: (Constant), Gonio_Lflex, Gonio_Rrot, Algometer_3, Gonio_ext, Gonio_Rflex, Gonio_flex, Gonio_Lrot, Algometer_1, Algometer_2

Table 4.26 Coefficients of multiple regression for NDI in the Simillimum group

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	42.433	36.092		1.176	.293
	Algometer_1	-4.686	3.151	-2.537	-1.487	.197
	Algometer_2	-2.623	4.699	-1.390	-.558	.601
	Algometer_3	8.459	3.864	3.867	2.189	.080
	Gonio_flex	-.362	.261	-1.027	-1.385	.225
	Gonio_ext	.360	.357	.564	1.008	.360

	Gonio_Rrot	.705	.717	.488	.984	.370
	Gonio_Lrot	-.772	.768	-.532	-1.005	.361
	Gonio_Rflex	.280	.458	.216	.610	.568
	Gonio_Lflex	-1.265	.721	-1.067	-1.754	.140

a. Dependent Variable: NDI

Within all three tables above there are no significant variables or statistically significant values seen for NDI in the similmum group.

In all of the regression models, none of the significant values in the last columns of the coefficients table show any significant contribution. In all the other variables, namely Algometer and CROM-II Goniometer, there were no significant correlations, hence the tables have been summarised.

4.5 HOMOEOPATHIC REMEDIES PRESCRIBED

The following table shows the list of Homoeopathic remedies given to participants as similmum treatment.

Table 4.27 Table of Homoeopathic remedies prescribed

Participant	Similmum remedy chosen	Group (A or B)
001	*Pulsatilla nigricans*	A
002	*Delphinium staphysagria*	A
003	*Pulsatilla nigricans*	B
004	*Delphinium staphysagria*	A
005	*Sepia officinalis*	B
006	*Sepia officinalis*	B
007	*Ledum palustre*	A
008	*Pulsatilla nigricans*	A
009	*Ignatia amara*	B
010	*Pulsatilla nigricans*	A
011	*Lycopodium clavatum*	B
012	*Silica marina*	A
013	*Helium*	B
014	*Cannabis indica*	B
015	*Nux vomica*	A
016	*Pulsatilla nigricans*	B
017	*Atropa belladonna*	A
018	*Rhus toxicodendron*	B

019	*Sepia officinalis*	B
020	*Rhus toxicodendron*	A
021	*Delphinium staphysagria*	A
022	*Nux vomica*	B
023	*Ruta graveolens*	A
024	*Rhus toxicodendron*	B
025	*Aurum metallicum*	A
026	*Pulsatilla nigricans*	A
027	*Lachesis mutus*	B
028	*Silica marina*	A
029	*Lycopodium clavatum*	B
030	*Delphinium staphysagria*	B

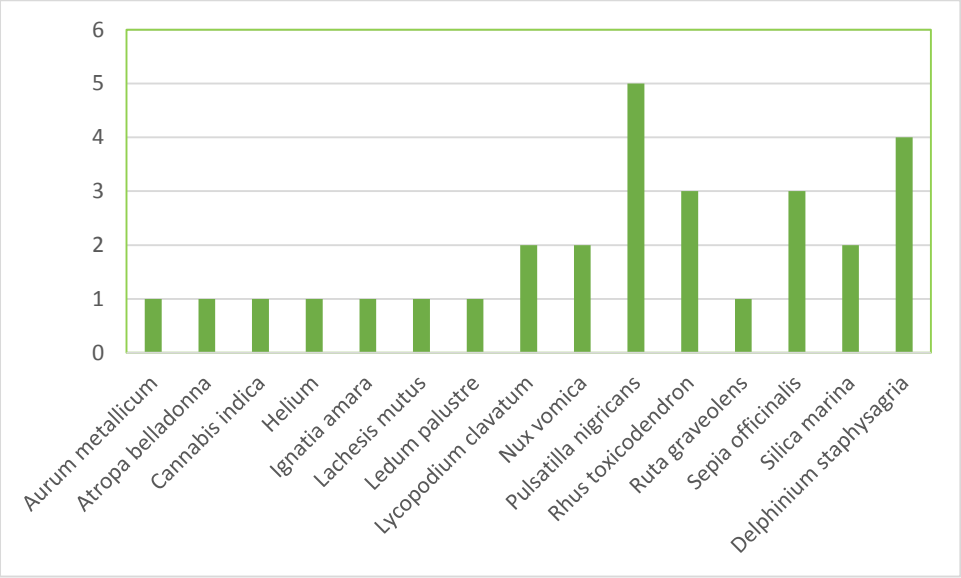


Figure 4.8 Frequency of prescription of Homoeopathic Simillimum remedies

4.6 CONCLUSION

As it can be seen by the results displayed in Chapter Four, subjective and objective changes were demonstrated in both the treatment and placebo groups. Baseline readings and demographics of both groups were shown to provide a clearer outlook of the sample population and their characteristics. All subjective and objective measures were represented (in both groups) and statistically and clinically significant subjective/objective clinical measures were presented and will be discussed in further detail in Chapter Five.

CHAPTER FIVE

DISCUSSION

5.1 INTRODUCTION

This Chapter will explain and discuss the results in greater detail and comparisons will be made with current literature. The discussion is based on:

1. Demographic data collected at the outset of the study.

2.1 Subjective clinical measures

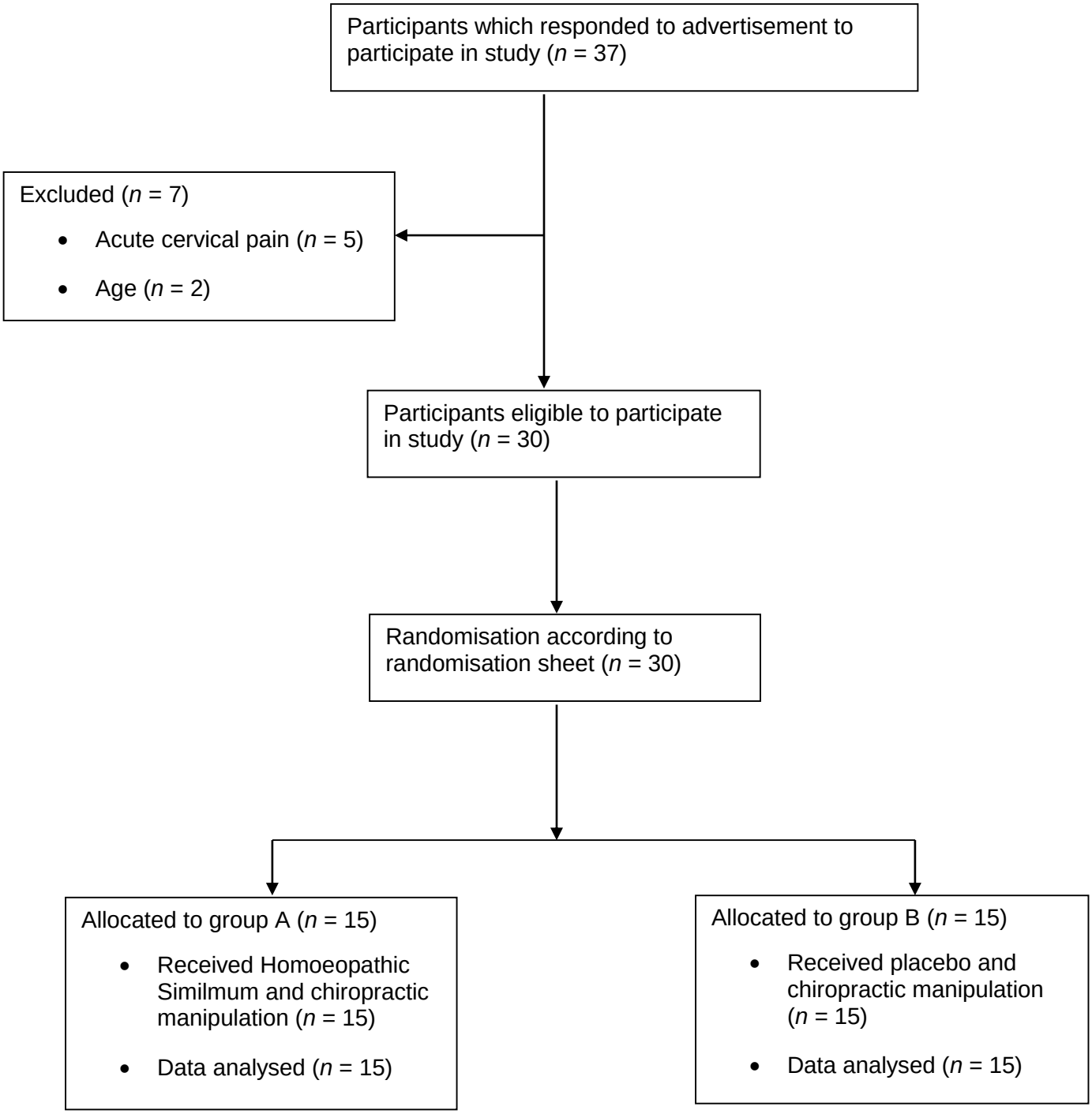
- NRS and
- CMCC NDI.

2.2 Objective clinical measures

- Algometer readings and
- CROM-II Goniometer readings.

All data were collected at the beginning of each of the three visits.

5.2 <u>FLOW DIAGRAM</u> (Adapted from Schulz, Douglas and Moher (2010))



5.3 DEMOGRAPHIC DATA DISCUSSION

5.3.1 Gender

There were no statistical differences noted between groups with respect to demographic data. In the total population group there were twenty five females (*n* = 25) which equates to 83.3% and five males (*n* = 5) which accounts for 16.7%. However the split between the groups was very similar and therefore of no notable difference (*p* = 0.624). Garrick (1977) reported that there was no gender predisposition for experiencing neck pain. Results of this study, are in keeping with, a Scandinavian study by Borenstein, Wiesel and Boden (1996) that showed the prevalence of neck pain to be greater in females than in males.

5.3.2 Race

No statistical differences were noted in the ethnicity distribution between the groups, with 86.7% of the study being White (*n* = 26), 6.7% being African (*n* = 2), 3.3% were Asian (*n* = 1) and another 3.3% of the population were Coloured (*n* = 1). Although no statistically significant findings were noted with regard to ethnic distribution (*p* = 0.261), it is evident that the white ethnicity represented a larger percentage of the study population.

5.3.3 Age

In terms of age as a demographic variable, the mean age of the Simillimum group was 32.8 years and 36 years in the placebo group. The range of ages was 18 - 55 years for the entire study population with the range of ages between 18 and 53 for the Simillimum group and 26 and 55 for the placebo group. The age group was restricted to a relatively young population such that pain caused by degenerative disc or joint disease was kept to a minimum (Esenyel, Caglar and Aldemir 2000). According to Borenstein, Wiesel and Boden (1996), neck pain increases with age. Bland and Boushey (1994) stated that working individuals between the ages 25 - 29 years have a 25 - 30 percent incidence of neck pain with individuals over the age of 45 having a 50 percent incidence of neck pain.

5.3.4 Occupation

As seen in Chapter Four, no statistical difference was noted within the occupations between each of the groups. The most common occupations in this study were

housewife (*n* = 5) with 16.7% of the study population, engineers (*n* = 4) with 13.3% and students (*n* = 3) with 10% of the study group. No statistical difference between the groups was noted.

5.3.5 Chronicity

In terms of chronicity of the cervical pain, participants were asked for how many weeks they had suffered with the pain and the average for the Simillimum group was 119 weeks with the placebo group averaging 138 weeks. Therefore the placebo group was noted to have had the pain for an extended period of time than the Simillimum group.

5.3.6 Conclusion of demographic data

Furthermore, there were no statistical differences between the two groups, in terms of demographic data at the outset of the study. This indicates that both groups were similar at the outset and no biases and statistical adjustments could be proposed. This indicates that all the criteria were met in ensuring that homogeneity was evident in both groups.

5.4 RESULTS DISCUSSED WITH RESPECT TO THE SUBJECTIVE AND OBJECTIVE MEASURES

5.4.1 Numerical Pain Rating Scale

This scale was used to monitor levels of pain perception experienced by participants. A reduction in the mean score indicates a reduction in their pain experience. In this study, participants scored their pain at the initial consultation to determine a baseline. Further scoring was done at every consultation prior to treatment. This was done to establish conclusive evidence about the participant's pain in response to the treatment.

Chiropractic treatment in the form of spinal manipulation has been shown to be effective in reducing pain in patients suffering from neck pain (Giles and Muller 1999 and Windsor 2004). Furthermore Homoeopathic Simillimum has been shown to be superior over placebo in the treatment of musculoskeletal conditions such as osteoarthritis and rheumatoid arthritis in terms of pain and disability (Weiner and Ernst 2004).

As could be seen in Figure 4.1 and Table 4.6 the mean scores for NRS in the Simillimum group were 5.07, 4.20 and 2.80 respectively, the placebo group had mean scores of 5.00, 3.87 and 2.67 (rating out of a possible 10). When noticing the patterns, the Simillimum group showed higher levels for the NRS with a decreasing trend i.e. the groups total pain was slightly higher to start off with but the pain reduction was more significant than the placebo group, but not statistically significantly ($p = 0.850$). Futhermore as can be noted from Tables 4.13 and 4.14, the correlation value between NRS and NDI for both Simillimum and placebo was significant and directly proportional. As NRS increased, so did NDI, and vice versa.

Within the multiple regression tables there was a strong relationship noted between the dependent variable (NRS) and the independent variables (all other measures) for the placebo group. However in the ANOVA table the *p* - value was greater than 0.05, ($p = 0.136$ for placebo and $p = 0.684$ for Simillimum) and it therefore implied that the predictors do not collectively describe the dependent.

Overall both groups pain perception decreased over the three treatments however the Simillimum group did not fare better than the placebo group.

These results are in keeping with the above literature that states manipulation reduces participant's pain. However, participants were responsible for scoring themselves at every consultation which could have created a deviation. Furthermore, the Simillimum was administered in a relatively close time frame and may not have had a long enough window to become fully active.

5.4.2 CMCC Neck Disability Index

CMCC NDI was a questionnaire used to assess neck pain levels experienced by participants. The questionnaire was scored out of 50 and involves questions that investigate pain levels with regards to aggravating factors, relieving factors and day to day activity. Participants answered the questionnaire at initial consultation for a baseline reading and at every consultation before treatment to monitor progression and regression of pain (Vernon and Mior 1991). A reduction in the mean score indicates a reduction in their pain experience.

Spinal manipulation has shown to be an effective tool in reducing pain in patients suffering from neck pain (Giles and Muller 1999; Windsor 2004). Moreover Homoeopathic Simillimum has too been shown by Weiner and Ernst (2004) to be more potent than placebo in the treatment of musculoskeletal conditions in terms of pain and disability and therefore we expected the NDI to be reduced over consultations within this study.

The mean scores for NDI in the Simillimum group are as follows: 12.13, 9.93 and 7.93 with the placebo group means being: 13.27, 10.80 and 8.60. Therefore both groups were similar at the onset but the placebo group had a slightly higher average, however both groups readings decreased over time indicating an improvement in pain and ability yet not significantly so ($p = 0.560$). Futhermore as can be noted from Tables 4.13 and 4.14, the correlation value between NRS and NDI for both Simillimum and placebo was significant and directly proportional. As NRS increased, so did NDI, and vice versa.

Within the multiple regression tables there was a strong relationship noted between the dependent variable (NDI) and the independent variables (all other measures) for the placebo group. However in the ANOVA table the *p* - value was greater than 0.05, ($p = 0.903$ for placebo and $p = 0.428$ for Simillimum) and it therefore implied that the predictors do not collectively describe the dependent.

Overall both group's pain perception and disability decreased over the three treatments however the Simillimum group did not improve more than the placebo group.

5.4.3 Algometer

The Algometer was used within this study to measure the amount of force that the participant could tolerate around the neck region. An increase in readings indicated an increase in pain threshold resulting from decreased pain sensitivity.

Other research studies have shown us that spinal manipulation can resolve muscle guarding (Gibbon and Tehan 2001; Hong 2006) and aid in tissue release thereby reducing pain (Gatterman 1990; Simons, Travell and Simons 1999; Gross *et al*. 2002).

It is proposed that Homoeopathic remedies, such as those combined in Traumeel®S will also improve pain pressure threshold due to its anti-inflammatory and analgesic properties (Zenner and Metelman 1992; Birnesser *et al*. 2004).

The mean values for Algometer readings in the Simillimum group over the three sessions were 6.67, 6.97 and 7.01, and 6.96, 7.16 and 7.04 in the placebo group. Therefore both groups did improve in terms of pain sensitivity but not very noticeably or significantly (p = 0.604).

Within the correlation and multiple regression tables, there were some notable values amongst the data, however no solid correlations seemed to exist between the Algometer readings for both groups.

Overall both groups pain sensitivity was slightly reduced over the three sessions however not significantly and the Simillimum group fared the same as the placebo in all testing.

5.4.4 CROM-II Goniometer

The CROM-II Goniometer measures range of motion of the cervical spine. In this study flexion, extension, rotation and lateral flexion was assessed. Readings were taken at baseline and at every consultation before treatment to monitor changes in response to treatment (Youdas 1991).

Gatterman (1990) stated that the manipulative procedures correct abnormal joint movement, alignment and muscle imbalances. Homoeopathic Simillimum has been said to stimulate and strengthen the patient's intrinsic defence and curative mechanism (De Schepper 2000) and bring about healing and therefore should improve range of motion and reduce pain.

In terms of flexion, both groups had similar average baseline readings and both groups improved in terms of range of motion however not significantly (p = 0.597). In terms of extension, the Simillimum group had a higher mean baseline score average

however both groups improved in terms of range of motion though not significantly (p = 0.598).

In terms of rotation, the average rotational readings of the CROM-II Goniometer were higher in the similmum group, however an increasing trend in both groups was noticed, and this suggests both groups of participants had more range of motion with each treatment session. Some of the p - values are less than 0.05 (the level of significance), and this implies that a statistical difference was observed for CROM-II Goniometer right rotation (p = 0.038) i.e. the similmum group improved in terms of rotation on the right more so than the placebo group. This may be due to the intervention and theories mentioned above.

For lateral flexion, the average readings of the CROM-II Goniometer were similar in both groups and an increasing trend in both groups was noticed, and this suggests both groups of participants had more range of motion with each treatment session. A slight statistical significant value was noted for lateral flexion at the last session (p = 0.048) which is below 0.05 and therefore significant.

Within the correlation and multiple regression tables, there were some notable values amongst the data, however no solid correlations seemed to exist between the CROM-II Goniometer readings for both groups.

Overall both groups range of motion was slightly reduced over the three sessions and the Simillimum group improved significantly for right rotation however overall there was not a large significant change and the Simillimum group fared the same as the placebo.

5.5 CLINICAL SIGNIFICANCE

- NRS: A 1.39 change in the NRS is to be noted for MCID to be met for this parameter and for clinical significance to be reached (Kendrick and Strout 2005). Clinically significant improvement was achieved in 73.3% (eleven out of fifteen) of the participants in the Simillimum group, identical to the 73.3% (eleven out of fifteen) in the placebo group.

- NDI: The MCID for the CMCC NDI is a change of 10.5 for clinical significance to be met (Pool *et al.* 2007). Clinically significant improvement was achieved in 0% (zero out of thirty) of the total participants in this study.
- Algometer: The MCID is an improvement of 1.77kg.cm^2 for this parameter in order for clinical significance to be met (Chesterton *et al.* 2007). Clinically significant improvement was achieved in 6.6% (one out of fifteen) of the participants in the Simillimum group, compared to 0% (zero out of fifteen) in the placebo group.
- CROM-II Goniometer: No MCID exists for the Goniometer however it has been suggested by Vernon and Mior (1991) that a 20% change would be seen as clinically significant. In this study 0% (zero out of thirty) of the total participants made a 20% change in total Goniometer readings over the three sessions.

5.6 HOMOEOPATHIC REMEDIES

5.6.1 Homoeopathic remedies used in this study

Regarding the Homoeopathic prescriptions, it is important to note the remedies most commonly prescribed. The prescription of these remedies was based on a full, detailed Homoeopathic case history (Appendix C). Analysis of the case history resulted in a Simillimum being prescribed. The Homoeopathic *Materia Medica (*Vermeulen 2002) and The Essential Synthesis Homoeopathic repertory (Schroyens 2007) was used to confirm the selection of each remedy.

As can be seen by Table 4.27 and Figure 4.8, the most predominant remedies prescribed were *Pustilla nigricans, Delphinium staphisagria, Sepia officinallis and Rhus toxicodendron. Pulsatilla* was prescribed in 16.6% of the cases, *Staphisagria* in 13.3%, *Sepia* for 10% and *Rhus tox* for another 10% of all the cases. The main mental and physical symptoms of these four remedies are discussed below.

Pulsatilla nigricans is a member of the *Ranunculacea* family and as the name of the plant, wind flower, suggests it has great variability which is a prominent feature of a patient requiring this plant in Homoeopathic form. The patient may be described as tender-hearted, easily hurt or discouraged, but responding rapidly to kindness and

consolation (Sankaran 1997). Patients that require or were given this remedy are generally good-tempered, mild and yielding, but may exhibit surprising irritability if upset and can have moods that vary like the wind. Physically, they may be somewhat overweight, with a tendency to swelling of the feet and ankles, which feel tired and heavy (Vermeulen 2002). The veins may be distended and become varicose and any exudate produced is green or yellowish in colour (Morrison 1993). *Pulsatilla* patients also may have a tendency to bleed, with burning or itching pains that are relieved by cold applications (Sankaran 1997). The patient needing *Pulsatilla* needs lots of fresh air and is intolerant of heat.

Delphinium staphysagria is another remedy belonging to the plant kingdom family. These individuals are morbidly sensitive. They set themselves up for a task that is nearly impossible to achieve, but feel they have to in order to maintain their dignity despite being beaten down or insulted (Sankaran 1997). The main feeling in this remedy is an intense sense of pride and honour, which makes them appear haughty (Morrison 1993). They develop this feeling through their fear that others will see their weakness and thereby get power over him. They like to be superior to others and develop an anxiety of control; they must either control or they will be controlled. Pride, arrogance and tremendous ambition are characteristic of this remedy (Sankaran 1997).

Sepia officinalis is a remedy belonging to the animal kingdom and is made from the inky juice of the cuttlefish. The main feeling in this remedy is of being forced to undertake things opposed to her intentions and forced to accept situations against her will because of her feeling of not being good enough (Sankaran 1997). This is a predominantly female remedy in which the individual is trying to find a balance between domestic life and achieving in her career, but added to this is her need to be perfect in both areas of her life. It is said that *Sepia* can be a great career woman or a dedicated housewife. A state of collapse occurs when she cannot keep the balance anymore and life gets all too much for her to handle. In this situation, *Sepia* develops the mental symptoms of „stasis" where she has confusion, absent-mindedness, dullness and difficult thinking. They also develop and indifference to their loved ones and prefer to be left alone. She develops a negative attitude and is always nagging,

complaining and dissatisfied. They can also be very defensive and weepy (Vermeulen 2002).

Rhus toxicodendron is a plant from the *Loganiaceae* family and has an affinity for the joints and ligaments, producing arthritic symptoms. Mentally, Morrison (1993) describes several stages to the psychological state of *Rhus toxicodendron* where the early healthy stage depicts traits such as cheerfulness, friendliness and elevated levels of energy. This stage of the *Rhus tox* is replaced by inner restlessness, agitation, impatience and the patient becomes easily frustrated and irritable. Another common symptom of *Rhus tox* is a serious hardworking driven nature of the individuals (Vermeulen 2002). As the pathology deepens the *Rhus tox* patient experiences stiffness and rigidity on the physical and the emotional planes, feelings of depression and moroseness as well as apathy and tiredness may appear (Morrison 1993). Furthermore, *Rhus tox* has an elective action on the skin, mucosa, and nervous system and upon the periarticular fibro connective tissues namely the tendons and ligaments (Sankaran 1997). Patients often experience coldness, contraction, numbness, restlessness and stiffness of limbs, and with *Rhus tox* there is a sensation of paralysis and tearing pains. Most of these complaints are brought on by sprains, over lifting, overstretching or overwork and exposure (Boericke 2005). The main modality of *Rhus tox* is that symptoms are better for continued motion.

Most of these remedies are commonly used polychrests. Polychrests are generally better known and studied by Homoeopaths, and more extensively documented and represented in repertories. It is a possibility that the researcher may have missed the smaller, under-represented remedies over these polychrests, which may have hindered the prescribing of the true Simillimum.

An important aspect that must be considered in placebo-controlled studies with Homoeopathic Simillimum is that it often takes time to find the Simillimum. It is never a surety when analysing and prescribing on a case that the prescriber finds the ideal remedy at the first consult. This can even be a problem with experienced Homoeopaths, and since the researcher is only a student this may have contributed to the study's findings. With that being said, the researcher did discuss the case with

a fully qualified and experienced Homoeopathic clinician and therefore utmost care was taken to try avoid this.

An incorrect prescription is not always due to the Homoeopath's mistake. The patient could be withholding information for various reasons (e.g. abuse, shame, comfort) (De Schepper 2006), or could be finding difficulty describing their symptoms, leading to changeability and preventing the discovery of a clear symptom picture and the Simillimum. In such cases it may take time to gain the trust of the patient and clarify symptoms before you are shown the true symptom picture.

With this said Milgrom (2002: 244) has attempted to develop a metaphor for Homoeopathy based on the transactional interpretation of quantum mechanics. He mentioned that the 'medicine is to be seen not only in deterministic, biomedical terms but also within the context of an entangled relationship between the patient and the practitioner', therefore the 'wrong' remedy may still have great benefits due to the relationship between the practitioner and the patient.

In this study there were only three treatment sessions to find the Simillimum and in some cases it was felt that the true Simillimum was perhaps not given. Furthermore, in clinical practice one may have persisted with a remedy for longer before changing it but in the trial there was only limited time to prescribe and the decision that not enough change had been observed was made fairly hastily. This emphasises the importance of a longer duration study. Therefore in conclusion, a treatment that one cannot be sure is even being administered, is being compared to placebo, which could perhaps explain the similarity in results within the two groups.

5.6.2 Traumeel®S

As mentioned previously within the literature review, a Homoeopathic alternative to NSAIDS is Traumeel®S, as it fulfils all the criteria for a locally acting therapeutic medication (Zell *et al.* 1989). A study by Hepburn (2000), compared the efficacy of oral Traumeel®S against NSAIDs in the treatment of cervical facet syndrome, the results showed no statistical difference between the two treatment options.

However in this study, such results were not achieved, this may be due to the difference in remedies, potency and posology of the Traumeel®S. Traumeel®S ingredients and potencies are below:

Table 5.1 Table of remedies and potencies for Traumeel®S

Remedy	Potency
Arnica montana	D2
Calendula officinalis	D2
Hamamelis virginiana	D2
Achillea millefolium	D3
Atropa belladonna	D4
Aconitum napellus	D3
Mercurius solubilis Hahnemanni	D8
Hepar sulfuris	D8
Chamomilla recutita	D3
Symphytum officinale	D8
Bellis perennis	D2
Echinacea angustifolia	D2
Echinacea purpurea	D2
Hypericum perforatum	D2

As one can see from the above table, the potency of the Traumeel®S remedies are extremely low and there are many varying remedies, where as in this study, the potency is substantially higher and only one remedy was prescribed for the participant.

Therefore perhaps the more clinical and widespread approach may result in a more rapid and notable change within the participant.

5.7 PLACEBO

The well-known definition of placebo is that it is a tool that allows for objective and unbiased evaluation of a therapy in the context of a randomised control trial, as it is considered physiologically inactive. Double-blind, placebo-controlled procedure is seen as the only way to conclusively find out if the contribution and impact of the proposed treatment on the condition is making an impact effectively (Kupers and Marchand 2005). This is said to ensure the validity of the study in making sure the treatment is effective and not just the researcher or the participant imagining improvements. In this study the researcher, clinicians and participants were blind as to which participants were given placebo to rule out the possibility of inadvertently influencing the results. This was to give the results of the study further credibility.

When dealing with placebo-controlled studies one has to take into consideration the placebo effect. On statistical comparison between placebo and treatment, placebo treatment outcomes may in fact mask, diminish, or increase the calculated treatment effect (Diederich and Goetz 2008). Many improvements seen in clinical trials are a result of positive patient expectations.

Diederich and Goetz (2008) noted that greater placebo responses were documented in studies that had 50% placebo assignment likelihood to those with lower placebo assignment likelihood, bringing in the role of expectation. The placebo effect appears to be directly related to the level of uncertainty. This could be due to the fact that patients are aware that they may be on placebo and are thus more sensitised to any changes experienced and may be trying to determine for themselves whether they are on treatment or not. They will thus be primed and sensitised to the study, increasing the mental anticipation of improvement, making them more likely to show positive results. Placebo treatment may be one of the most effective medicines and is seen by some as the perfect medicine. The placebo effect may be regarded as a valid aspect of any therapeutic encounter and positive patient interaction. When one considers

placebo in this light it may be seen as a valid treatment, making the results admissible for consideration (Brooks 2008). It still does not bring us closer to the objective of this study (i.e. to determine the efficacy of Homoeopathic Simillimum in the treatment of CMNP) but does aid us in accepting that making direct comparisons with placebo is not quite so simple or conclusive. Taking these views into consideration makes the statistical insignificance of the results of this study a little less insignificant.

5.8 REVISION OF AIMS, OBJECTIVES AND HYPOTHESES OF THIS STUDY

The aim of this study was to determine if spinal manipulation in combination with Homoeopathic Simillimum are more effective than spinal manipulation and placebo in the treatment of CMNP. The specific objectives of this study were:

5.8.1 The first objective and hypothesis

5.8.1.1 The first objective

To compare spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by means of NRS.

5.8.1.2 The first null hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show no greater reduction in pain on the NRS than the spinal manipulation and placebo group. This null hypothesis was accepted as there was no statistical difference between the Simillimum and placebo groups.

5.8.1.3 The first alternative hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show greater reduction in pain on the NRS than the spinal manipulation and placebo group. This alternative hypothesis was rejected as there was no statistical difference between the Simillimum and placebo groups.

5.8.2 The second objective and hypothesis

5.8.2.1 The second objective

To compare spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by means of the CMCC NDI.

5.8.2.2 The second null hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show no greater improvement on the CMCC NDI than the spinal manipulation and placebo group. This null hypothesis was accepted as there was no statistical difference between the Simillimum and placebo groups.

5.8.2.3 The second alternative hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show greater improvement on the CMCC NDI than the spinal manipulation and placebo group. This alternative hypothesis was rejected as there was no statistical difference between the Simillimum and placebo groups.

5.8.3 The third objective and hypothesis

5.8.3.1 The third objective

To compare spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by using an Algometer, to measure participant's pain threshold.

5.8.3.2 The third null hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show no greater reduction in pain on the Algometer than the spinal manipulation and placebo group. This null hypothesis was accepted as there was no statistical difference between the Simillimum and placebo groups.

5.8.3.3 The third alternative hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show greater reduction in pain on the Algometer than the spinal manipulation and placebo group.

This alternative hypothesis was rejected as there was no statistical difference between the Simillimum and placebo groups.

5.8.4 The fourth objective and hypothesis

5.8.4.1 The fourth objective

To compare spinal manipulation and Homoeopathic Simillimum vs. spinal manipulation and placebo by using a CROM-II Goniometer to measure cervical spine range of motion

5.8.4.2 The fourth null hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show no greater improvement on the CROM-II Goniometer than the spinal manipulation and placebo group. This null hypothesis was accepted as there was no statistical difference between the Simillimum and placebo groups.

5.8.4.3 The fourth alternative hypothesis

The spinal manipulation and Homoeopathic Simillimum group will show greater improvement on the CROM-II Goniometer than the spinal manipulation and placebo group. This alternative hypothesis was rejected as there was no statistical difference between the Simillimum and placebo groups.

5.9 LIMITATIONS OF THE STUDY

- Even though a blinded independent research assistant performed all the objective and subjective parameter testing, it is possible that some of the objective data may have been subject to human error and observer bias (Mouton 1996).
- The Hawthorne effect (Mouton 1996) should be taken into account with respect to the subjective outcomes, this deals with the participants need to produce results that they believe the researcher wishes to see. Additionally, human error

(Mouton 1996) should too be taken into consideration despite efforts to reduce this completely.

5.10 CONCLUSION

This chapter focused on the results of this study and the theories based on the results as well as the objective and subjective parameter findings. As can be noted, the Homoeopathic Simillimum in combination with spinal manipulation did not has the impact that it was anticipated to have. This may be due to a variety of factors, namely the length of the study, the limited number of participants, the testing objectives or even the administering of medicines. Homoeopathy not only works on the physical level, as tested in this study, but the mental and emotional state of the patient too. This was not taken into account, participants may have benefited greatly but not on the physical level. Nevertheless, it can be seen that there is a gap within the literature when it comes to a multi-disciplinary approach to musculoskeletal disorders and further research conducted in this sphere would be of great benefit to the Complementary health field.

The following chapter will assess the conclusions, limitations and recommendations for future studies.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 INTRODUCTION

This chapter discusses the outcomes of this study and makes suggestions for future studies on CMNP and Homoeopathic Simillimum.

6.2 CONCLUSION

6.2.1 The aim of the study

The aim of this study was to determine if spinal manipulation and Homoeopathic Simillimum in combination are more effective than spinal manipulation and placebo in the treatment of CMNP. This was done via a blinded, randomised, comparative, placebo controlled quantitative clinical trial.

The goals were to determine whether associations existed between the change in the subjective and objective variables and the group's treatment protocol i.e. did the group that received similmum fare better than those who received placebo.

6.2.2 Summary

In conclusion, it can be seen that in this study both groups improved in terms of subjective pain and disability as well as objective pain and range of motion, however group A who received Simillimum and manipulation fared no better than group B who received placebo and manipulation. Both treatment regimens are thus below are the recommendations for further studies in this field.

6.3 RECOMMENDATIONS

Due to the fact that the Simillimum fared no better than the placebo in this study, the following further recommendations have been made that may improve the study methodology for future studies:

a. Participants with varying chronicity were allowed to enter the study. Therefore, participants with longer term pain logically would take a longer time to improve and for the subjective/objective outcomes to change than a participant with a more recent injury. To further ensure homogeneity and to perhaps improve results of future studies, the chronicity should be limited to a certain time frame of chronicity, or a stratification process could be incorporated in order to separate the varying stages of chronicity and therefore the chronicity should be capped to maintain homogeneity.
b. It is recommended that the study takes place over a larger time span. In this study the time span was 2 - 5 days between treatments and no longer than two weeks for all three treatments to be carried out. This time frame may be too small of a window for the Simillimum to work.
c. It is recommended that further research be carried out comparing Simillimum and placebo in combination style treatment, in other spinal conditions, in order to assess the generalizability of the study results to all joints/areas of the body.
d. Ideally, studies involving treatment with Simillimum should be carried out by experienced practitioners. They should be experienced both in Simillimum prescribing and the specific sample group or disorder that is being studied. This would decrease the variable of an inexperienced practitioner. To lessen the chance of conducting a placebo-controlled Simillimum trial with the incorrect Simillimum, a study design like Frei *et al*. (2007) whereby treatment with Simillimum is carried out until the participant reaches a pre-defined level of improvement should be implemented. After participants reach this level they are then randomly divided into a treatment and a placebo group and this second phase of the study is conducted as a double-blind placebo-controlled study, with

treatment being the individual's pre-determined Simillimum. This would mean a very long-duration study but a far more accurate method of comparing Simillimum with placebo. It would also lessen the impact of being in the placebo group, for the participants, as they would have had successful treatment before, and the placebo period was of a relatively short duration (6 weeks), compared to the treatment period (mean time of 5 months). The current study could not be conducted in this manner due to time and budget constraints.

e. Although generally ethically unsound, a study design incorporating a non-intervention group could eliminate the complication of placebo effect improvements.
f. When analysed, there were no statistically significant differences between the two groups in terms of ethnicity, age, gender, occupation etc. in this study. However the population that participated was a small representation of the South African population and a sample with varying stratified ethnicity groups, ages, genders and occupations etc. may construct a greater clinical picture. In order to ensure homogeneity (in future studies) and ensure that no statistically significant difference occurs (in future studies), stratification of ethnicity groups as well as other variables e.g. age, gender, and occupation is recommended where possible.
g. This study was conducted on thirty participants, 15 in each group, another recommendation to be made is to repeat the study with larger numbers to allow for a more accurate assessment.
h. To standardise the repertory process (process of choosing the Simillimum remedy), a software program can be chosen and only this be used to determine the correct remedy for the participant.

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Appendix A Advertisement

Do you suffer with

neck pain?

And are between the ages of 18-55?

Research is currently being conducted and free treatment is now available at the Durban University of Technology Homoeopathic Clinic for those who qualify.

Please contact Kym Belling 031-3732041 for information or an appointment!

Appendix B

LETTER OF INFORMATION

Dear Participant

Title of the Research Study: The relative effectiveness of the combination of spinal manipulation and Homoeopathic Simillimum in the treatment of chronic mechanical neck pain.

Principle Investigator/s/researcher: Dr Kym Belling (M.Tech:Chiro) (B.Tech:Hom)
Co-Investigator/s/supervisor/s: Dr I Couchman (M.Tech:Hom) and Dr D Lubbe (M.Tech:Chiro)

Brief Introduction and Purpose of the Study:
Outline of the Procedures: Welcome and thank you for taking part in this research study. You have been chosen to take part in this study, which is comparing two forms of treatment for your neck pain at the Homoeopathy Clinic at DUT. Neck pain is a common condition treated by Homoeopaths, and therefore different types of treatments need to be tested to help the profession get more knowledge for better treatment outcomes for the patient.

This study will involve two groups of fifteen participants. One group will receive a Homoeopathic medicine as well as spinal manipulation and the other group will receive a placebo medicine and spinal manipulation. However the placebo group will be offered Homoeopathic treatment after the end of the study. You will be randomly allocated to a group and shall receive three treatments over a period of one week. The initial visit will be an hour and half at maximum, and the follow up visits will be half an hour with tests and treatment performed at each visit.

Risks or Discomforts to the Participant: Spinal manipulation may cause brief discomfort and some post treatment soreness in participants. However the potential discomfort is relatively low in this study.

Benefit: The benefit of being part of this study is that you will possibly gain pain relief for their neck pain.

Reason/s why the Participant May Be Withdrawn from the Study: You are not forced to partake in the study and may withdraw at any given time. However you may be taken off the study if you do not follow the instructions carefully, or become ill or have adverse reactions to the treatment.

Remuneration: You will not receive any money for taking part in this study.

Costs of the Study: You will not have to pay any monies for taking part in the study.

Confidentiality: Participant confidentiality will be maintained at all times with only the researcher knowing the results and consult details (numbers will be used instead of names). You may request to see the results at the end of the study. The full research thesis will be made available at the DUT library.

Research-related Injury: In common with all medical treatment, no assurance can be given that no injury will be sustained during treatment however utmost care will be taken to provide the best treatment and service to the participants.

Persons to Contact in the Event of Any Problems or Queries:
Please contact the researcher Kym Belling (0845867768), my supervisor Dr Ingrid Couchman (031-3732482) or the Institutional Research Ethics administrator on 031 373 2900. Complaints can be reported to the DVC: TIP, Prof F. Otieno on 031 373 2382 or dvctip@dut.ac.za.

Thank you for your time and investment in this study.

Thank you
Dr Kym Belling (M.Tech:Chiro) (B.Tech:Hom)
Dr I Couchman (M.Tech:Hom) and Dr D Lubbe (M.Tech:Chiro)

CONSENT

Statement of Agreement to Participate in the Research Study:

I hereby confirm that I have been informed by the researcher, _____ (name of researcher), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: _____,

I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.

I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.

In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.

I may, at any stage, without prejudice, withdraw my consent and participation in the study.

I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

_____ _____ _____ _____

Full Name of Participant Date Time Signature / Right Thumbprint

I, _____ (name of researcher) herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

_____ _____ _____

Full Name of Researcher Date Signature

_____ _____ _____

Full Name of Witness (If applicable) Date Signature

_____ _____ _____

Full Name of Legal Guardian (If applicable) Date Signature

Appendix C (Rajballi 2015).

Homoeopathic Case History

Date of case history_____
Patient Number: _____
Surname: _____
First names: _____
Address: _____
Telephone no: (work) _____ (home) _____ (cell) _____
Sex: _____ Age: _____
Marital status: _____
No. of children: _____
Occupation: _____

Main Complaint

History, onset, location, aetiology, duration, character, modalities, concomitant symptoms, radiation, sensation.

Past medical and surgical history

Any past surgeries or serious diseases that may or may not have required hospitalization.

Past Drug History

Includes any medication the patient may have been on in the past or is currently taking.

Vaccination

Allergies

Childhood Diseases

Mumps, measles, chicken pox, German measles, tuberculosis

Family History

TB, diabetes, heart disease, hypertension, stroke, eczema, asthma, arthritis, sinusitis, hay fever, cancer, mental illness, miscarriage.

Father

Mother

Grandparents: Maternal and Paternal

Siblings

Children

Social History

Drug abuse, smoking, alcohol: how much and how often

Generals

Menses

Gastro-intestinal: Appetite
Desires or cravings
Aversions
Aggravations or allergies
Bowel movements
Urination
Thirst

Energy levels

Weather preferences and modalities

Sleep: position, dreams

Perspiration including quantity and location

Libido

Mental and Emotional

Fears, phobias, apprehensions, traumas, losses, grief, failure, worries.

Systems Review

Head: Headaches, location, frequency, duration, sensation, modalities

Hair: hair loss, change in texture

Eyes: Vision, pain, redness, discharge

Ear: Hearing difficulties, tinnitus, vertigo, earache, discharges, itching

Nose and Sinuses: Pain, congestion, discharge, hay fever or sinusitis, rhinitis, smell

Teeth: loss of teeth, discolouration

Throat: Pain, dysphagia, swollen glands

Respiratory system: difficulty breathing, cough, sputum, asthma, TB

Cardiovascular system: Chest pain, hypertension, heart disease

Gastro-intestinal system: Bowel habits, haemorrhoids, bleeding, abdominal pain, flatulence, gastric ulcers, colitis, Irritable bowel syndrome

Urogenital system: difficulty urinating, frequency, colour, rashes, sores, warts, leucorrhoea

Musculo-skeletal: arthritis, joint pain, stiffness, gout

Neurological: numbness, paralysis, loss of function, weakness

Endocrine: Thyroid function, Diabetes

Skin: acne, warts, eczema, psoriasis, fungal infections

Nails: deformation, brittleness, marks or colours

Appendix D (Abdul-Rasheed 2013).

DURBAN UNIVERSITY OF TECHNOLOGY
REGIONAL EXAMINATION - CERVICAL SPINE

Patient: _____ File No: _____

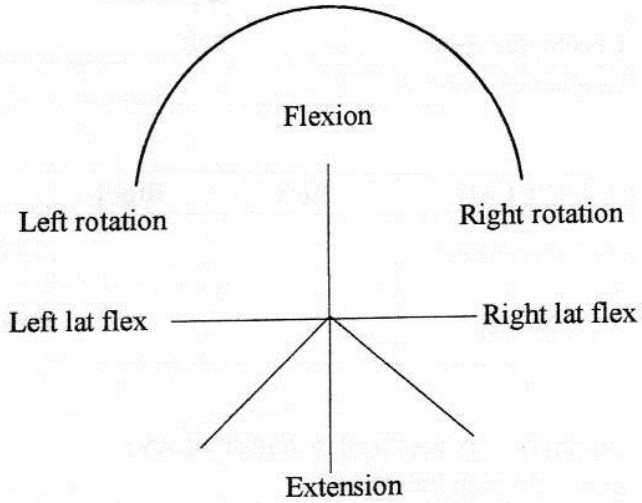
Date: _____ Student: _____

Clinician: _____ Sign: _____

OBSERVATION:
Posture
Swellings
Scars, discolouration
Hair line
Body and soft tissue contours

Shoulder position
Left :
Right :
Shoulder dominance (hand):
Facial expression:

RANGE OF MOTION:
Extension (70°):
L/R Rotation (70°):
L/R Lat flex (45°):
Flexion (45°):



PALPATION:
Lymph nodes
Thyroid Gland
Trachea

ORTHOPAEDIC EXAMINATION:

Tenderness		Right	Left
Trigger Points:	SCM		
	Scalenii		
	Post Cervicals		
	Trapezius		
	Lev scapular		

	Right	Left		Right	Left
Doorbell sign			Cervical compression		
Kemp's test			Lateral compression		
Cervical distraction			Adson's test		
Halstead's test			Costoclavicular test		
Hyper-abduction test			Eden's test		
Shoulder abduction test			Shoulder compression test		
Dizziness rotation test			Lhermitte's sign		
Brachial plexus test					

NEUROLOGICAL EXAMINATION:

Dermatones	Left	Right	Myotomes	Left	Right	Reflexes	Left	Right
C2			C1			C5		
C3			C2			C6		
C4			C3			C7		
C5			C4					
C6			C5					
C7			C6					
C8			C7					
T1			C8					
			T1					

Cerebellar tests:	Left	Right
Disdiadochokinesis		

VASCULAR:	**Left**	**Right**	**Left**	**Right**
Blood pressure			Subclavian arts.	
Carotid arts.			Wallenberg's test	

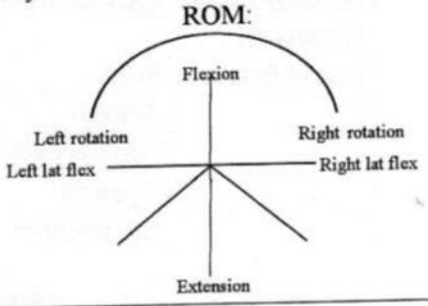
MOTION PALPATION & JOINT PLAY:
Left: Motion Palpation:
Joint Play:
Right: Motion Palpation:
Joint Play:

BASIC EXAM: SHOULDER:
Case History:

ROM: Active:
Passive:
RIM:
Orthopaedic:
Neuro:
Vascular:

BASIC EXAM: THORACIC SPINE:
Case History:

ROM:



Motion Palpation:	
Orthopaedic:	
Neuro:	
Vascular:	
Observ/Palpation:	
Joint Play:	

Appendix E (Jensen, Karoly and Braver 1986).

Numerical Pain Rating Scale

Participant name/number:_____ Age:_____

Date:_____

Kindly circle your current pain rating with 0 being the least and 10 the worst

0 1 2 3 4 5 6 7 8 9 10

Appendix F (Vernon and Mior 1991).

CMCC Neck Disability Index

Participant Name/Number: _____ Age: _____
Date: _____

This questionnaire has been designed to ascertain information as to how your neck pain has affected your ability to manage in everyday life.
Please answer every section and mark in each section only the ONE box which applies to you.

	Section 1 – Pain intensity		**Section 2 – Personal care (Washing and Dressing)**
	I have no pain at the moment.		I can look after myself normally without causing extra pain.
	The pain is very mild at the moment.		I can look after myself normally but it causes extra pain
	The pain is moderate at the moment.		It is painful to look after myself and I am slow and careful.
	The pain is fairly severe at the moment.		I need some help but manage most of my personal care.
	The pain is very severe at the moment.		I need help every day in most aspects of self-care.
	The pain is the worst imaginable at the moment.		I do not get dressed, I wash with difficulty and stay in bed.
	Section 3 – Lifting		**Section 4 – Reading**
	I can lift heavy weights without extra pain.		I can read as much as I want to with no pain in my neck.
	I can lift heavy weights but it gives extra pain.		I can read as much as I want to with slight pain in my neck.
	Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example on a table.		I can read as much as I want with moderate pain in my neck.
	Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.		I cannot read as much as I want because of moderate pain in my neck.
	I can lift very light weights		I can hardly read at all because of severe pain in my neck.
	I cannot lift or carry anything at all.		I cannot read at all.
	Section 5 – Headaches		**Section 6 – Concentration**
	I have no headaches at all		I can concentrate fully when I want to with no difficulty.
	I have slight headaches which come infrequently.		I can concentrate fully when I want to with slight difficulty.
	I have moderate headaches which come infrequently.		I have a fair degree of difficulty in concentrating when I want to.
	I have moderate headaches which come frequently.		I have a lot of difficulty in concentrating when I want to.
	I have severe headaches which come frequently		I have a great deal of difficulty in concentrating when I want to.
	I have headaches almost all the time.		I cannot concentrate at all.

	Section 7 – Work		**Section 8 – Driving**
	I can do as much work as I want to.		I can drive my car without any neck pain.
	I can only do my usual work, but no more		I can drive my car as long as I want with slight pain in my neck.
	I can do most of my usual work, but no more.		I can drive my car as long as I want with moderate pain in my neck.
	I cannot do my usual work.		I cannot drive my car as long as I want because of moderate pain in my neck.
	I can hardly do any work at all.		can hardly drive at all because of severe pain in my neck.
	I cannot do any work at all.		I cannot drive my car at all.
	Section 9 – Sleeping		**Section 10 – Recreation**
	I have no trouble sleeping.		I am able to engage in all my recreation activities with no neck pain at all.
	My sleep is slightly disturbed (less than 1 hr sleepless).		I am able to engage in all my recreation activities, with some pain in my neck.
	My sleep is mildly disturbed (1-2 hrs sleepless).		I am able to engage in most, but not all of my usual recreation activities because of pain in my neck.
	My sleep is moderately disturbed (2-3 hrs sleepless).		I am able to engage in a few of my usual recreation activities because of pain in my neck.
	My sleep is greatly disturbed (3-5 hrs sleepless).		I can hardly do any recreation activities because of pain in my neck.
	My sleep is completely disturbed (5-7 hrs sleepless).		I cannot do any recreation activities at all.

Scoring and interpretation

Each item is scored out of five (with the no disability response given a score of 0) giving a total score for the questionnaire out of 50. Higher scores represent greater disability. The result can be expressed as a percentage (score out of 100) by doubling the total score..

An NDI score of >40/100 at initial assessment (first consultation following an injury) is associated with ongoing pain and disability after whiplash. The guidelines indicate that 'recovery' is represented by an NDI score of less than 8/100, at which time treatment should be ceased.

Appendix G (Potter, McCarthy and Oldham 2006).

Algometer sheet

Participant Name/Number: _____ Age: _____

Date: _____

	Initial consult			**Follow up (1)**			**Follow up (2)**		
DATE									
READING									

Appendix H (Arrandale 2005).

CROM-II Goniometer sheet

Participant name/number: _____ Age:_____
Date: _____

Normal Range of Motion	**Initial Consult**	**Follow up (1)**	**Follow up (2)**
Flexion (45 -90°)			
Extension (55-70°)			
Right Rotation (70 -90°)			
Left Rotation (70-90°)			
Right Lateral Flexion (20-45°)			
Left Lateral Flexion (20-45°)			

Appendix I SOAPE Note

DURBAN UNIVERSITY OF TECHNOLOGY

Patient Name: ***File #:*** ***Page:***

Date: ***Visit:*** ***Intern:***

Attending Clinician: ***Signature:***

S: ***Numerical Pain Rating Scale (Patient)*** ***Intern Rating*** ***A:***

Least 0 1 2 3 4 5 6 7 8 9 10 Worst

☐

0: ***P:***

E:

Special attention to: ***Next appointment:***

Date: ***Visit:*** ***Intern:***

Attending Clinician: ***Signature:***

S: ***Numerical Pain Rating Scale (Patient)*** ***Intern Rating*** ***A:***

Least 0 1 2 3 4 5 6 7 8 9 10 Worst ☐

O: ***P:***

E:

Special attention to: ***Next appointment:***

Date: ***Visit:*** ***Intern:***

Attending Clinician: ***Signature***

S: ***Numerical Pain Rating Scale (Patient)*** ***Intern Rating*** ***A:***

Least 0 1 2 3 4 5 6 7 8 9 10 Worst ☐

O: ***P:***

E:

Special attention to: ***Next appointment:***

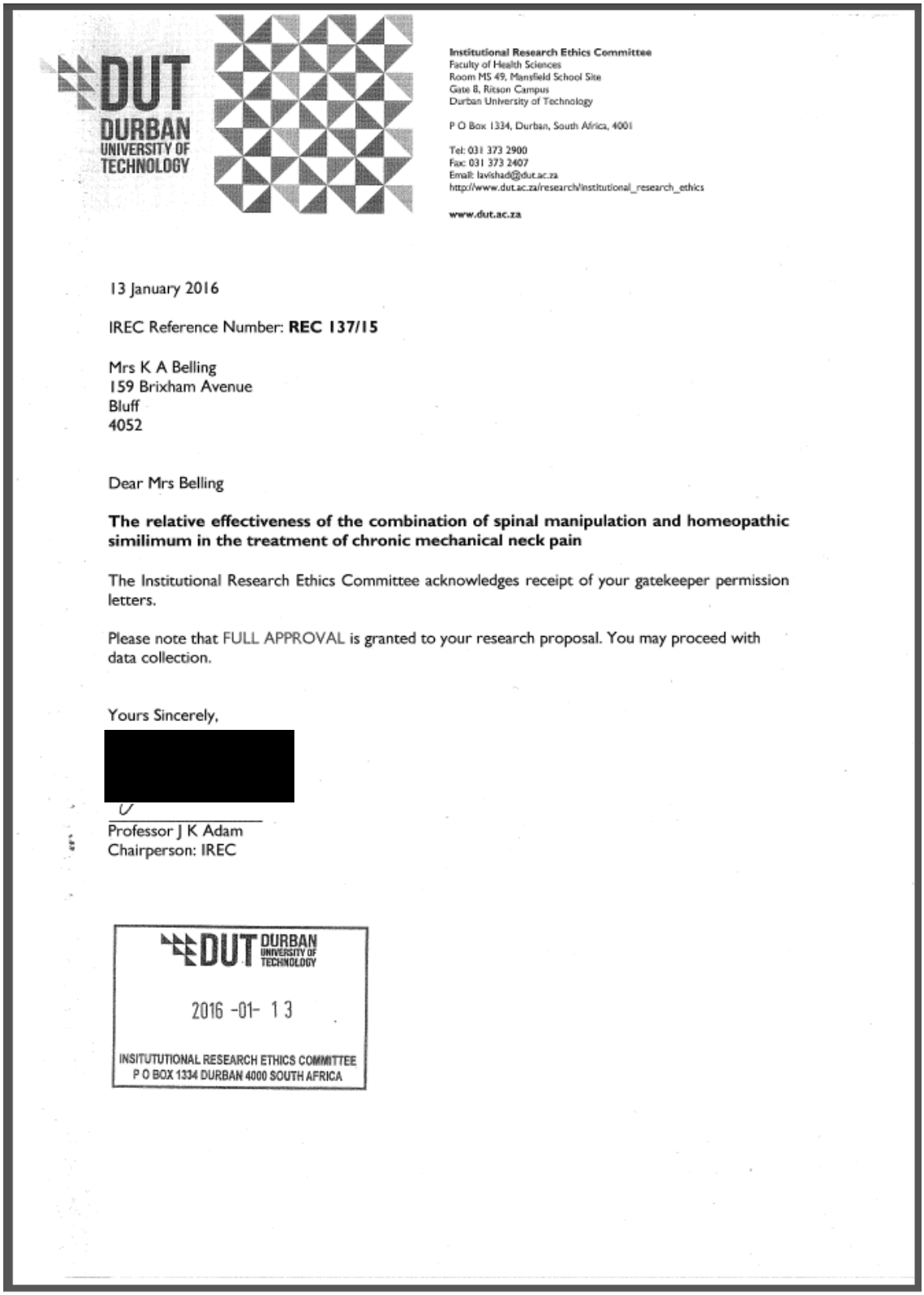
Appendix J

RANDOMISATION TABLE FOR DR KYM BELLING

DRAWN UP BY DR M MAHARAJ ON 12/10/2015

PARTICIPANT NUMBER	GROUP ONE Spinal manipulation and Simillimum	GROUP TWO Spinal manipulation and placebo
1	√	
2	√	
3		√
4	√	
5		√
6		√
7	√	
8	√	
9		√
10	√	
11		√
12	√	
13		√
14		√
15	√	
16		√
17	√	
18		√
19		√
20	√	
21	√	
22		√
23	√	
24		√
25	√	
26	√	
27		√
28	√	
29		√
30		√
31		√
32	√	
33		√
34	√	

Appendix K DUT Ethics Clearance



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www.dut.ac.za

13 January 2016

IREC Reference Number: **REC 137/15**

Mrs K A Belling
159 Brixham Avenue
Bluff
4052

Dear Mrs Belling

The relative effectiveness of the combination of spinal manipulation and homeopathic similimum in the treatment of chronic mechanical neck pain

The Institutional Research Ethics Committee acknowledges receipt of your gatekeeper permission letters.

Please note that FULL APPROVAL is granted to your research proposal. You may proceed with data collection.

Yours Sincerely,

[redacted]

Professor J K Adam
Chairperson: IREC

DUT DURBAN UNIVERSITY OF TECHNOLOGY
2016 -01- 13
INSITUTUTIONAL RESEARCH ETHICS COMMITTEE
P O BOX 1334 DURBAN 4000 SOUTH AFRICA

Appendix L Medication details

Details of Granules and Alcohol used in Medicine and Placebo preparation

Granules: Fushion Homoeopathic, unmedicated granules, BN: I15027, EXP: 05/2017. Contains sucrose.

Alcohol standards: Anhydrous alcohol 99.9%, Illovo- 72 Ballantree Road Merebank Durban 4052. IMO shipping, ethanol, hazchem code: 2 SE, PRODUCT REFERENCE: 500, BATCH NUMBER 52/12/67, CLASS3, 25 LT, UN NUMBER: 1170.