The Relative Effectiveness of Homoeopathic Simillimum Versus Oral Traumeel® in the Treatment of Acute Mechanical Neck Pain

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

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In loving memory of my brother Shivez Talish Rajballi.
For being my shepherd along this journey.

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ABSTRACT

INTRODUCTION

There is no proper definition of acute mechanical neck pain (AMNP) but it has been theorized that it has a sudden onset pain and lasts for a relatively short time. It occurs with or without injury and presents with pain in the shoulder and upper arm. Acute mechanical neck pain should not be accompanied by an inflammatory disease, neurological disease, fracture, dislocation, neoplasm or infection

AIM

The purpose of this study was to compare the relative effectiveness of homoeopathic Simillimum against Traumeel® (a commercial homoeopathic complex) in the treatment of acute mechanical neck pain using the neck disability scale, range of motion measurements and a subjective observation.

METHODOLOGY

This study was a double blind, quantitative, comparative; clinical trial that involved two treatment groups: Half the participants received the homoeopathic Simillimum and the other half received oral Traumeel® drops.

Patients self-selected homoeopathic treatment. Patients were screened and only those who fit the inclusion criteria of suffering from AMNP of maximal two weeks duration, were English conversant and between the ages of 18 and 55 were included. Those suffering with AMNP were required to sign an informed consent form after the procedure was explained thoroughly. Each patient read through the procedure of the clinical trial and were informed that their participation was on a voluntary basis and they could withdraw at any time.

Convenience sampling was utilised in which an independent person, using a simple sampling method, randomly allocated the patients into the respective groups. Of the 30 patients, 15 received Traumeel® and 15 received homoeopathic Simillimum. It was hypothesized that the homoeopathic Simillimum treatment would be more effective in the treatment of acute mechanical neck pain than oral Traumeel®.

The treatment protocol consisted of three homoeopathic consultations within a seven day period, with the consultations scheduled on days one, three and seven. Subjective and objective measurements were taken at each of the three consultations, Durban University of Technology Homoeopathic Day Clinic, Steve Biko Campus.

A Simillimum treatment was prescribed for every patient based on full homoeopathic case history. This Simillimum was confirmed by the co-supervisor. Half of the patients were dispensed the Simillimum and the other half received Traumeel® according to the randomisation list.

At the first follow up, on day three, the patients were reassessed according to their progress, perception and their range of motion, and the progress of the patient was analysed. In the last consultation on day seven, the progress of the patient was analysed using the perceptive questionnaire of the Neck Disability Index and the objective cervical range of motion. Full physical examinations were carried out during all three consultations.

Upon collection of data, the statistical package SPSS 22.0 was used to record and analyse the data. Non parametric statistical tests were used as the data were non parametric - it does not follow any distribution, was ordinal (not relying on numbers but rather a ranking order of sorts). Inter-group comparisons were made using Mann-Whitney U-test.

RESULTS

The effectiveness of Traumeel® and homoeopathic Simillimum was measured firstly, in terms of the patients' perception of the responses to the treatment applying the Neck Disability Index and secondly the increase in degree of movement in the range of motion of the cervical region.

When applying an ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores between groups were statistically not significantly different ($p = 0.112$).

CONCLUSION

Both the Traumeel® and Simillimum treatments were effective in the treatment of acute mechanical neck pain, but there was no evidence that one treatment was more beneficial than the other. The p-values (sig.) reported were greater than 0.05, thus implying that there is no significant difference between the groups.

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DEFINITION OF TERMS

Acute mechanical neck pain

Acute mechanical neck pain which is theorized to have a sudden onset and lasts for a relatively short time. AMNP occurs with or without injury and presents with pain in the shoulder and upper arm. AMNP should not be accompanied by an inflammatory disease, neurological disease, fracture, dislocation, neoplasm or infection.

Complex

Simultaneous prescription of two or more remedies to treat a particular disease. This method of treatment entails no individualization like Simillimum treatment. Many patients suffering from a condition will receive the same medicine (O'Reilly, 2001).

Simillimum

According to Gaier (1991:509), Simillimum is defined as the single Homoeopathic medicine, prescribed according to the drug picture of which most nearly approaches the total symptom complex of the patient. The Simillimum should cure the patient if the patient's condition is within reversible limits.

Cervical Range of Motion

Cervical Range of Motion instrument used to measure neck disability and has shown good intra and inter examiner reliability in measuring patients cervical ranges of motion (Youdas, 1991).

Bone and Joint decade

The Bone and Joint decade is an initiative by the United Nations and the World Health Organization to advance musculoskeletal health throughout the world. The neck pain task team recommended that patients seeking treatment for their neck ailment be categorised into 4 groups. Patients with Grade I and Grade II neck pain, required non- invasive treatment for short term relief.

LIST OF ABBREVIATIONS

AMNP - Acute mechanical neck pain

AE - Adverse Events

BJD - Bone and Joint

COX - Cyclo-oxygenase

COX 1 - Cyclo-oxygenase 1

COX 2 - Cyclo-oxygenase 2

CROM - Cervical Range of Motion

ECCH - The European Council for Classical Homoeopathy

NDI – Neck Disability Index

NSAID - Non steroidal inflammatory drugs.

SADR - Serious Adverse Drug Reactions

SAE - Serious Adverse Events

CHAPTER 1

INTRODUCTION

Acute mechanical neck pain is a common neuromusculoskeletal disorder around the world. There is no proper definition of acute mechanical neck pain (AMNP) but it has been theorized that it has a sudden onset pain and lasts for a relatively short time. It occurs with or without injury and presents with pain in the shoulder and upper arm. Acute mechanical neck pain should not be accompanied by an inflammatory disease, neurological disease, fracture, dislocation, neoplasm or infection (Haneline, 2004).

According to the research published by Vos, Verhagen, Passchier and Koes, (2007), acute mechanical neck pain complaints in primary healthcare is common and the role of general practitioner in management of this condition has yet to be described.

Homoeopathy plays an important role in the treatment of any back pain or injury to the spine, including the neck, to increase muscle tone, improve general health and to decrease inflammation of muscles and nerves (Morrison, 1998).

The parameters of treatment protocol lack documented effective long term management of this condition in the allopathic regime. Thus, there is a need for alternate treatment. AMNP and other acute mechanical muscles spasms and pain have been effectively treated by Homoeopathic Simillimum and complexes such as Traumeel® in the past (Arora *et al.*, 2002).

Traumeel® is a homoeopathic complex which is widely used to treat acute muscle spasms and pain. It had been used in United States since 1986 and in Germany since 1937 (Arora, Harris & Scherer, 2002). Traumeel® consists of 12 botanical and one mineral substance and is safe and well tolerated by patients (Arora *et al.*, 2002).

1.1 CONTEXT OF RESEARCH

In the United States it is prevalent in 13-18% of the general population (Haneline, 2004). The prevalence of neck pain among the Indian population in Durban, South Africa is 37%, with an annual incidence of 29% (Muchna, 2011).

AMNP has a huge impact on the wellbeing and quality of life of sufferers. Two-thirds of the population will experience neck pain at some point in their life (Binder, 2006). Only 15–27% of individuals seek a healthcare provider for neck pain, they simply wait and suffer through the pain (Woolf, Zeidler, Haglund, Carr, Chaussade, Cucinotta, Veale & Mola, 2004).

Allopathic treatment for most pain is usually nonsteroidal anti-inflammatory drugs (Koes, Scholten, Mens, Bouter, 1997). There are many side effects of NSAID's, and these include indigestion, stomach ulcers, gastrointestinal bleeding, anaemia, shortness of breath and tiredness (NHS, 2012). Thus the need for a safe alternative is in demand.

Alternate treatment of AMNP eg: homoeopathy needs to be explored due to many reasons.
Homoeopathy is a non-invasive, cost effective safe and nontoxic (Jayasuria, 2010). According to Weiner, Ernst (2004), in muscular skeletal conditions, such as osteoarthritis and rheumatoid arthritis , homoeopathic Simillimum is shown to be superior over placebo.
Traumeel® has potentially many uses in this form and is a "broad spectrum" musculoskeletal treatment. Traumeel® acts homoeopathically as anti-oedematous, anti-exudative, anti-inflammatory analgesic, thus is used to treat inflammation and injuries by stimulating wound healing, providing pain relief, stopping bleeding, improving muscle tone, and has a potential antiviral effect (Arora *et al.*, 2002).

Thus in light of the above information it is appropriate that alternative therapies, such as homoeopathy, be carefully researched and be made available to the public. Homoeopathy does not produce any side effects and aims to increase the quality of life as it heals (De Schepper, 2005:455).

1.2 PROBLEM STATEMENT

Neck pain is one of the most common musculoskeletal complaints (Vos, Verhagen, Passchier & Koes, 2007). There is a lack of clinical guidance as well as effective therapeutic interventions for neck pain thus this has prompted a variety of treatments and referrals. Prevalence rates of neck pain in general practice have been estimated to be between 18 and 23 per 1000 registered patients per year (Vos, Verhagen, Passchier & Koes, 2007).

AMNP is rife in the community and efforts to improve the quality of life of sufferers needs to be addressed.

1.3 AIM OF THE STUDY

This aim of this study was to compare the relative effectiveness of homoeopathic Simillimum against Traumeel® (homoeopathic complex) in the treatment of acute mechanical neck pain using the neck disability scale, range of motion and observation.

1.4 OBJECTIVE OF THE STUDY

The following information was ascertained:

- The effectiveness of homoeopathic Simillimum in the treatment of acute mechanical neck pain.
- The effectiveness of oral Traumeel® complex in the treatment acute mechanical neck pain.
- The relative effectiveness of the two treatment methods in the treatment of acute mechanical neck pain.

1.5 HYPOTHESES

- The homoeopathic Simillimum is effective in the treatment of acute mechanical neck pain.
- The oral Traumeel® complex is effective in the treatment of acute mechanical neck pain.

- The homoeopathic Simillimum is more effective than the oral Traumeel® complex in the treatment of acute mechanical neck pain.

1.6 DELIMITATIONS

This study did not:

- Seek to investigate the effectiveness of other dosage forms of Traumeel®
- Test a population above the age of 55 as they were considered a higher risk of organic disease.

The advantage of the convenience sampling method was that it was cheap and executed quickly. Disadvantages are that it can lead naturally to sampling error and bias (Ally, 2013).

1.7 ASSUMPTIONS

It was assumed that:

- All participants adhered to the treatment regime
- No patient received any treatment outside this study for their AMNP
- Participants did not change their lifestyles, such as initiate daily neck exercises, for the duration of the study.

1.8 CONCLUSION

Research needs to be continually conducted into safer, more effective ways of treatment for AMNP. Vast amounts of time and money are invested into pharmaceutical companies to design new drugs for pain relief, which may still produce unwanted side effects. By conducting a case study using homoeopathic Simillimum and a homoeopathic complex, one is able to ascertain whether homoeopathic treatment produced a positive effect on AMNP.

CHAPTER 2

REVIEW OF RELATED LITERATURE

2.1 DEFINITION AND CLASSIFICATION

There is no proper definition of acute mechanical neck pain (AMNP) but, as mentioned in the abstract, it has been theorized that it has a sudden onset pain and lasts for a relatively short time it occurs with or without injury. It presents with pain in the shoulder and upper arm. Acute mechanical neck pain should not be accompanied by an inflammatory disease, neurological disease, fracture, dislocation, neoplasm or infection (Haneline, 2004).

Neck pain is pain located in the anatomical region of the neck (C1-C8) which may or may not radiate to the head, trunk, and upper limbs (Guzman, Haldeman, Carroll, Carragee, Hurwitz, Peloso, Nordin, Cassidy, Holm, Côté, Velde & Johnson, 2008). Non-specific neck pain is defined as simple neck pain without a specific underlying disease that causes the pain. There are different forms of neck pain, namely acute, subacute or chronic neck pain (Tsakitzidis, Remmen, Peremans, Van Royen, Duchesnes, Paulus, Eyssen, 2009). Neck pain is divided into four groups or grades rating from least harmful to most (Guzman *et al.*, 2008).

Acute mechanical neck pain usually requires non-invasive treatment and is not as serious as those associated with a disease or with a degenerative process (Guzman *et al.*, 2002).

2.2 INCIDENCE AND PREVALENCE

Two-thirds of the population will experience neck pain at some point in their life (Binder, 2006), thus making it one of the most common musculoskeletal complaints (Vos, Verhagen, Passchier & Koes, 2007). Prevalence rates of neck pain in general practice has been estimated to be between 18 and 23 per 1000 registered patients per year (Vos, Verhagen, Passchier & Koes, 2007).

2.3 AETIOLOGY

AMNP usually results from injuries such as whiplash, caused by automobile accidents. Whiplash is defined as hyperextension of the soft tissues in the neck. This causes trauma which is absorbed by the ligaments and muscles which are stretched (Luc De Schepper, 1994). This results in bones, muscles, intervertebral disc-facet joints, tendons, and ligaments being injured which cause pain. AMNP is also associated with normal activities, such as awkward sleeping positions, prolonged static postures (office work) or are idiopathic (Haneline, 2004). Torticollis is another cause and defined as a painful rotation of the neck with the tilting of the head to the opposite direction (Luc De Schepper, 1994).

2.4 THE BONE AND JOINT DECADE TASK TEAM

The Bone and Joint decade (BJD) is an initiative by the United Nations and the World Health Organization to advance musculoskeletal health throughout the world. The neck pain task team recommended that patients seeking treatment for their neck ailment are categorised into four groups:

- Grade I neck pain with no signs of major pathology and no or little interference with daily activities
- Grade II neck pain with no signs of major pathology, but interference with daily activities
- Grade III neck pain with neurologic signs of nerve compression
- Grade IV neck pain with signs of major pathology (Guzman *et al.*, 2002)

This article concluded that the best treatment for Grade I and Grade II would be non-invasive treatment for short-term relief. This research would thus concentrate on Grade I and Grade II.

2.5 TREATMENT

2.5.1 SURGERY

Surgery is recommended to patients with combined neck or radicular pain with neurologic symptoms and signs which are confirmed using imaging studies showing neurological

compression. Surgery can relieve specific nerve impingement (Guzman *et al.*, 2002). These cases are classified as Grade III or Grade IV according to the BJD (Guzman *et al.*, 2002).

2.5.2 NON STEROIDAL INFLAMMATORY DRUGS

These drugs are usually used as an analgesic. This group of drugs are commonly used for pain with inflammation and fever. Prostaglandins are produced within the body's cells by the enzyme cyclo-oxygenase (COX). There are two COX enzymes, COX-1 and COX-2; these enzymes promote inflammation, pain, and fever. NSAIDs block the COX enzymes and reduce prostaglandins throughout the body. This is the only drug known to be used in the treatment of AMNP (Odbru, 2012).

The problem with the use of this anti-inflammatory drug is that it has many side effects including nausea, vomiting, diarrhoea, constipation, decreased appetite, rash, dizziness, headache, drowsiness, fluid retention which leads to oedema. There may also be oedema of the brain, suppression of bone marrow and allergies such as asthma (Dreyer, 2009). The most severe side effect is that of kidney failure. A relatively new risk is that NSAID use increases the risk of non-fatal Myocardial Infarction (Rodríguez, Pérez, Bueno & Hwa, 2011)

Alternative medicines such as painkillers and muscle relaxants are commonly used in everyday treatment of acute neck pain.

2.5.3 HOMOEOPATHIC SIMILLIMUM

Homoeopathy is a medical discipline that is a non-invasive, cost efficient, safe and nontoxic. It requires a holistic approach towards the sick person and treats their disturbances on the emotional, mental and physical levels in an integrated manner. This is done to bring back the lost equilibrium on all three levels, thus stimulating and strengthening the person’s intrinsic defence and curative mechanism (Jayasuiriya, 2010). In order for the above to be achieved a homoeopathic Simillimum is prescribed based on the Law of Similars and chosen according to the individual remedy picture. It entails the taking of a full case history, followed by the repertorisation of the patient’s mental, emotion and physical characteristics, resulting in the prescription of a medicine based on the similarity existing between the medicine and the patient’s symptomatology.

Homoeopathic Simillimum has been shown to be superior over placebo in the treatment of musculoskeletal conditions such as osteoarthritis and rheumatoid arthritis (Weiner, Ernst, 2004).

2.5.3.1 Homoeopathic Remedies for Treatments of AMNP

According to Hershoff (1996) in acute cases of muscular conditions of the Cervical Spine the following remedies are used:

- *Cimicifuga racemosa* – used for stiffness and contraction of neck muscles (Vermeulen, 2001).
- *Chelidonium majus* – used for pain causing the neck to draw to one side (Vermeulen, 2001).
- *Bryonia alba* - used for painful stiffness in nape of neck (Vermeulen, 2001)
- *Atropa belladonna* - used for stiff neck with swelling of glands on the neck (Vermeulen, 2001).
- *Nux vomica* - used for cervico-brachial neuralgia causing a painful and stiff neck (Vermeulen, 2001).
- *Gelsemium sempervirens* - used for pain in neck especially the upper sternocleidomastoid muscles (Vermeulen, 2001).
- *Kalmia latifolia* - used for pain from neck down arm (Vermeulen, 2001).

One of the fundamental principles of homoeopathy is that only one remedy should be prescribed at a time. If this is not the case and more than one remedy is prescribed, such as complex prescription, any beneficial or adverse effects of the therapy cannot be ascertained with accuracy (Vithoulkas, 1980). Vithoulkas' (1980) argument is 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. 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. Prescribing complexes versus Simillimum treatment in a disease is a controversial topic and its relative effectiveness will be ascertained in this clinical trial.

2.5.3.2 Safety of Homoeopathic Medicines

There is currently no registration of individual homoeopathic medicines in South Africa, but they are recorded in the Chiropractors, Homoeopaths and Allied Health Professions Second Amendment Act 63 of 1982 (Department of Health, 2000), noted as medicines used by homoeopaths to treat their patients. The Department of Health (2011) published comment guidelines in Act 101 of 1965 which govern Complimentary Medicines, including homoeopathic medicines.

Homoeopathic medicines are regarded as safe due to the high dilutions used. However, according to Thompson, Barron and Spence (2204:203), some adverse events have been described. Dantas (2000) (as quoted by Thompson, Barron and Spense, 2004:204) found the incidence of adverse effects to be 9.1 in the homoeopathic group, and 6.17 in the placebo group, thus illustrating that adverse events were more common in verum groups. Thompson, Barron and Spense (2004:204), stated that the best known remedy reactions is a homoeopathic aggravation, defined as a brief worsening of the presenting symptoms occurring close to the time of taking the remedy which is followed by symptoms settling to their previous state or by an overall improvement of symptoms. Thus this was taken as evidence that the patient was sensitive to the medication and was not considered an adverse effect.

The European Council for Classical Homoeopathy (ECCH) (2009), published a paper entitled *The Safety of Homeopathy,* which considered literature and various studies on the matter, concluding that homoeopathic medicine may provoke adverse events (AE) which are generally mild and transient. The AE noted were mostly headaches, some localised pain, dryness of skin, eye irritation, digestive problems, feelings of heat, agitation and psychological symptoms such as increased irritability and depression. No cases resulted in hospitalization, persistent or significant disability, congenital abnormality, birth defect or any life-threatening situations. Thus no cases of serious adverse events (SAE) or serious adverse drug reactions were (SADR) were noted.

2.5.3.3 The Potency Scale

Hahnemann progressively reduced the dose of a substance by diluting it on a definite scale. Hahnemann attempted to reduce the severity of the aggravation and termed this method "Potentization". Hahnemann theorized that crude substances acted on living organisms in three ways: mechanical, chemical and dynamic. "Potentization" removed the mechanical and chemical aspect and enhanced the drugs dynamic properties. It reduces the crude substance but increases the qualitative, medicinal or therapeutic property of the drug. Potency is the unit drug strength. Three scales are used in the preparation of potencies, namely the decimal scale, centesimal scale and fifty millesimal scales (Chauhan and Gupta, 2007:50).

2.5.4 TRAUMEEL®

Traumeel® is a commercially available unscheduled homeopathic complex which contains 12 botanical substances and 2 mineral substances. It is used as an anti-inflammatory, analgesic, antiedematous, and antiexudative drug. Due to this effect it is widely used for temporary relief of symptoms associated with inflammation, exudative or degenerative processes. These could be due to acute trauma, repetitive or overuse injuries, pain from osteoarthritis, rheumatoid arthritis, gouty arthritis or ankylosing spondylitis (Arora, Harris & Scherer, 2002).

The ingredients of Traumeel® are as follows:

- *Achillea millefolium* is used to treat bruising with haemorrhaging after violent exertion (Vermeulen, 2001)
- *Aconitum napellus* is used for the sudden stiffness in the nape of the neck causing tearing pain which is worse for movement (Vermeulen, 2001)
- *Arnica montana* treats any inflammatory pain from trauma as well as neuralgias(Vermeulen, 2001)
- *Atropa belladonna* is commonly prescribed for neuralgic pain that comes and goes suddenly. Pains are usually sharp, throbbing, cutting, shooting with spasms or twitching (Vermeulen, 2001)
- *Bellis perennis* treats muscular soreness (sprains or bruises) with pain with lameness as if it were sprained. This is especially prescribed when there is injury to deeper tissues (Vermeulen, 2001)

- *Calendula officinalis* is useful for open wounds or parts that does not heal and promotes rapid healing (Vermeulen, 2001)
- *Echinacea angustifolia* and *Echinacea purpurea* is used treat patients who are weak and tired with aching muscles causing them to have slowness in every action. This is also a helpful remedy in rheumatism (Vermeulen, 2001)
- *Hamamelis virginiana* is considered due to its cure of a bruised soreness of the affected part (Vermeulen, 2001)
- *Hepar sulphuris calcareum* for its great sensitiveness of all parts causing great pain (Vermeulen, 2001)
- *Hypericum perforatum* for the nerve damage or neuralgic pain (Vermeulen, 2001)
- *Matricaria chamomilla* treats violent rheumatic pain with joint soreness as if they were bruised or tired out (Vermeulen, 2001)
- *Mercurius solubilis* is recommended for oedematous swelling causing pain with destructive inflammation (Vermeulen, 2001)
- *Symphytum officinale* stimulates growth of epithelium on ulcerated surfaces and promotes healing of bone and cartilage (Vermeulen, 2001)

Research has shown that Traumeel® can be considered as a safer alternative for patients at high risk for gastrointestinal bleeding than the use of NSAIDS (Arora *et al.*, 2002). According to Schneider (2011) the clinical trial proved the relative effectiveness of Traumeel® in treating acute musculoskeletal injury without side effects.

Homoeopathic research conducted by Cape (2005) showed Traumeel® to be effective in treating Cervical Facet Syndrome. This elicited a significant improvement in the range of movement of these patients, without pain.

Parsons (2009) concluded that Traumeel® is superior to placebo in the treatment of sports injuries, ankle sprains and compares favourably to diclofenac gel in the treatment of tendonopathy and acute epicondylitis. Traumeel® is shown to be effective, well tolerated and safe to use as conventional treatment in the management of moderate injuries in musculoskeletal conditions (Schneider, Schneider, Hanisch, Haselen , 2007).

Traumeel® effectiveness was also shown in the Chiropractic research conducted by Arrandale (2005) in which Traumeel® were administered orally as well parenterally to

patients suffering with posterior neck pain. This clinical trial was conducted to determine the effectiveness of Traumeel® versus chiropractic manipulation in the treatment of Cervical Facet Syndrome. In the conclusion of this study both Traumeel® as well as the manipulation treatment showed a positive improvement.

2.5.5 PHYSICAL MANIPULATION

2.5.5.1 Chiropractic Adjustment

According to Haldeman (1992:641), Spinal manipulation is defined as "all procedures where the hands are used to mobilise, adjust, stimulate or otherwise influence the spinal and paraspinal tissue with the aim of influencing the patient's health".

According to Harpham (2005), Chiropractors seek out areas within the cervical spine that have decreased movement due to neck pain using a method called palpation, once found, the affected joint/s are treated via manipulation to release the joint and restore movement. The Chiropratic adjustment provides an effective way of producing the force needed for restoration of movement (Schafer and Faye 1990).

Cassidy *et al.* (1992), utilised spinal manipulation and the mobilization technique on a 100 patients, to determine which was more effective. The study determined that a single manipulation was more effective than mobilization in decreasing pain in patients with mechanical range of motion.

2.5.5.2 Physiotherapy and Exercise

The active treatments available for neck injury, such as whiplash, are mobilization, manipulation and active manipulation. These treatments were identified as options with the most scientific validity (Moulder, 2003). According to (Spitzer *et al*., 1995), the independent benefit of using exercise as a treatment could not be established, yet was recommended as an adjunct to other therapies.

Studies (Jenson and Harms-Ringdahl, 2007:Hurwitz *et al*., 2008) showed exercise to be an effective treatment plan for neck pain, particularly if cervical motion is performed habitually several times a week.

2.5.6 ENERGETIC THERAPY

Heat, cryotherapy, electrical modalities, traction with joint mobilization showed to be effective treatments (Weisel *et al*., 1992). According to Jenson and Harms-Ringdahl (2007), and Hurwitz (2008), transcutaneous electric nerve stimulation (TENS) and low level laser treatments (LLLT) were shown to be effective treatments for short term symptom reduction in neck pain.

2.5.6.1 Trigger Point Injection

According to Alvarez and Rockwell (2002), Speed (2003) and Kamanli *et al.* (2005), trigger point injection can effectively inactivate trigger points and activate prompt symptomatic relief. Speed (2003), compared this mechanism of action to that similar to needling whereby the injection is said to cause mechanical disruption of the trigger point and desensitization of the area. Various studies have shown that combination therapies are superior in pain relief in the treatment of neck pain (Hurwitz *et al*., 2008).

2.6 CONCLUSION

Patients seek alternatives to taking allopathic medicines with increase in awareness of complementary alternate medicine. Thus there is a need for a replacement drug therapy which equates to NSAID's action in the body. Traumeel®, a homoeopathic preparation, is a proven alternative to NSAIDs as demonstrated in treating epicondylitis (Birnesser, 2004). There is a need to assess the effectiveness of homoeopathic medicines on inflammatory conditions. This study investigated the use of Traumeel® and homoeopathic Simillimum instead of an NSAID to achieve this effect.

CHAPTER 3

MATERIALS AND METHODS

3.1 INTRODUCTION

This study was a double-blinded, randomised clinical trial to ascertain the effectiveness of the homoeopathic Simillimum and Traumeel® in the treatment of AMNP. The study also investigated the relative effectiveness of the two treatment regimes, through quantitative methods and comparisons thereof.

3.2 POPULATION, SAMPLE, PATIENT RECRUITMENT AND SELECTION

The study population included all persons between the ages of 18 and 55 with AMNP living in the Greater Durban area. Of these, 30 participants were recruited based on convenience sampling.

Patients who had acute mechanical neck pain self selected homoeopathic treatment. The 30 participants were randomly allocated to a treatment group by an external clinician. Their numbers were written down individually and each piece of paper was placed in a hat. The external clinician drew names out of a hat randomly and assigned patients to receive either the Simillimum or Traumeel® treatment.

The study was limited to the greater Durban area and the population were informed of the research by advertisements at the Durban University of Technology Homoeopathic Day Clinic as well as other regional meeting places and newspapers. Permission was requested from all places where the advert was placed, such as from management and Doctors in charge of shopping malls and clinics respectively, in the Greater Durban area. Advertisements were in the form of posters and pamphlets (Appendix D).

3.3 SCREENING CRITERIA

Certain screening criteria were utilised prior to conduction of the initial consultation. This was done to determine if the patient met the inclusion criteria and was redeemed fit for the study, limiting any complications.

The following criteria illustrate the screening process:

- Patients were required to be between the ages of 18-55
- Patient were to have acute neck pain not lasting more than two weeks
- Patients experienced pain with an acute onset and associated with asymmetrical restriction of the neck (Boon, Colledge, Walker, 2006).
- Patient had a history of awkward posture or trauma (Boon *et al.*, 2006)
- Pain had not come with arm or leg weakness or paraesthesia, changes in bowel function or bladder (Boon *et al.*, 2006)
- The patient were asked the chronicity, quality and severity of the pain (Boon *et al.*, 2006)
- The researcher conducted a visual inspection for signs of inflammation
- Appendix A2 was completed to assess the pain and disability

3.3.1 INCLUSION CRITERIA

Aside from the screening tools utilised, patients were required to fit inclusion criteria of the following for their participation to be considered in the study.

The inclusion criteria were:

- Only patients between the ages of 18 – 55 were accepted (Lau, Wing Chiu, Lam, 2011)
- Patients of any race and gender were included
- Only cases of acute or Sub-acute AMNP were accepted. This is defined as the onset being no longer than two weeks before the start of the trial (Haneline, 2004)
- Patients had neck pain Grade I and Grade II without major signs of pathology and with or without interference with daily activity (Guzman *et al.*, 2002)
- Patients had to be English conversant to facilitate homoeopathic Simillimum prescription.

3.3.2 EXCLUSION CRITERIA

Patients were excluded on certain criteria due to the specificity of the study.

The exclusion criteria were as follows:

- Patients were excluded if they had neck pain for longer than 2 weeks
- If the patient showed the presence of bone infection or spinal tumours
- If the patient had a history of Rheumatoid Arthritis or any other arthritides.
- If they showed any contraindications to Traumeel®
- Hypersensitivity or anaphylactic reaction to any ingredient of Traumeel®
- Presence of a progressive systemic disease such as TB, Collagen disorders, Multiple Sclerosis, HIV/AIDS infection or any other autoimmune disorders
- If the patient was on any anti-inflammatory or taking any of the following e.g.: Aspirin, Lithium, methotrexate or heparin during the course of the study
- If the patient saw any other practitioner with regard to the current acute neck pain such as a Chiropractitioner or Physiotherapist throughout the duration of the study
- If patient had any other form of treatment for acute neck pain during the duration of the study
- If the patient was not conversant in English

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

3.4 ETHICAL CONSIDERATION

The procedure was fully explained to the patient. Ethical clearance, Reference number :REC 58/13, was awarded for this clinical trial and is attached (Appendix E). The patients were given a Letter of Information and consent (Appendix B) and allowed to ask questions, after which they were asked to sign a consent to be screened (Appendix B) according the checklist. If the patient then fitted into our criteria they were asked to read and sign consent for screening (Appendix B). Each patient was read through the procedure of the clinical trial and explained the process thoroughly and informed that they will participate on a voluntary basis and they could withdraw at any time. After this they were asked to sign an informed consent agreeing to participate (Appendix B).

The patients were then briefed on the formalities of the consultations to follow. It was explained to the patients that during the first consult a full case history (Appendix C) will be

taken and the subjective Neck Disability Index (Appendix A1) will be completed and a range of motion assessment will be performed (Appendix A2). It was also explained that a full homoeopathic case history would be taken and a homoeopathic Simillimum will be prescribed, but depending on which group the patient was placed in, Traumeel® or Simillimum would be dispensed. The dosage, instructions on how to take the medication and possible treatment outcomes were also explained to the participants.

Patients in all groups benefited from the treatment as each received a different form of treatment for acute mechanical neck pain. All information was kept confidential at all times. Participants were issued with a number, meaning that no names or personal identifiers were present on any data collected. All medication and consultations will be provided free of charge for the duration of the study.

The study was given ethical clearance by the Durban University of Technology Institutional Research Ethics Committee, clearance number IREC 073/13 (Appendix E).

3.5 CONSULTATIONS

The first consult was scheduled on day one, with the follow-up scheduled on days three and seven (Harpham, 2005; Hepburn, 2000).

3.5.1 INITIAL CONSULTATION

The procedure was fully explained to the patient. They were given a Letter of Information and consent (Appendix B) and allowed to ask questions, after which they were asked to sign a consent to be screened (Appendix B) according to the checklist. If the patient then fitted into our criteria they were then asked to read and sign consent for screening (Appendix B). Each patient were read through the procedure of the clinical trial and explained thoroughly and informed that they will participate on a voluntary basis and they can withdraw at any time. After this they were asked to sign an informed consent agreeing to participate (Appendix B).

The patient's full case history according to (Appendix C), important symptoms were recorded and analysed. A full homoeopathic case history was ascertained according to homoeopathic principles. A physical examination was performed and the patients' vital signs were noted. Their temperature, blood pressure, respiratory rate, height and weight were taken. Any unusual observations on physical examination were noted.

The patient was then asked to answer a perceptive survey in the form of the Neck Disability Index (Appendix A1). The patients Range of Motion was done using a Cervical Range of Motion measuring scale, known as the CROM and results recorded during each consult (Appendix A2).

A Simillimum treatment was prescribed for every patient based on his or her full case history. This Simillimum was confirmed by the co-supervisor. Only half of the patients seen were dispensed the Simillimum according to the randomisation list. The other half were dispensed Traumeel® drops.

3.5.2 FOLLOW UP CONSULTATION NUMBER 1 (DAY 3)

The first follow-up was conducted three days after the patient took the first dose of medication. During this consult, the patient was asked to perceptively describe their progress, inform the researcher of any new symptoms, or loss of an old symptom, and describe their daily activities since the medication. The patient's vital signs were again noted, a physical examination performed, and the cervical range of motion noted (Appendix A2).

3.5.3 FOLLOW UP CONSULTATION NUMBER 2 (DAY 7)

This was the final consultation for the patients. Patients were asked to describe their progress and note any new or old symptomatology. They were once again asked to analyse their neck disability using the perceptive survey (Appendix A1). Their vital signs were noted, a full physical examination was performed, unusual observations were noted, and range of motion conducted using the CROM (Appendix A2).

3.6 DISPENSING AND DOSAGE

Both the oral Traumeel® liquid potency and the homoeopathic Simillimum in 30CH liquid potency were dispensed in identical bottles with identical instructions for use. In an acute injury to the back, where the patient is not under constitutional treatment, Morrison (1998) advises the use of the 30CH potency.

The 30CH liquid potency was be made by adding 10 granules in 30ml of 30% ethanol, the same alcohol percentage as Traumeel®. Both treatments were administered orally as 5 drops three times a day (the recommended dosage for oral Traumeel®).

The dispensing of the Simillimum and the Traumeel® were carried out according to the randomisation list by an external person. The researcher did not know which patients received oral Traumeel® or which received the Simillimum.

3.7 EVALUATION OF THE RESPONSE TO TREATMENT

3.7.1 MEASUREMENT TOOLS

The Neck Disability Index (NDI) is designed to measure neck-specific disability. The NDI is a well-researched questionnaire. According to Howel (2011) and Schellingerhout *et al* (2011) the NDI has shown to have adequate internal consistency, validity and responsiveness.

The NDI (Appendix A1) questionnaire consists of 10 items concerning pain and activities. Each item is scored out of a score of 5 (with no disability response given a score of 0). The total score for the questionnaire is out of 50. Higher scores in the questionnaire, represent greater disability. The result is expressed as a percentage (score out of 100) by simply doubling the total score. If there is an NDI score of greater than 40/100 at the initial assessment, it is associated with an on-going pain and disability after whiplash. The proposed guidelines indicate that 'recovery' is represented by an NDI score of less than 8/100, at which time treatment should be stopped (Vernon, 1991).

The Neck Disability Index (NDI) (Appendix A1) is a subjective questionnaire in which the patient is asked to fill in their range of disability in everyday activities. The NDI is a well-

researched questionnaire. According to Howel (2011) and Schellingerhout *et al* (2011) the NDI has been shown to have adequate internal consistency, validity and responsiveness.

The range of motion was carried out using diagnostic evaluation of flexion, extension and rotation and measuring the angle (Appendix A2). The cervical range of motion instrument (Performance Attainment Associates; Patient no. 4,777,965 & 4,928,709) 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 Durban University of Technology and has been shown to be effective (Hepburn, 2000, Harpam, 2005).

Both of these procedures were reassessed at each consult.

3.7.2 FACTOR ANALYSIS FOR THE NDI

Factor analysis is a statistical technique whose main goal is data reduction. A typical use of factor analysis is in survey research, where a researcher wishes to represent a number of questions with a small number of hypothetical factors. For example, as part of a national survey on political opinions, participants may answer three separate questions regarding environmental policy, reflecting issues at the local, state and national level. Each question, by itself, would be an inadequate measure of attitude towards environmental policy, but *together* they may provide a better measure of the attitude. Factor analysis can be used to establish whether the three measures do, in fact, measure the same thing. If so, they can then be combined to create a new variable, a factor score variable that contains a score for each respondent on the factor. Factor techniques are applicable to a variety of situations (Singh, 2014).

Each matrix table is preceded by a table that reflects the results of Kaiser-Meyer-Olkin (KMO) and Bartlett's Test. The requirement is that KMO's test of Measure of Sampling Adequacy should be greater than 0.50 and Bartlett's Test of Sphericity less than 0.05. In all instances, the conditions are satisfied which allows for the factor analysis procedure, apart from section E, which also contributed to the lower reliability score (Singh, 2014).

Table 3-1 Kaiser-Meyer-Olkin Measure of Sampling Adequacy and Bartlett's Test of Sphericity

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.656
Bartlett's Test of Sphericity	Approx. Chi-Square	111.071
	Df	45
	Sig.	.000

Certain components divided into finer components. This is explained below in the rotated component matrix.

Table 3-2 Factor analysis components

	Initial Consult			Follow-up		
	Component			Component		
	1	2	3	1	2	3
Section 1	-415	.697	.112	.676	-.243	-.137
Section 2	.543	.027	.526	-.168	-.090	.803
Section 3	.776	.168	.036	.714	-.127	.031
Section4	-022	.148	.783	.386	.122	.784
Section 5	.555	-.259	.602	-.015	.927	.128
Section 6	.885	.110	.219	.044	.928	-.132
Section 7	.557	.664	.090	.832	.351	.064
Section 8	.339	.811	.012	.876	-.144	.028
Section 9	.201	.365	.781	.796	.254	.249
Section 10	.056	.565	.174	.812	.338	.043

With reference to Table 3-2 above:

- The principle component analysis was used as the extraction method, and the rotation method was Varimax with Kaiser Normalization. This is an orthogonal rotation method that minimizes the number of variables that have high loadings on each factor. It simplifies the interpretation of the factors.
- Factor analysis/loading show inter-correlations between variables.
- Items of questions that loaded similarly, imply measurement along a similar factor. An examination of the content of items loading at or above 0.5 (and using the higher or highest loading in instances where items cross-loaded at greater than this value) effectively measured along the various components.

It is noted that the variables that constituted the 10 items split along three components. This implies that respondents identified certain aspects of the sub-themes as belonging to other sub-sections. It is also noted that some items realigned after the follow up (Singh, 2014).

3.8 RELIABILITY STATISTICS

The two most important aspects of precision are reliability and validity. Reliability is computed by taking several measurements on the same subjects. A reliability coefficient of 0.70 or higher is considered as "acceptable" (Singh, 2014).

The tables below (Tables 3-3 – 3-5) reflects the Cronbach's alpha score for all the items that constituted the questionnaire.

Table 3-3 Initial Consult

Case Processing Summary			
		N	%
Cases	Valid	30	100.0
	Excluded[a]	0	.0
	Total	30	100.0
a. Listwise deletion based on all variables in the procedure.			

Reliability Statistics	
Cronbach's Alpha	N of Items
.795	10

Table 3-4 Follow up

Case Processing Summary			
		N	%
Cases	Valid	30	100.0
	Excluded[a]	0	.0
	Total	30	100.0
a. Listwise deletion based on all variables in the procedure.			

Reliability Statistics	
Cronbach's Alpha	N of Items
.786	10

Table 3-5 Overall

Case Processing Summary			
		N	%
Cases	Valid	30	100.0
	Excluded[a]	0	.0
	Total	30	100.0
a. Listwise deletion based on all variables in the procedure.			

Reliability Statistics	
Cronbach's Alpha	N of Items
.841	20

The reliability scores of each section exceeds the recommended value of 0.700. This indicates a high (overall) degree of acceptable, consistent scoring for the research for all sections.

3.9 NON PARAMETRIC TESTS

A family of statistical procedures that do not rely on the restrictive assumptions of parametric tests, i.e. they do not assume that the data are normally distributed (Field, 2009).

3.9.1 FRIEDMAN'S ANOVA

A non-parametric test to see whether more than one group differs. It is used for the testing of differences between multiple conditions in the same participants. It is the non-parametric version of the one-way repeated measures ANOVA (Field, 2009).

There is no easy way to convert a chi-square statistic to an effect size, so it is advised to conduct a Wilcoxon signed rank tests and calculate the effect size from there as a follow up (Field, 2009).

3.9.2 WILCOXON'S SIGNED RANK TEST

A non-parametric test that looks for the differences between two independent samples. It looks for the differences between two related samples from the same population (Field, 2009).

CHAPTER 4

RESULTS

This chapter presents the results obtained during the data collection phase in this study. The data collected from the responses were analysed with SPSS version 22.0. The results present the descriptive statistics in the form of graphs, cross tabulations and other figures for the qualitative data that collected. Inferential techniques include the use of correlations and chi square test values; which were interpreted using the p-values.

4.1 DESCRIPTIVE STATISTICS

In total, 30 patients were recruited and those tested were random allocated to one of the groups of 15 each. One group received oral Traumeel® complex whilst the other received the individualised Simillimum treatment.

4.1.1 BIOGRAPHICAL DATA

This section summarises the biographical characteristics of the respondents.

Table 4-1 describes the gender distribution by age.

Table 4-1 Gender Distribution by Age

			Gender		Total
			Female	Male	
Age (coded)	10 - < 20	Count	0	2	2
		% within Age (coded)	0.0%	100.0%	100.0%
		% within Gender	0.0%	25.0%	6.7%
		% of Total	0.0%	6.7%	6.7%
	20 - < 30	Count	8	2	10
		% within Age (coded)	80.0%	20.0%	100.0%
		% within Gender	36.4%	25.0%	33.3%
		% of Total	26.7%	6.7%	33.3%
	30 - < 40	Count	5	3	8
		% within Age (coded)	62.5%	37.5%	100.0%
		% within Gender	22.7%	37.5%	26.7%
		% of Total	16.7%	10.0%	26.7%

	40 - < 50	Count	2	0	2
		% within Age (coded)	100.0%	0.0%	100.0%
		% within Gender	9.1%	0.0%	6.7%
		% of Total	6.7%	0.0%	6.7%
	50 - < 60	Count	5	1	6
		% within Age (coded)	83.3%	16.7%	100.0%
		% within Gender	22.7%	12.5%	20.0%
		% of Total	16.7%	3.3%	20.0%
	22.00	Count	1	0	1
		% within Age (coded)	100.0%	0.0%	100.0%
		% within Gender	4.5%	0.0%	3.3%
		% of Total	3.3%	0.0%	3.3%
	55.00	Count	1	0	1
		% within Age (coded)	100.0%	0.0%	100.0%
		% within Gender	4.5%	0.0%	3.3%
		% of Total	3.3%	0.0%	3.3%
Total		Count	22	8	30
		% within Age (coded)	73.3%	26.7%	100.0%
		% within Gender	100.0%	100.0%	100.0%
		% of Total	73.3%	26.7%	100.0%

From Table 4-1 it is evident that the ratio of females to males is approximately 3:1 (73.3%: 26.7%). Within the age category of 40 to 50 years, 100.0% were female (n = 2). Within the category of females (only), 9.1% were between the ages of 40 to 50 years. This category of females between the ages of 40 to 50 years formed 6.7% of the total sample.

4.1.2 AGE

The study consisted of 30 participants between 18 and 55 years of age. As illustrated in Table 4-2, There were two participants (6.7%) between the ages of 18 -20, eleven participants (36.6%) between 20-30 years old and eight participants (26.7%) between 30-40 years old. Between 40-50 years old, there were 2 participants (6.7%). There were 7 (23.3%) participants between the ages of 50-55.

Table 4-2 Complex and Simillimum prescription in Study according to age distribution.

Age Group	Number And Percentage Of Participants	Complex Prescription	Simillimum Prescription
18-20	2 - 6.7%	1	1
20-29	11 - 36.6%	6	5
30-39	8 - 26.7%	3	5
40-49	2 - 6.7%	1	1
50-55	7 - 23.3%	4	3

4.1.3 RACE

The study population consisted of eight (26.7%) African participants, four (13.3%) Caucasian participants and eighteen (60%) Indian participants. This is illustrated in Table 4-3

Table 4-3 Ethnicity of the Participants

			Group		
			A - Traumeel	B - Simillimum	Total
Ethnicity	African	Count	3	5	8
		% within Group	20.0%	33.3%	26.7%
	Caucasian	Count	2	2	4
		% within Group	13.3%	13.3%	13.3%
	Indian	Count	10	8	18
		% within Group	66.7%	53.3%	60.0%
Total		Count	15	15	30
		% within Group	100.0%	100.0%	100.0%

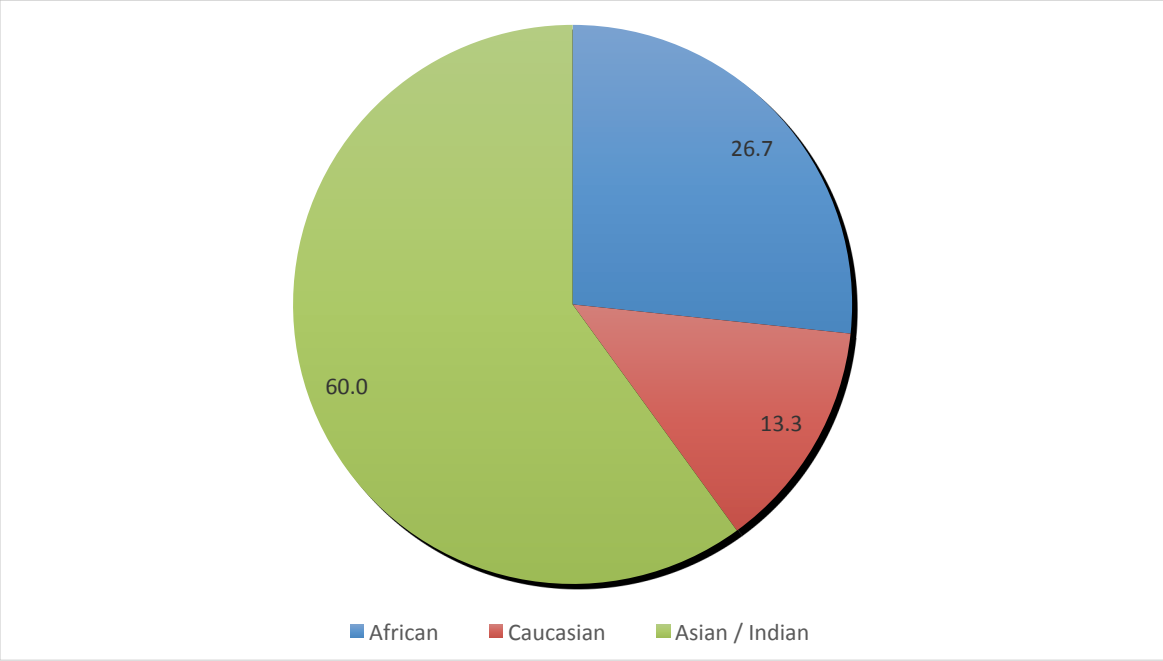

Figure 4-1 Ethnicity of the Participants

4.1.4 OCCUPATION

Participants who presented with AMNP were categorised into occupation groupings.

40% of participants worked in a Deskwork job such as Information technology and computer specialists, 40% were students, 10% were unemployed, 6.7% were in manual labour fields such as construction and carpentry and 3.3% worked in the health field.

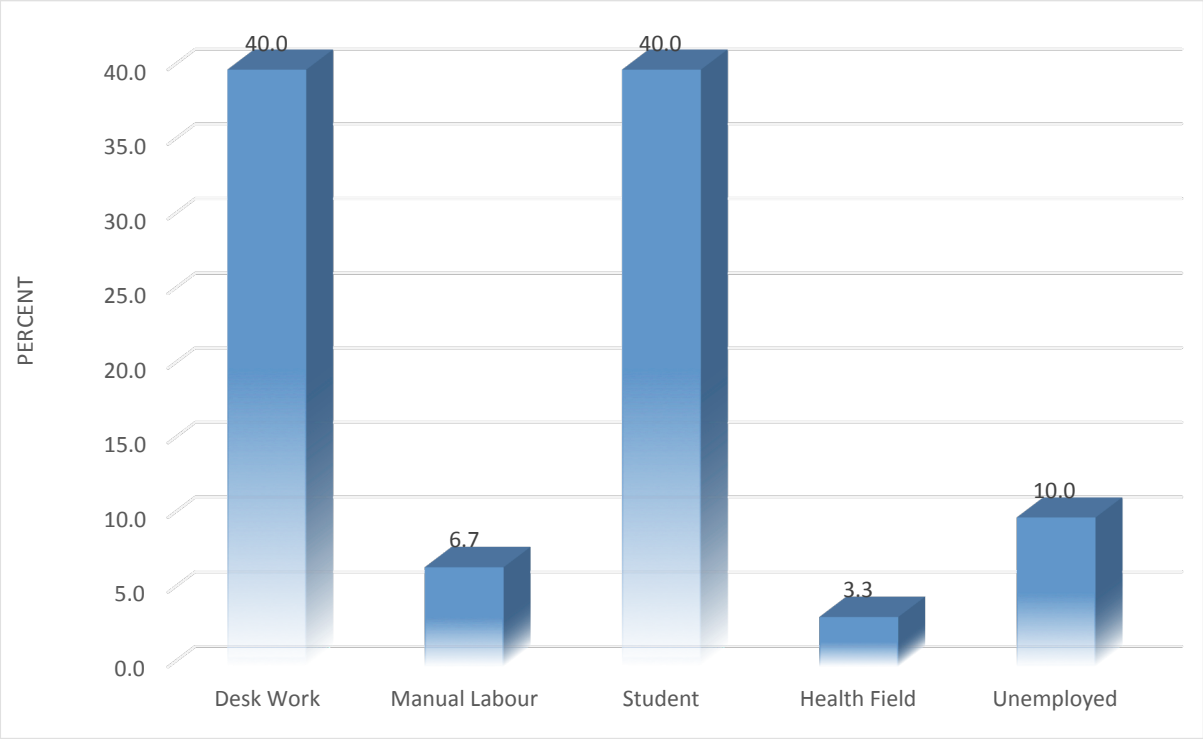

Figure 4-2 Graph to show Occupation of participants

The majority of respondents were either working a Desk Work or a Student (40.0% respectively). The remaining categories were no more than 10.0%.

4.1.5 HISTORY OF NECK PAIN

During the study participants were asked during their initial consult if they had a history or neck pain. 20% of the participant had no history of neck pain and 80% of the patients had neck pain previously.

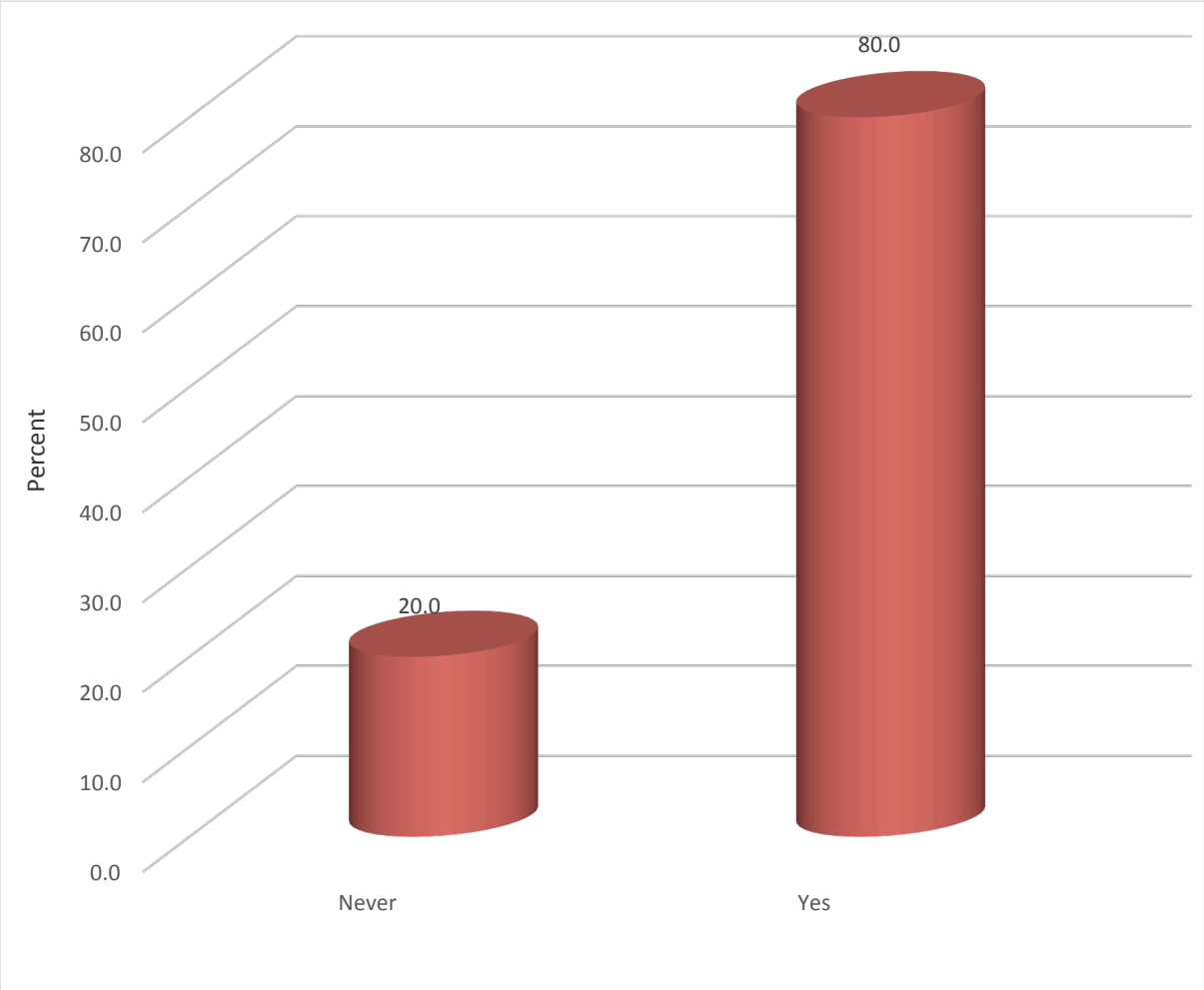

Figure 4-3 Graph to illustrate participants with or without a history of neck pain

Eight out of every ten (80.0%) respondents indicated that they had previously suffered from neck pain.

4.2. INTRA-GROUP ANALYSIS

4.2.1 CLINICAL ANALYSIS

The section that follows analyses the patterns of the respondents per variable tested per section.

Table 4-4 Descriptive Statistics for the CROM Variables per Group

Group	A – Traumeel			B - Simillimum			Total		
	N	Mean	Std. Deviation	N	Mean	Std. Deviation	N	Mean	Std. Deviation
Flexion_A	15	50.4000	13.74669	15	49.4000	10.12634	30	49.9000	11.87391
Extension_A	15	58.8000	8.05517	15	54.1333	10.40513	30	56.4667	9.44579
Right Rotation_A	15	58.0667	12.15652	15	62.3333	14.25115	30	60.2000	13.19457
Left Rotation_A	15	60.0667	8.88391	15	61.2667	11.32927	30	60.6667	10.02182
Right Lateral Flexion_A	15	34.7333	8.63933	15	36.1333	7.00884	30	35.4333	7.76235
Left Lateral Flexion_A	15	36.9333	8.01308	15	39.1333	9.03854	30	38.0333	8.46691
Flexion_B	15	57.6000	11.35656	15	55.2667	13.29053	30	56.4333	12.20425
Extension_B	15	65.0667	7.08587	15	61.8000	7.21308	30	63.4333	7.21915
Right Rotation_B	15	66.9333	8.59790	15	69.7333	11.18971	30	68.3333	9.90762
Left Rotation_B	15	66.2000	8.01071	15	72.0000	7.51190	30	69.1000	8.18051
Right Lateral Flexion_B	15	41.1333	6.30042	15	43.0667	5.68792	30	42.1000	5.97899
Left Lateral Flexion_B	15	41.9333	6.90204	15	43.0000	9.11827	30	42.4667	7.96429
Flexion_C	15	61.0667	10.04608	15	63.9333	13.25824	30	62.5000	11.64933
Extension_C	15	68.0000	5.12696	15	65.9333	7.51633	30	66.9667	6.40842
Right Rotation_C	15	71.7333	7.23549	15	76.2667	7.49730	30	74.0000	7.59764
Left Rotation_C	15	71.8667	6.33434	15	78.6667	5.31395	30	75.2667	6.70529
Right Lateral Flexion_C	15	44.1333	4.86778	15	47.1333	6.45718	30	45.6333	5.82198
Left Lateral Flexion_C	15	45.4000	5.70463	15	48.6667	6.53197	30	47.0333	6.25043
Total_A_Percent	15	20.67	14.903	15	21.07	7.554	30	20.87	11.611
Total_B_Percent	15	4.67	7.237	15	1.33	1.633	30	3.00	5.427

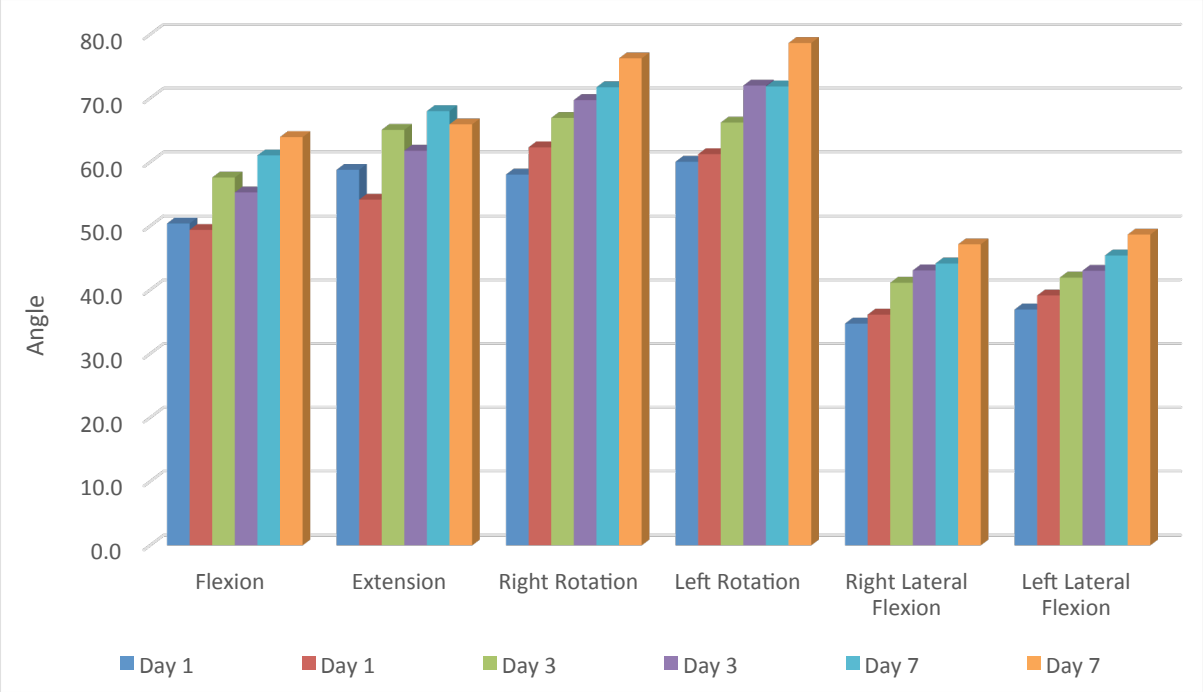

Figure 4-4 CROM Readings per Variable per visit

***The first day 1 is Traumeel® and the second one is Simillimum**

It is noted that the values for Left and Right Rotation are similar with the Simillimum values slightly higher than those for Traumeel®. For the most part, these patterns are repeated for Flexion, Extension and the Right- and Left-Lateral Flexion. The patterns also indicate an increase over time. The values however for the Right Lateral Flexion and Left-Lateral Flexion are nearly half in magnitude to the first 4 variables in the figure due to the fact that normal range of motion are between 20 to 45 degrees.

Table 4-5 Summary of Significant Differences in the Median Values between the Groups for All Variables

	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)	Exact Sig. [2*(1-tailed Sig.)]
Flexion_BA	109.500	229.500	-.126	.900	0.902
Flexion_CA	80.000	200.000	-1.377	.169	0.187
Extension_BA	105.000	225.000	-.315	.753	0.775
Extension_CA	87.500	207.500	-1.042	.298	0.305
Right_Rotation_BA	107.500	227.500	-.212	.832	0.838
Right_Rotation_CA	112.000	232.000	-.021	.983	1.000
Left_Rotation_BA	62.000	182.000	-2.143	.032	0.037
Left_Rotation_CA	80.500	200.500	-1.334	.182	0.187
Right_Lateral_Flexion_BA	100.000	220.000	-.528	.598	0.624
Right_Lateral_Flexion_CA	94.500	214.500	-.753	.451	0.461
Left_Lateral_Flexion_BA	97.500	217.500	-.632	.528	0.539
Left_Lateral_Flexion_CA	104.500	224.500	-.336	.737	0.744

The only significant difference was obtained for Left Rotation for the 3rd reading (C).

4.2.2 INTER-GROUP COMPARISON

CA versus BA, separately for each group.

Table 4-6 Traumeel Inter-group comparison

Test Statistics[a]

	Flexion_CA - Flexion_BA	Extension_CA - Extension_BA	Right_Rotation_CA - Right_Rotation_BA	Left_Rotation_CA - Left_Rotation_BA	Right_Lateral_Flexion_CA - Right_Lateral_Flexion_BA	Left_Lateral_Flexion_CA - Left_Lateral_Flexion_BA
Z	-2.442[b]	-2.102[b]	-2.779[b]	-3.018[b]	-2.200[b]	-2.488[b]
Asymp. Sig. (2-tailed)	.015	.036	.005	.003	.028	.013

a. Wilcoxon Signed Ranks Test

b. Based on negative ranks.

It is noted that all of the pairings show a significant difference, There is a significant improvement between the initial and the post treatment reading.

Table 4-7 Simillimum inter group comparison

Test Statistics[a]

	Flexion_CA - Flexion_BA	Extension_CA - Extension_BA	Right_Rotation_CA - Right_Rotation_BA	Left_Rotation_CA - Left_Rotation_BA	Right_Lateral_Flexion_CA - Right_Lateral_Flexion_BA	Left_Lateral_Flexion_CA - Left_Lateral_Flexion_BA
Z	-3.064[b]	-3.075[b]	-2.919[b]	-2.942[b]	-2.373[b]	-2.810[b]
Asymp. Sig. (2-tailed)	.002	.002	.004	.003	.018	.005

a. Wilcoxon Signed Ranks Test

b. Based on negative ranks.

The reading signified a significant improvement between the initial and the post treatment reading.

Table 4-8 Total Score on the NDI

	Total Score	
	Traumeel	**Simillimum**
Before	20.7	21.1
After	4.7	1.3

An analysis for the total score (out of 100) for the NDI, revealed that there was not much difference between the before scores, apart from the Simillimum group having a higher score than that of the Traumeel® group. The scores after treatment indicate a vast reduction in comparison to the initial scores in both groups, with a lower score in the Simillimum group.

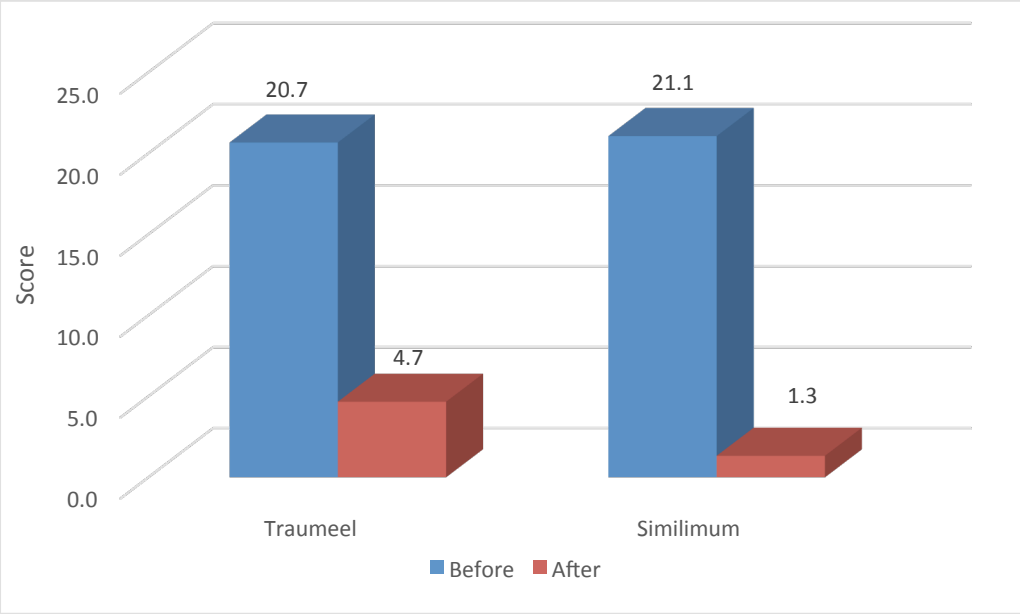

Figure 4-5 NDI results before and after treatment of Traumeel® versus Simillimum

Table 4-9 Wilcoxon comparison of the before and after scores per group

	Traumeel®	**Simillimum**
Sig. value	0.01	0.01

The reading signified a significant improvement between the initial and the post treatment reading for both Traumeel® and Simillimum treatment groups.

4.3 HYPOTHESIS TESTING

The traditional approach to reporting a result requires a statement of statistical significance. A p-value is generated from a test statistic. A significant result is indicated with "$p < 0.05$". These values are highlighted with a *.

Table 4-10 ANOVA TEST

		Sum of Squares	df	Mean Square	F	Sig.
Flexion_BA	Between Groups	13.333	1	13.333	.339	.565
	Within Groups	1100.133	28	39.290		
	Total	1113.467	29			
Flexion_CA	Between Groups	112.133	1	112.133	1.925	.176
	Within Groups	1631.067	28	58.252		
	Total	1743.200	29			
Extension_BA	Between Groups	14.700	1	14.700	.252	.620
	Within Groups	1636.267	28	58.438		
	Total	1650.967	29			
Extension_CA	Between Groups	50.700	1	50.700	.726	.401
	Within Groups	1954.800	28	69.814		
	Total	2005.500	29			
Right_Rotation_BA	Between Groups	16.133	1	16.133	.265	.611
	Within Groups	1705.333	28	60.905		
	Total	1721.467	29			
Right_Rotation_CA	Between Groups	.533	1	.533	.005	.942
	Within Groups	2728.267	28	97.438		
	Total	2728.800	29			
Left_Rotation_BA	Between Groups	158.700	1	158.700	4.423	.045
	Within Groups	1004.667	28	35.881		
	Total	1163.367	29			
Left_Rotation_CA	Between Groups	235.200	1	235.200	3.166	.086
	Within Groups	2080.000	28	74.286		
	Total	2315.200	29			
Right_Lateral_Flexion_BA	Between Groups	2.133	1	2.133	.069	.794
	Within Groups	860.533	28	30.733		
	Total	862.667	29			
Right_Lateral_Flexion_CA	Between Groups	19.200	1	19.200	.406	.529
	Within Groups	1323.600	28	47.271		
	Total	1342.800	29			
Left_Lateral_Flexion_BA	Between Groups	9.633	1	9.633	.390	.537
	Within Groups	691.733	28	24.705		
	Total	701.367	29			
Left_Lateral_Flexion_CA	Between Groups	8.533	1	8.533	.149	.703
	Within Groups	1607.467	28	57.410		
	Total	1616.000	29			

Table 4-11 Friedman Anova

		Flexion	Extension	Right rotation	Left Rotation	Right Lateral Flexion	Left Lateral flexion
All	Chi Square	49.8	36.14	43.91	49.00	45.88	38.52
N=30	Significance	0.000	0.000	0.000	0.000	0.000	0.000

Group 1 represents Traumeel® and group 2 represents Simillimum.
Analysis of the data showed a d=significance improvement in range of motion readings between day 1 and day 7.

Table 4-12 Wilcoxan signed rank test

		Flexion	Extension	Right rotation	Left Rotation	Right Lateral Flexion	Left Lateral flexion
All	Z	-4.65	-4.39	-4.57	-4.71	-4.55	-4.30
N=30	Effect size	-60.03	-56.67	-59.00	-60.81	-58.74	-55.51
	Significance	0.000	0.000	0.000	0.000	0.000	0.000
Traumeel®	Z	-3.18	-2.82	-3.06	-3.30	-3.31	-3.07
N=15	Effect size	-58.06	-51.49	-55.87	-60.25	-60.43	-56.05
	Significance	0.001	0.005	0.002	0.001	0.001	0.002
Simillimum	Z	-3.45	-3.31	-3.45	-3.42	-3.19	-3.07
N=15	Effect size	-62.99	-60.43	-62.99	-62.44	-58.24	-56.05
	Significance	0.001	0.001	0.001	0.001	0.001	0.002

Group 1 represents Traumeel® and group 2 represents Simillimum.
The Wilcoxan signed rank test showed that the effect size signified and increase in readings on day 7.

All differences are significant, with the effect size indication the final reading to be greater than the initial read. This indicates that both methods are effective.

4.3.1 FLEXION

The Tests of Within-Subjects Effects table tells us if there was an overall significant difference between the means at the different time points.

Table 4-13 Tests of Within- Subjects Effects

Measure: MEASURE_1							
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Flexion	Sphericity Assumed	2382.489	2	1191.244	50.179	.000	.642
	Greenhouse-Geisser	2382.489	1.894	1258.107	50.179	.000	.642
	Huynh-Feldt	2382.489	2.000	1191.244	50.179	.000	.642
	Lower-bound	2382.489	1.000	2382.489	50.179	.000	.642
Flexion * Group	Sphericity Assumed	109.422	2	54.711	2.305	.109	.076
	Greenhouse-Geisser	109.422	1.894	57.782	2.305	.112	.076
	Huynh-Feldt	109.422	2.000	54.711	2.305	.109	.076
	Lower-bound	109.422	1.000	109.422	2.305	.140	.076
Error(Flexion)	Sphericity Assumed	1329.422	56	23.740			
	Greenhouse-Geisser	1329.422	53.024	25.072			
	Huynh-Feldt	1329.422	56.000	23.740			
	Lower-bound	1329.422	28.000	47.479			

It is reported that when using an ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores between groups were statistically not significantly different (p = 0.112).

Mauchly's Test of Sphericity tests the null hypothesis that the variances of the differences are equal. Thus, if Mauchly's Test of Sphericity is statistically significant ($p < .05$), the null hypothesis can be rejected and the alternative hypothesis accepted that the variances of the differences are not equal (i.e., sphericity has been violated). Results from Mauchly's Test of Sphericity are shown below for flexion data:

Table 4-14 Mauchly's Test of Sphericity (FLEXION)

Measure: MEASURE_1							
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Flexion	.944	1.560	2	.458	.947	1.000	.500
Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.							

a. Design: Intercept + Group; Within Subjects Design: Flexion
b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

Since the significance value is greater than 0.05, it implies that sphericity has not been violated.

Thus both the Traumeel® group and the Simillimum group participants showed significant improvement in the flexion movement.

This table gives us the significance level for differences between the individual time points

Table 4-15 Tests of Within-Subjects Contrasts (FLEXION)

Measure: MEASURE_1							
Source	Flexion	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Flexion	Linear	2381.400	1	2381.400	81.761	.000	.745
	Quadratic	1.089	1	1.089	.059	.809	.002
Flexion * Group	Linear	56.067	1	56.067	1.925	.176	.064
	Quadratic	53.356	1	53.356	2.907	.099	.094
Error(Flexion)	Linear	815.533	28	29.126			
	Quadratic	513.889	28	18.353			

It is noted that there was no significant difference between the two groups (p = .176).

Upon tests of within- subjects contrasts (Flexion) , results showed that Traumeel® was as effective in the improvement of the Flexion movement as homoeopathic Simillimum.

4.3.2 EXTENSION

Table 4-16 Multivariate Tests (Extension)

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared
Extension	Pillai's Trace	.642	24.239[b]	2.000	27.000	.000	.642
	Wilks' Lambda	.358	24.239[b]	2.000	27.000	.000	.642
	Hotelling's Trace	1.796	24.239[b]	2.000	27.000	.000	.642
	Roy's Largest Root	1.796	24.239[b]	2.000	27.000	.000	.642
Extension * Group	Pillai's Trace	.032	.441[b]	2.000	27.000	.648	.032
	Wilks' Lambda	.968	.441[b]	2.000	27.000	.648	.032
	Hotelling's Trace	.033	.441[b]	2.000	27.000	.648	.032
	Roy's Largest Root	.033	.441[b]	2.000	27.000	.648	.032

a. Design: Intercept + Group
Within Subjects Design: Extension

b. Exact statistic

Multivariate analysis of variance is also known as multiple analysis of variance (MANOVA), is a statistical test procedure for comparing multivariate (population) means of several groups. The table above shows Multivariate analysis for Extension.

Table 4-17 Mauchly's Test of Sphericity (Extension)

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Extension	.610	13.342	2	.001	.719	.775	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept + Group
Within Subjects Design: Extension

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

If sphericity is violated, the Greenhouse-Geisser p-value can be used.

Table 4-18 Tests of Within-Subjects Effects (Extension)

Measure: MEASURE_1							
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Extension	Sphericity Assumed	1712.689	2	856.344	34.853	.000	.555
	Greenhouse-Geisser	1712.689	1.439	1190.242	34.853	.000	.555
	Huynh-Feldt	1712.689	1.550	1104.998	34.853	.000	.555
	Lower-bound	1712.689	1.000	1712.689	34.853	.000	.555
Extension * Group	Sphericity Assumed	25.400	2	12.700	.517	.599	.018
	Greenhouse-Geisser	25.400	1.439	17.652	.517	.541	.018
	Huynh-Feldt	25.400	1.550	16.388	.517	.554	.018
	Lower-bound	25.400	1.000	25.400	.517	.478	.018
Error(Extension)	Sphericity Assumed	1375.911	56	24.570			
	Greenhouse-Geisser	1375.911	40.290	34.150			
	Huynh-Feldt	1375.911	43.399	31.704			
	Lower-bound	1375.911	28.000	49.140			

The Tests of Within-Subjects Effects table tells us if there was an overall significant difference between the means at the different time points.

It is noted that there was no significant difference between the two groups (p = .176).

Upon tests of within- subjects contrasts (Extension), results showed that Traumeel® was as effective in the improvement of the Extension movement as homoeopathic Simillimum.

Table 4-19 Tests of Within-Subjects Contrasts (Extension)

Measure: MEASURE_1							
Source	Extension	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Extension	Linear	1653.750	1	1653.750	47.376	.000	.629
	Quadratic	58.939	1	58.939	4.141	.051	.129
Extension * Group	Linear	25.350	1	25.350	.726	.401	.025
	Quadratic	.050	1	.050	.004	.953	.000
Error(Extension)	Linear	977.400	28	34.907			
	Quadratic	398.511	28	14.233			

Tests of Within-Subjects Contrasts shows the significance level for differences between the individual time points. It is noted that there was no significant difference between the two groups (p = .176).

4.3.3 RIGHT ROTATION

Table 4-20 Multivariate Tests (Right Rotation)

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared
Right_Rotation	Pillai's Trace	.677	28.270[b]	2.000	27.000	.000	.677
	Wilks' Lambda	.323	28.270[b]	2.000	27.000	.000	.677
	Hotelling's Trace	2.094	28.270[b]	2.000	27.000	.000	.677
	Roy's Largest Root	2.094	28.270[b]	2.000	27.000	.000	.677
Right_Rotation * Group	Pillai's Trace	.025	.353[b]	2.000	27.000	.706	.025
	Wilks' Lambda	.975	.353[b]	2.000	27.000	.706	.025
	Hotelling's Trace	.026	.353[b]	2.000	27.000	.706	.025
	Roy's Largest Root	.026	.353[b]	2.000	27.000	.706	.025

a. Design: Intercept + Group
Within Subjects Design: Right_Rotation

b. Exact statistic

Multivariate analysis of variance is also known as multiple analysis of variance (MANOVA), is a statistical test procedure for comparing multivariate (population) means of several groups. The table above shows Multivariate analysis for Right Rotation.

Table 4-21 Mauchly's Test of Sphericity (Right Rotation)

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Right_Rotation	.779	6.750	2	.034	.819	.894	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept + Group
Within Subjects Design: Right_Rotation

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

Since the significance value is greater than 0.05, it implies that sphericity has not been violated.

Thus both the Traumeel® group and the Simillimum group participants showed significant improvement in the Right rotation movement.

Table 4-22 Tests of Within-Subjects Effects (Right Rotation)

Measure: MEASURE_1							
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Right_Rotation	Sphericity Assumed	2887.022	2	1443.511	42.863	.000	.605
	Greenhouse-Geisser	2887.022	1.638	1762.821	42.863	.000	.605
	Huynh-Feldt	2887.022	1.788	1614.799	42.863	.000	.605
	Lower-bound	2887.022	1.000	2887.022	42.863	.000	.605
Right_Rotation * Group	Sphericity Assumed	13.067	2	6.533	.194	.824	.007
	Greenhouse-Geisser	13.067	1.638	7.979	.194	.781	.007
	Huynh-Feldt	13.067	1.788	7.309	.194	.800	.007
	Lower-bound	13.067	1.000	13.067	.194	.663	.007
Error(Right_Rotation)	Sphericity Assumed	1885.911	56	33.677			
	Greenhouse-Geisser	1885.911	45.856	41.126			
	Huynh-Feldt	1885.911	50.060	37.673			
	Lower-bound	1885.911	28.000	67.354			

The Tests of Within-Subjects Effects table tells us if there was an overall significant difference between the means at the different time points.

It is noted that there was no significant difference between the two groups (p = .176).

Upon tests of within- subjects contrasts (Right Rotation), results showed that Traumeel® was as effective in the improvement of the Right Rotation movement as Homoeopathic Simillimum.

Table 4-23 Tests of Within-Subjects Contrasts (Right Rotation)

Measure: MEASURE_1							
Source	Right_Rotation	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Right_Rotation	Linear	2856.600	1	2856.600	58.634	.000	.677
	Quadratic	30.422	1	30.422	1.633	.212	.055
Right_Rotation * Group	Linear	.267	1	.267	.005	.942	.000
	Quadratic	12.800	1	12.800	.687	.414	.024
Error(Right_Rotation)	Linear	1364.133	28	48.719			
	Quadratic	521.778	28	18.635			

Tests of Within-Subjects Contrasts shows the significance level for differences between the individual time points. It is noted that there was no significant difference between the two groups.

4.3.4 LEFT ROTATION

Table 4-24 Multivariate Tests (Left Rotation)

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared
Left_Rotation	Pillai's Trace	.764	43.604[b]	2.000	27.000	.000	.764
	Wilks' Lambda	.236	43.604[b]	2.000	27.000	.000	.764
	Hotelling's Trace	3.230	43.604[b]	2.000	27.000	.000	.764
	Roy's Largest Root	3.230	43.604[b]	2.000	27.000	.000	.764
Left_Rotation * Group	Pillai's Trace	.143	2.260[b]	2.000	27.000	.124	.143
	Wilks' Lambda	.857	2.260[b]	2.000	27.000	.124	.143
	Hotelling's Trace	.167	2.260[b]	2.000	27.000	.124	.143
	Roy's Largest Root	.167	2.260[b]	2.000	27.000	.124	.143

a. Design: Intercept + Group
Within Subjects Design: Left_Rotation

b. Exact statistic

Multivariate analysis of variance is also known as multiple analysis of variance (MANOVA), is a statistical test procedure for comparing multivariate (population) means of several groups. The table above shows Multivariate analysis for Left Rotation.

Table 4-25 Mauchly's Test of Sphericity (Left Rotation)

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Left_Rotation	.777	6.800	2	.033	.818	.893	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept + Group
Within Subjects Design: Left_Rotation

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

Since the significance value is greater than 0.05, it implies that sphericity has not been violated.

Thus both the Traumeel® group and the Simillimum group participants showed significant improvement in the Left rotation movement.

Table 4-26 Tests of Within-Subjects Effects (Left Rotation)

Measure: MEASURE_1							
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Left_Rotation	Sphericity Assumed	3223.089	2	1611.544	63.653	.000	.695
	Greenhouse-Geisser	3223.089	1.636	1970.320	63.653	.000	.695
	Huynh-Feldt	3223.089	1.786	1805.094	63.653	.000	.695
	Lower-bound	3223.089	1.000	3223.089	63.653	.000	.695
Left_Rotation * Group	Sphericity Assumed	133.800	2	66.900	2.642	.080	.086
	Greenhouse-Geisser	133.800	1.636	81.794	2.642	.092	.086
	Huynh-Feldt	133.800	1.786	74.935	2.642	.087	.086
	Lower-bound	133.800	1.000	133.800	2.642	.115	.086
Error(Left_Rotation)	Sphericity Assumed	1417.778	56	25.317			
	Greenhouse-Geisser	1417.778	45.803	30.954			
	Huynh-Feldt	1417.778	49.995	28.358			
	Lower-bound	1417.778	28.000	50.635			

The Tests of Within-Subjects Effects table tells us if there was an overall significant difference between the means at the different time points.

It is noted that there was no significant difference between the two groups (p = .176).

Upon tests of within- subjects contrasts (Left Rotation) , results showed that Traumeel® was as effective in the improvement of the Left Rotation movement as homoeopathic Simillimum.

Table 4-27 Tests of Within-Subjects Contrasts (Left Rotation)

Measure: MEASURE_1							
Source	Left_Rotation	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Left_Rotation	Linear	3197.400	1	3197.400	86.084	.000	.755
	Quadratic	25.689	1	25.689	1.904	.179	.064
Left_Rotation * Group	Linear	117.600	1	117.600	3.166	.086	.102
	Quadratic	16.200	1	16.200	1.201	.283	.041
Error(Left_Rotation)	Linear	1040.000	28	37.143			
	Quadratic	377.778	28	13.492			

Tests of Within-Subjects Contrasts shows the significance level for differences between the individual time points. It is noted that there was no significant difference between the two groups.

4.3.5 RIGHT LATERAL FLEXION

Table 4-28 Multivariate Tests (Right Lateral Flexion)

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared
Right_Lateral_Flexion	Pillai's Trace	.711	33.271[b]	2.000	27.000	.000	.711
	Wilks' Lambda	.289	33.271[b]	2.000	27.000	.000	.711
	Hotelling's Trace	2.465	33.271[b]	2.000	27.000	.000	.711
	Roy's Largest Root	2.465	33.271[b]	2.000	27.000	.000	.711
Right_Lateral_Flexion * Group	Pillai's Trace	.016	.215[b]	2.000	27.000	.808	.016
	Wilks' Lambda	.984	.215[b]	2.000	27.000	.808	.016
	Hotelling's Trace	.016	.215[b]	2.000	27.000	.808	.016
	Roy's Largest Root	.016	.215[b]	2.000	27.000	.808	.016

a. Design: Intercept + Group
Within Subjects Design: Right_Lateral_Flexion

b. Exact statistic

Multivariate analysis of variance is also known as multiple analysis of variance (MANOVA), is a statistical test procedure for comparing multivariate (population) means of several groups. The table above shows Multivariate analysis for Right Lateral Flexion.

Table 4-29 Mauchly's Test of Sphericity Right Lateral Flexion)

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Right_Lateral_Flexion	.889	3.174	2	.205	.900	.993	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept + Group
Within Subjects Design: Right_Lateral_Flexion

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

Since the significance value is greater than 0.05, it implies that sphericity has not been violated.

Thus both the Traumeel® group and the Simillimum group participants showed significant improvement in the Right lateral flexion movement.

Table 4-30 Tests of Within-Subjects Effects (Right Lateral Flexion)

Measure: MEASURE_1							
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Right_Lateral_Flexion	Sphericity Assumed	1609.689	2	804.844	45.327	.000	.618
	Greenhouse-Geisser	1609.689	1.800	894.114	45.327	.000	.618
	Huynh-Feldt	1609.689	1.985	810.877	45.327	.000	.618
	Lower-bound	1609.689	1.000	1609.689	45.327	.000	.618
Right_Lateral_Flexion * Group	Sphericity Assumed	9.956	2	4.978	.280	.757	.010
	Greenhouse-Geisser	9.956	1.800	5.530	.280	.734	.010
	Huynh-Feldt	9.956	1.985	5.015	.280	.755	.010
	Lower-bound	9.956	1.000	9.956	.280	.601	.010
Error(Right_Lateral_Flexion)	Sphericity Assumed	994.356	56	17.756			
	Greenhouse-Geisser	994.356	50.409	19.726			
	Huynh-Feldt	994.356	55.583	17.889			
	Lower-bound	994.356	28.000	35.513			

The Tests of Within-Subjects Effects table tells us if there was an overall significant difference between the means at the different time points.

It is noted that there was no significant difference between the two groups (p = .176).

Upon tests of within- subjects contrasts (Right Lateral Flexion), results showed that Traumeel® was as effective in the improvement of the Right Lateral Flexion movement as homoeopathic Simillimum.

Table 4-31 Tests of Within-Subjects Contrasts (Right Lateral Flexion)

Measure: MEASURE_1							
Source	Right_Lateral_Flexion	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Right_Lateral_Flexion	Linear	1560.600	1	1560.600	66.027	.000	.702
	Quadratic	49.089	1	49.089	4.133	.052	.129
Right_Lateral_Flexion * Group	Linear	9.600	1	9.600	.406	.529	.014
	Quadratic	.356	1	.356	.030	.864	.001
Error(Right_Lateral_Flexion)	Linear	661.800	28	23.636			
	Quadratic	332.556	28	11.877			

Tests of Within-Subjects Contrasts shows the significance level for differences between the individual time points. It is noted that there was no significant difference between the two groups.

4.3.6 LEFT LATERAL FLEXION

Table 4-32 Multivariate Tests (Left Lateral Flexion)

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared
Left_Lateral_Flexion	Pillai's Trace	.623	22.332[b]	2.000	27.000	.000	.623
	Wilks' Lambda	.377	22.332[b]	2.000	27.000	.000	.623
	Hotelling's Trace	1.654	22.332[b]	2.000	27.000	.000	.623
	Roy's Largest Root	1.654	22.332[b]	2.000	27.000	.000	.623
Left_Lateral_Flexion * Group	Pillai's Trace	.035	.484[b]	2.000	27.000	.622	.035
	Wilks' Lambda	.965	.484[b]	2.000	27.000	.622	.035
	Hotelling's Trace	.036	.484[b]	2.000	27.000	.622	.035
	Roy's Largest Root	.036	.484[b]	2.000	27.000	.622	.035

a. Design: Intercept + Group
Within Subjects Design: Left_Lateral_Flexion

b. Exact statistic

Multivariate analysis of variance is also known as multiple analysis of variance (MANOVA), is a statistical test procedure for comparing multivariate (population) means of several groups. The table above shows Multivariate analysis for Left Lateral Flexion.

Table 4-33 Mauchly's Test of Sphericity (Left Lateral Flexion)

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Left_Lateral_Flexion	.798	6.079	2	.048	.832	.910	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept + Group
Within Subjects Design: Left_Lateral_Flexion

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

Since the significance value is greater than 0.05, it implies that sphericity has not been violated.

Thus both the Traumeel® group and the Simillimum group participants showed significant improvement in the Left Lateral Flexion movement.

Table 4-34 Tests of Within-Subjects Effects (Left Lateral Flexion)

Measure: MEASURE_1							
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Left_Lateral_Flexion	Sphericity Assumed	1215.089	2	607.544	28.492	.000	.504
	Greenhouse-Geisser	1215.089	1.664	730.021	28.492	.000	.504
	Huynh-Feldt	1215.089	1.820	667.588	28.492	.000	.504
	Lower-bound	1215.089	1.000	1215.089	28.492	.000	.504
Left_Lateral_Flexion * Group	Sphericity Assumed	18.156	2	9.078	.426	.655	.015
	Greenhouse-Geisser	18.156	1.664	10.908	.426	.619	.015
	Huynh-Feldt	18.156	1.820	9.975	.426	.637	.015
	Lower-bound	18.156	1.000	18.156	.426	.519	.015
Error(Left_Lateral_Flexion)	Sphericity Assumed	1194.089	56	21.323			
	Greenhouse-Geisser	1194.089	46.605	25.622			
	Huynh-Feldt	1194.089	50.963	23.430			
	Lower-bound	1194.089	28.000	42.646			

The Tests of Within-Subjects Effects table tells us if there was an overall significant difference between the means at the different time points.

It is noted that there was no significant difference between the two groups (p = .176).

Upon tests of within- subjects contrasts (Left Lateral Flexion) , results showed that Traumeel® was as effective in the improvement of the Left lateral flexion movement as homoeopathic Simillimum.

Table 4-35 Tests of Within-Subjects Contrasts (Left Lateral Flexion)

Measure: MEASURE_1							
Source	Left_Lateral_Flexion	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Left_Lateral_Flexion	Linear	1215.000	1	1215.000	42.327	.000	.602
	Quadratic	.089	1	.089	.006	.937	.000
Left_Lateral_Flexion * Group	Linear	4.267	1	4.267	.149	.703	.005
	Quadratic	13.889	1	13.889	.996	.327	.034
Error(Left_Lateral_Flexion)	Linear	803.733	28	28.705			
	Quadratic	390.356	28	13.941			

Tests of Within-Subjects Contrasts shows the significance level for differences between the individual time points. It is noted that there was no significant difference between the two groups.

4.4 HOMOEOPATHIC REMEDIES PRESCRIBED

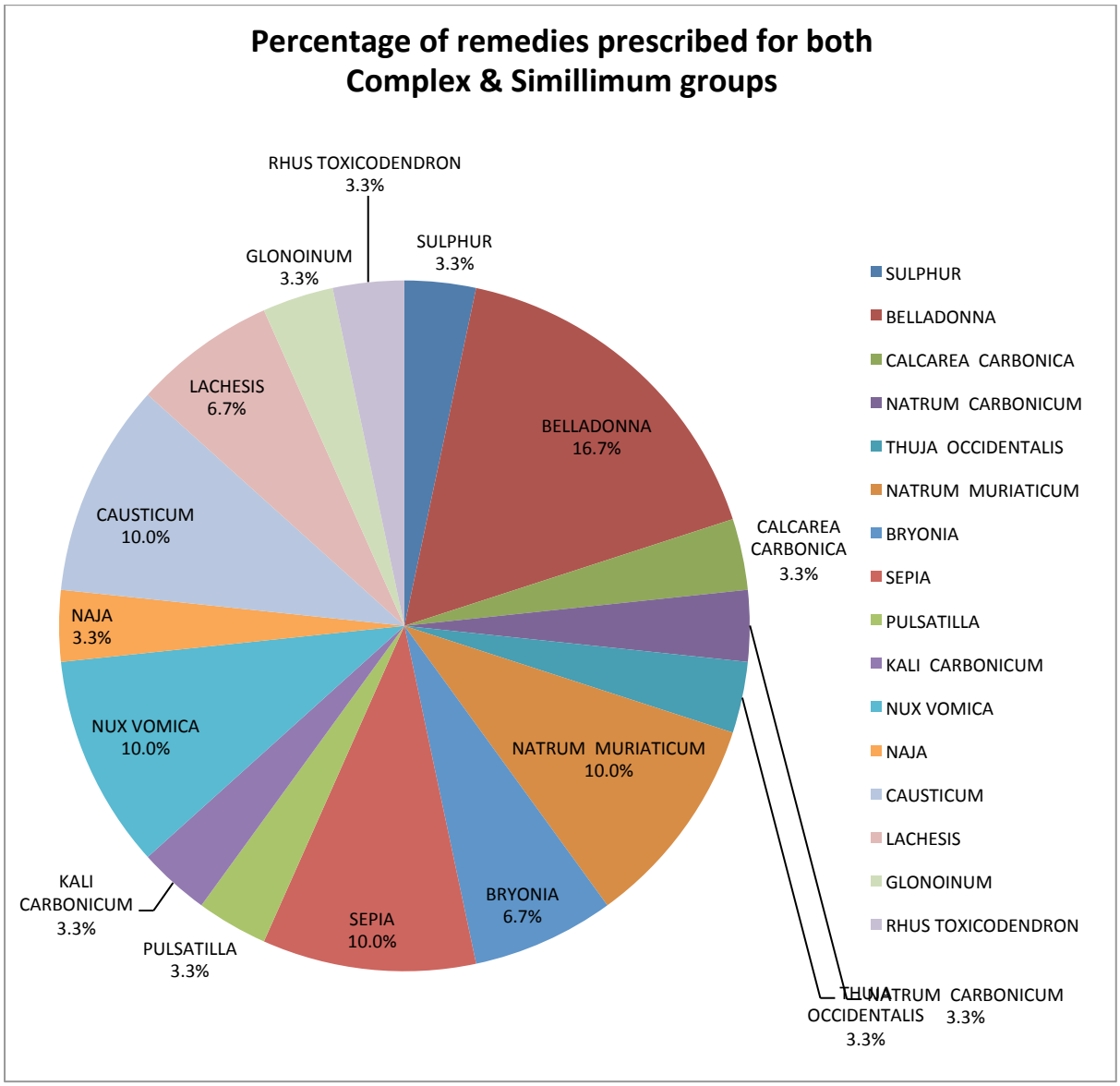

Figure 4-6 Percentage of remedies prescribed for both Complex and Simillimum groups

There were 30 Homoeopathic remedies prescribed during the study. Figure 4.6 illustrates the percentage of remedies prescribed for both complex and Simillimum groups. The most predominate remedies were *Belladonna, Natrum Muriaticum, Nux vomica, Sepia* and *Causticum.*

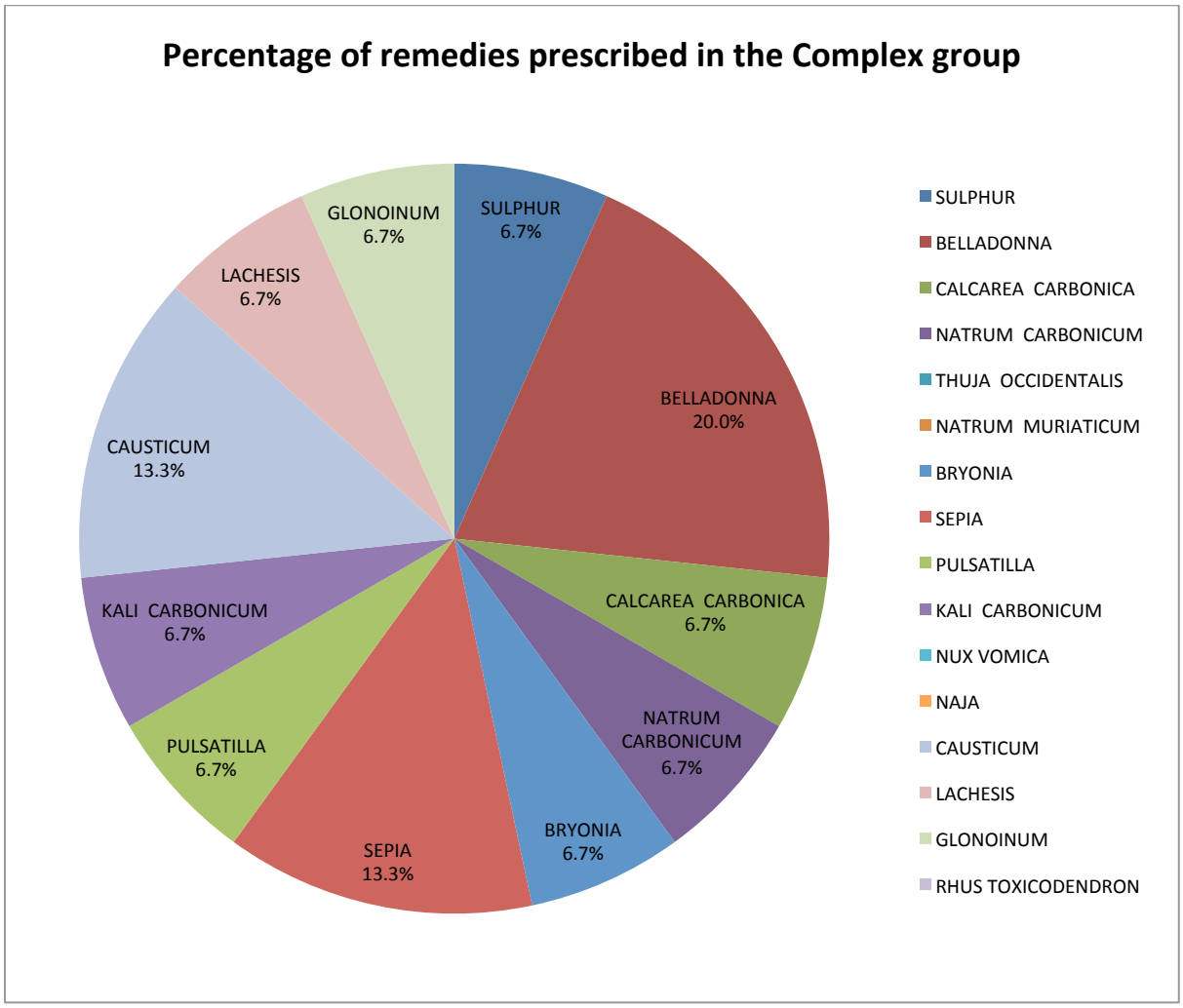

Figure 4-7 Percentage of remedies prescribed in the complex group

There were 15 remedies prescribed but not dispensed to the participants in the Complex group. The remedies predominated prescribed were *Belladonna, Sepia* and *Causticum*. This is evident in figure 4.7.

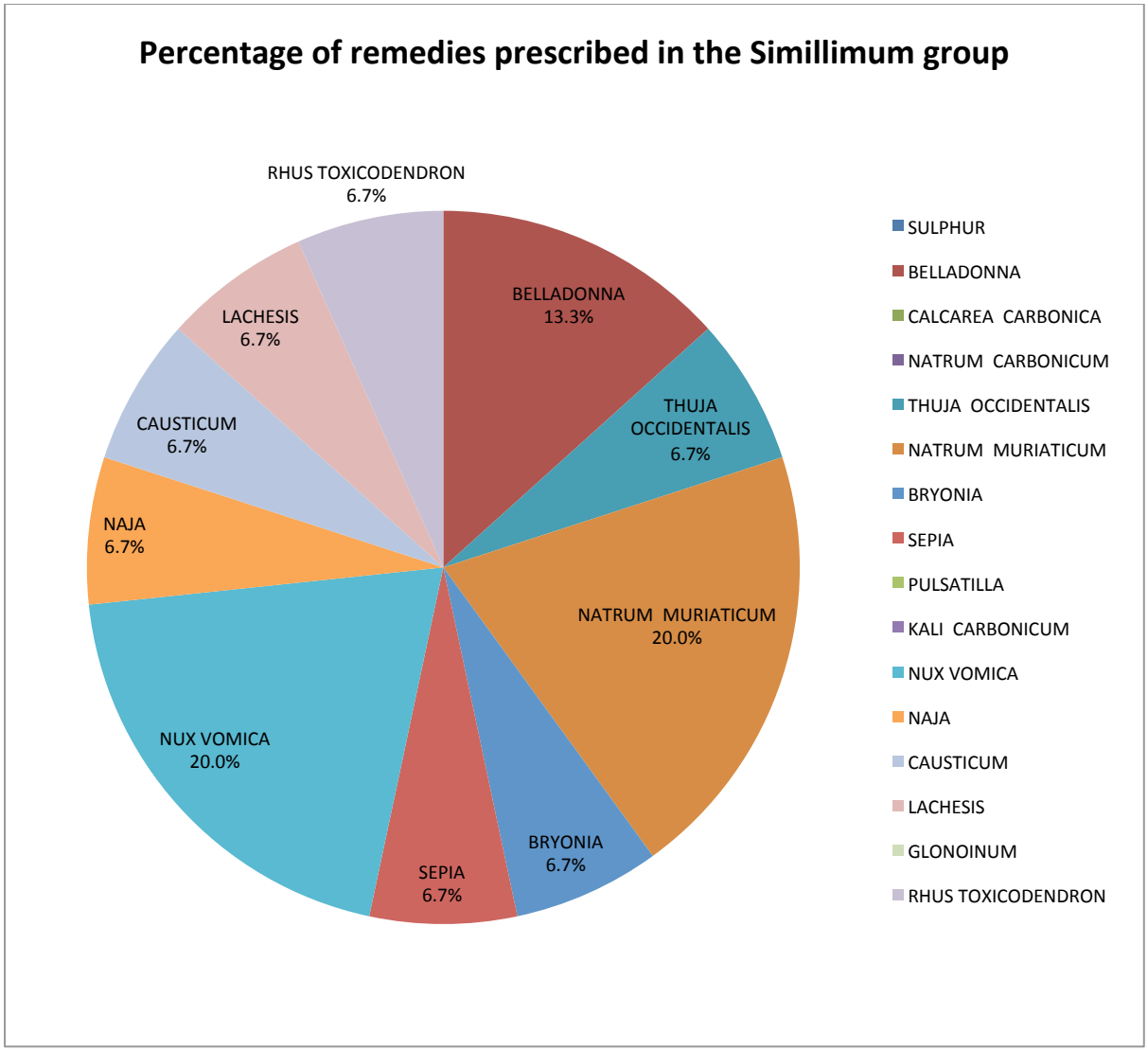

Figure 4-8 Percentage of remedies prescribed in the Simillimum group

There were 15 remedies prescribed and dispensed to the participants in the Simillimum group.

The remedies predominately prescribed and dispensed were *Naturum Muriaticum, Nux Vomica* and *Belladonna.* This is evident in figure 4.8.

4.5 CONCLUSION

Both the Simillimum and complex treatments were effective in the treatment of acute mechanical neck pain, but there was no evidence to show that one treatment was more beneficial than the other, since the ranges of motion and Neck Disability Index indicated similar improvements in the follow up consultations for both groups.

CHAPTER 5

DISCUSSION

5.1 INTRODUCTION

The results presented in the previous chapter, show significant improvement in the neck pain intensity subjectively, according to the Neck Disability Index (Appendix A1) done on the first and final consultation. There was also improvement in cervical range of motion according to data collected in the two follow up consultations on day 3 and day 7. The data clearly illustrates the acceptance of the first and second hypothesis and rejection of the third. This leads one to conclude that Traumeel® is as effective as homoeopathic Simillimum in the treatment of acute mechanical neck pain.

5.2 DEMOGRAPHIC DATA

A review of the demographic pie chart indicates that 26.7% of the participants were of African descent, 13.3% were of Caucasian descent and 60% Indian descent. The majority of the participants were between the ages of 20 – 29 years of age (33.6%). This data correlates with median age of 23 years of age in Kwa-Zulu Natal reported in the South African census in 2011.

5.3 COMPLEX GROUP ANALYSES

A total of 15 patients received Traumeel® (complex treatment). Ten female participants (73.3%) and 5 male participants (26.7%) received Traumeel®. Of the participants 33% who received Traumeel® worked at a desk, 46.7% were students, 6.7% worked in the health field, 6.7% worked in a manual labour job and 6.7% were unemployed. The racial demographics indicated that 20% of the complex group participants were of African descent, 13.3% were

Caucasian and 66.7% were of Indian descent. From the patient histories it emerged that 26.7% did not have any prior neck pain and 73.3% had a history of neck pain.

5.4 SIMILLIMUM GROUP ANALYSES

A total of 15 patients received homoeopathic Simillimum treatment. Twelve females (80%) and 3 males (20%) received Simillimum treatment. Of the participants, 46.7% who received Simillimum worked at a desk, 33.3% were students, 6.7% worked in a manual labour job and 13.3% were unemployed. The racial demographics indicated that 33.3% of the Simillimum group participants were of African descent, 13.3% were Caucasian and 53.3% were of Indian descent. From the patient histories it emerged that 13.3% did not have any prior neck pain before and 86.7% had a history of neck pain.

5.5 COMPLEX AND SIMILLIMUM REMEDY ANALYSIS

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, 2001) and The Essential Synthesis homoeopathic repertory (Schroyens, 2007) was used to confirm the selection of each remedy.

As seen in Figure 4.3, the most predominant remedies prescribed were *Belladonna, Natrum Muriaticum, Nux vomica, Sepia and Causticum*. *Belladonna* was prescribed in 16.7% of the cases, *Natrum Muriaticum* in 10%, *Nux Vomica* for 10%, Sepia for 10% and *Causticum* for 10% of all cases.

The most commonly prescribed remedies in complex group were *Belladonna* (20%)*, Sepia* (13.6%) and *Causticum* (13.6%). These remedies were prescribed but Traumeel® was dispensed instead of the Simillimum. The most commonly prescribed remedies in Simillimum group were *Naturum Muriaticum* (20.0%)*, Nux Vomica (*20.0%) *and Belladonna* (13.3%).

Atropa belladonna is commonly prescribed for neuralgic pain that comes and goes suddenly. Pains are usually sharp, throbbing, cutting, shooting with spasms or twitching. The pain is characterised by a stiff neck and shoulder with a pain specific to the nape of the neck (Vermeulen, 2001).

Natrum Muriaticum is prescribed for a stiff neck with a bruised backache sensation. Patients experience stitches in the region of the neck with violent pulsations in the small of the back. Patients may experience a desire for firm support and a paralytic sensation may be felt in the small of the back (Vermeulen, 2001).

Nux vomica is prescribed when the patient complains of a weak feeling in their neck and their head drops forward towards the chest. Pain is experienced along the spinal region from the neck to sacrum region. Backache and neuralgia of the sacrum may accompany the neck pain. Patients are usually overworked and exhausted and an abuse of substances is not uncommon. The patient may also have a headache caused photosensitivity with nausea (Vermeulen, 2001).

Sepia is a common remedy prescribed in menopausal women with pains that extend to the back. Along with the aching pain between the shoulder blades, there is coldness between the shoulders. Patients experience headaches that nay come in "terrible shocks" which is pulsating. The pain is accompanied by excessive prostration and exhaustion (Vermeulen, 2001).

Causticum is a commonly prescribed remedy for patients who describe their pain as "caught", spasmodic or paralytic. There is a dull pain in the nape of the neck with stiffness of the neck and back on rising from a seated position. There could be stiffness of the neck and throat, & pain in the occiput where the muscles feel bound (Vermeulen, 2001).

Atropa belladonna was the only remedy that was prescribed as a Simillimum and dispensed in the Simillimum group, that is a known ingredient in Traumeel®.

Although the study elicited positive results, certain methodology recommendations need to be considered. The follow up consultations were done on day 1, 3 and 7. Patients may have

benefited from longer periods apart between follow ups, allowing the medicine to effectively show a change in the range of motion, and decrease in pain.

Even though the majority of the patients showed an improvement in the second consultation, the second consult was spaced too closely and patients became disheartened with the only slight improvement.

CHAPTER 6

CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

The purpose of this study was to compare the relative effectiveness of homoeopathic Simillimum against Traumeel® (homoeopathic complex) in the treatment of acute mechanical neck pain using the neck disability scale, range of motion measurements and a subjective observation.

It was noted that when using an ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores between groups were statistically not significantly different (p = 0.112). The p-values (sig.) are greater than 0.05, it implies that there is no significant difference between the groups.

Therefore, both the Traumeel® and Simillimum treatments were effective in the treatment of acute mechanical neck pain, but there was no evidence that one treatment was more beneficial than the other.

The results of the study led to the conclusion that both treatment methods are effective in the treatment acute mechanical neck pain in the African, Caucasian and Asian populations and that both treatments are equally as beneficial. Therefore homoeopathic treatment can be suggested for future treatment of acute mechanical neck pain, with homoeopathic complex (Traumeel®) being used as a standard treatment method as it is time saving and can be standardized to be used in hospitals and clinics in the public sector.

6.2 RECOMMENDATIONS

This clinical trial can be improved in the following ways:

- The period in which the trial runs could be extended to 2 weeks, with consultations scheduled on day 1, day 7 and day 14. This allows the medicine a maximum amount of time to act and for the patient to see results by the second consultation.
- The sample group could be increased to provide a greater statistical interpretation and to decrease the margins of bias.
- The sample group could include equal amounts of male and female participants to ascertain whether a faster pattern of improvement were to occur in either gender.
- Repertorizing should be standardised using a computer program.
- A complex comprising of *Atropa belladonna , Natrum Muriaticum, Nux vomica, Sepia* and *Causticum* should be tested in the treatment of AMNP.
- A study done on male and females separately is recommended.

REFERENCES

Aboobaker, R. 2011. *A comparison of the efficacy of two homoeopathic interventions in the treatment of primary hypertension in adult females. M:Hom.dissertation,Durban University of Technology.*

Ackelman, B. H; Lindgren, U. 2002. Validity and reliability of a modified version of the Neck Disability Index. *Journal of Rehabilitation Medicine,* 34 (2002): 284–287.

Allied health professions council of South Africa .1982. Available at: http://www.ahpcsa.co.za/pdf_files/legislation/the-act/The%20Allied%20Health%20Professions%20Act%2063%20of%201982%20_as%20amended.pdf [Accessed 14 November 2014]

Ally, S. 2013. *The efficacy of a homoeopathic complex (Kalium bromatum 9CH, Natrum muriaticum 9CH, Selenium 9CH, Sulphur 9CH and Thuja occidentalis 9CH) in the treatment of acne vulgaris*. Mtech : Homoeopathy. Dissertation, Durban University of Technology.

Alvares, D.J., Rockwell, P.G. 2002. Trigger Points: Diagnosis and Management. *American Family Physician*. 65(4):1-7.

Arrandale, C. 2005. A Comparative study to determine the effectiveness of oral and parenteral Traumeel®S versus spinal manipulative therapy in the treatment of mechanical posterior neck pain. M.Tech:Chiropractic. Dissertation, University of Johannesburg.

Arora, S.; Harris, T.; Scherer, C. 2002. Clinical Safety of Traumeel®. *Department of Medicine, University of New Mexico Health Sciences Center*, 11(5).

Bergmann, T. F.; Perterson, D. H; Lawrence, D. J. 1993. *Chiropractic Technique*. New York: Churchill Livingstone.

Bickley, L. S., Szilagyi, P. G. 2009. Bate's Guide to Physical Examination and history taking. Philadelphia: Lippincott Williams & Wilkins. ISBN 1-6054-7400-2.

Binder, A. 2006. Neck pain. *Clinical Evidence,* 15: 1654–75.

Birnesser, H.; Oberbaum, M.; Klein, P.; Weiser, M. 2004. The Homeopathic preparation Traumeel® S compared with NSAIDs for symptomatic treatment of epicondylitis. *Journal of Musculoskeletal Research*. 8: 112-128.

Boon, N. A., Colledge, N. R., Walker, B. R. 2006. Davidson's Principles and Practice of Medicine. Edinburgh: Elsevier Limited. ISBN 978-0-443-10133-5.

Cape, M. 2005. A comparative Study to Determine the Efficacy of Oral and Parenteral Traumeel®S, in the treatment of Cervical Facet Syndrome. M.Tech:Hom. Dissertation, Technikon Witwatersrand. Johannesburg.

Cassidy, J.D., Lopes, D.C. and Yong-Hing, M.B. 1992. The immediate Effect of Manipulation versus Mobilization on Pain and Range of Motion in the Cervical Spine: A Pilot Study. *Journal of Manipulative and Physiological Therapeutics*. 15(9):570-575

Chauhan,V.K. and Gupta,M.2007. *Homeopathic principles and practice of medicines: a textbook for medical students and homoeopathic practitioners.* New Delhi: B.Jain Publisher (P) Ltd.

Cleland, A. J.; Walker, J. M.; Childs, J. D.; Whitman, M. J. 2008. Psychometric Properties of the Neck Disability Index and Numeric Pain Rating Scale in Patients With Mechanical Neck Pain. *Archives of Physical Medicine and Rehabilitation,* 89: 69–74.

(CROM) Cervical Range of Motion Instrument (Performance Attainment Associates; Patient no. 4,777,965 & 4,928,709)

Department of Health. 2000. *Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act.*Act 6 of 2000 Available at : http://www.health.gov.za/docs/acts/2000/a6-00.pdf [Accessed 17/11/2014]

Department of Health. 2011. *Complementary Medicines- Quality, Safety and Efficacy.* Firstpublication released for comment [online]. Available at : http://www.camcheck.co.za/wp-content/uploads/7%2001%20CAMs%20QSE%20Aug11%20v1%281%29.pdf [Accessed 17/11/2014]

De Schepper, L.2005. *Hahnemann revisted: A textbook of classical homeopathy for the professional.* New Delhi: B. Jain Publishers (P) Ltd.

Dreyer, M. S. 2009. *Pharmacology for nurses and other health workers*. Capetown: Pearson Education South Africa (Pty) Ltd.

European Council for Classical Homeopathy. 2009. *The safety of Homeopathy [online]*. Available at: http://www.homeopathy.org/research/basic/TheSafetyofHomeopathy.doc [Accessed 2 November 2011]

Field, A. 2009. *Discovering statistics using SPSS.* Third edition. London : Sage publishers.

Gaier, H. 1991 Thorsons Encyclopedica Dictionary of Homoeopathy: The definitive reference to all aspects of homoeopathy. London : Harper Collins.

Gatterman, M. I. 1990. *Chiropractic Management of Spine Related Disorders*. Baltimore: Williams and Wilkins.

Guzman J, Haldeman S, Carroll L. J, Carragee E. J, Hurwitz E. L, Peloso P, Nordin M, Cassidy J. D, Holm L. W, Côté P, van der Velde G, Hogg-Johnson S. Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. *Journal of Manipulative and Physiological Therapeutics*, 32: 199–213.

Hahnemann, S. 2011. *Organon of Medicine*. 5th and 6th edition combined. New Delhi: B. Jain Publishers.

Haldeman, S. 1992. *Principles and Practice of Chiropractic.* Second Edition. Conneticut: Appleton and Lange. 641p. ISBN: 0-8385-6360-0

Haneline, M. 2004. Acute Mechanical Neck Pain and the Continuum of Healing.*Chiropractic Philosophy & Clinical Technique, Palmer West College of Chiropractic.*

Hepburn, S. 2000. The Relative Effectiveness of Non-Steroidal Anti-Inflammatory Medication as compared to a Homoeopathic Complex in the Treatment of Cervical Facet Syndrome. M.Tech: Chiropractic. Dissertation, Durban University of Technology.

Harpham, G. 2005. The Reletive Effectiveness of Manipulation versus a Combination of Manipulation and Oral Traumeel® S in the Treatment of Mechanical Neck Pain. M.Tech: Chiropractic. Disseration, Durban University of Technology.

Hershoff, A.1996. *Homoeopathy for Musculoskeletal Healing*. Berkeley: North Atlantic Books.

Homeopathyresource. 2009. Extensive Study Concludes Homeopathic Remedies and Treatment Are Safe [online].
Available at: http://homeopathyresource.wordpress.com/tag/european-council-of-classical-homeopathy/ [Accessed 13 November 2014].

Howel, E.R. 2011. The association between neck pain, the Neck Disability Index and cervical ranges of motion: A narrative review. *Journal of Canadian Chiropractic Association,* 55(3):211-221.

Hurwitz, E.L, Carragee, E., van der Velde, G., Carrole, L., Nordin, M., Guzman, J., Peloso, Holm, L.W., Cote, P., Hogg-Johnson, S., David Cassidy, J., Haldemann, S. 2008. Treatment of neck pain : Noninvasive Interventions. *European Spine Journal.* 17:123-152.

Jenson, I.; Harms-Ringdahl, K. 2007. *Best Practice and Research Clinical Rheumatology,* 21(1): 93-108.

Kamanli, A. A., Kaya, A. O., Ardicoglu, A. S., Ozgocmen, F., Ozkurt Zengin, A., and Bayil, Y. 2005. Comparison of Lidocaine injection, butulinum injection, dry needling to trigger points in myofascial pain syndrome. *Rheumatology International.* 25:604-611.

Kent , K. 2005. *The Effectiveness Of An Oral Homoeopathic Preparation Of Selenium Sulphide 12x In The Management Of Dandruff (Seborrheic Dermatitis Of The Scalp). M:Hom.dissertation,Durban University of Technology.*

Koes, B.J.; Scholten, R. J. P. M.; Mens, J. M. A.; Bouter, L. M. 1997. Efficacy of Nonsteroidal Anti Inflammatory Drugs for Low Back Pain: A Systematic Review of Randomised Clinical Trials. *Annals of the Rheumatic Diseases*. 56:214-223.

Lau, HMC, Chiu, TTW & Lam, T-H. 2011. The effectiveness of thoracic manipulation on patients with chronic mechanical neck pain – A randomized controlled trial. *Manual Therapy*, 16 (2): 141-147.

Luc De Schepper. 1994. *Muscular Skeletal Diseases and Homeopathy*. Santa Fe: Full of life Publishing.

*Medicines and related substances amendment bill.*2014. Available at: http://www.parliament.gov.za/content/b%206%20%202014%20(medicines%20and%20related%20substances).pdf [Accessed 14 November 2014]

McCarthy, M. J. H.; Grevitt, M. P.; Silcocks, P.; Hobbs, G. 2007. The reliability of the Vernon and Mior Neck Disability Index, and its validity compared with the short form-36 health survey questionnaire. *European Spine Journal,* 16: 2111–2117.

Morrison, R. 1998. *Desktop Companion To Physical Pathology.* California: Hahnemann Clinic Publishing.

Moulder, N. 2003. *The Relative effectiveness of Proprioceptive Exercises as an Adjunct to Cervical Spine Manipulation in the Treatment of Chronic Cervical Spine Pain and Disability associated with Whiplash Injury.* M.tech : Chiropractic. Dissertation, Durban Institute of Technology.

Muchna, J. M. 2011. An epidemiological investigation into the risk factors associated with neck pain in the Indian population in the greater Durban area. M.Tech: Hom. Dissertation, Durban University of Technology.

Ogbru, O. 2012. Nonsteroidal Anti-inflammatory Drugs (NSAIDs) [online]. Available at: http://www.medicinenet.com [Accessed 17 May 2013].

O'Reilly, W.B.(ed.) 1996. *Organon of the medical art- Dr. Samuel Hahnemann.* 6th ed. Palo Alto, California: Birdcage Books.

O'Reilly, W.B. 2001. *Organon of the medical art- Dr. Samuel Hahnemann.* California: Birdcage Books.

Parsons, C. J. 2009. The use of Heel remedies in musculoskeletal disorders handout. Heel.

Rodríguez, L. A. G.; Pérez, A. G.; Bueno, H.; Hwa, J. 2011. NSAID Use Selectively Increases the Risk of Non-Fatal Myocardial Infarction: A Systematic Review of Randomised Trials and Observational Studies. *PLOS Clinical Trials,* 6(2).

Schafer,R. C. & Faye, L. J. Motion Palpation and Chiropractic Technique – Principals of Dynamic Chiropractic. 1990. 2nd ed. Huntington Beach: The motion Palpation Institute. Pp 88-103

Schafer, R. C. 2011. Physcial Examination of the Neck and Cervical Spine [online]. Available at: http://www.chiro.org/ACAPress/Physical_Examination_of_the_Neck.html#Motion_Palpation [Accessed 19 June 2013].

Schellingerhout, J.M., Verhagen, A.P., Heymans, M.W., Koes, B.W., De Vet, H.C., Terwee, C.B. 2011. Measurement properties of disease-specific questionnaires in patients with neck pain: A systematic review. *Springerlink:* Available: http://www.springerlink.com/content/q428336v4x110566v/ (Accessed 12/11/2014)

Schneider, C.; Münche, K. S. 2011. Traumeel® – an emerging option to nonsteroidal anti-inflammatory drugs in the management of acute musculoskeletal injuries. *International Journal of General Medicine*, 4: 225–234.

Schneider, C.; Schneider, B.; Hanish, J.; van Haselen, R. 2008. The role of a homoeopathic preparation compared with conventional therapy in the treatment of injuries: An observational cohort study. *Complementary Therapies in Medicine*, 16 (2008): 22-27.

Shroyens, F. 2007. *The Essential Synthesis*. London: Homeopathic Book Publishers

South African Demographic and Health survey. 2003. Available at: http://www.doh.gov.za/facts/sadhs1003/part2.pdf. [Accessed 12 November 2014]

Speed, C. 2003. Injection Therapies for Soft Tissue Lesions. *Best Practice and Research Clinical Rheumatology.* 17(1):167-181.

Spitzer W.O., Skovron, M.L and Salmi L.R. comps. 1995. *Scientific Monograph of the Quebec Taskforce on Whiplash-Associated Disorders: Redefining "Whiplash" and its management.* Spine. 20: 1s- 73S.
Statistics South Africa Census. 2011. Aavilable at: www.statssa.gov.za/Publications/P03014/P030142011.pdf [Accessed 14 November 2014]

Thompson, E., Barron, S. and Spence, D.2004. A preliminary audit investigating remedy reactions including adverse events in routine homeopathic practice. *Homeopathy* [online], 93(4):203-209. Available at http://www.sciencedirect.com [Accessed 3 March 2013].

Traumeel® [online]. 2012. Available at: http://www.healingedge.net/ [Accessed 17 May 2013].

Tsakitzidis G, Remmen R, Peremans L, V an Royen P , Duchesnes C, Paulus D , Eyssen M. Non-specific neck pain: diagnosis and treatment. Good Clinical Practice (GCP). Brussels: Belgian Health Care Knowledge Centre (KCE). 2009.

Vaithilingam, V.2008.*The effectiveness of a homoeopathic complex (Germanium metallicum 30CH, Nux vomica 12CH, Kalium phosphoricum 6CH, Picricum acidum 6CH) in the treatment of job burnout in the human services field.* M:Hom.dissertation,Durban University of Technology.

Vermeulen, F. 2001. *Concordant Materia Medica*. New Delhi: Indian Books & Periodical Publishers.

Vernon, H.; Mior, S. 1991. The Neck Disability Index: a study of reliability and validity. *Journal of Manipulative and Physiological Therapeutics*, 14: 409-415.

Vithoulkas, G. 1980. *The Science of Homeopathy.* New Delhi: B. Jain Publishers.

Vos, C.; Verhagen, A.; Passchier, J.; Koes, B. 2007. Management of acute neck pain in general practice: a prospective study. *The British Journal of General of General Practice,* 57(534): 23–28.

Weiner, D. K.; Ernst, E. 2004. Complementary and Alternate Approaches to the Treatment of Persistent Musculoskeletal Pain. *Clinical Journal of Pain,* 20 (4): 224-255.

Wiesel, S., Boden, S., Borenstein, D., Feffer, H. 1992. *Neck Pain.* 2ND ed. The Michie Company.

Woolf, A. D.; Zeidler, H.; Haglund, U.; Carr, A. J.; Chaussade, S.; Cucinotta, D.; Veale, D. J.; Martin-Mola, E. 2004. Musculoskeletal pain in Europe: its impact and a comparison of population and medical perceptions of treatment in eight European countries. *British Medical Journal*, 63(4): 342-7.

Youdas, J.W. 1991. Reliability of Measurements of Cervical Spine Range of Motion – Comparison of Three Methods. Physical Therapy, Vol. 71, no.2 , pp.98-106.

Young, A. B.; Walker, J. M.; Strunce, B. J. 2009. Responsiveness of the Neck Disability Index in patients with mechanical neck disorders - Clinical Study. *The Spine Journal,* 9 (2009): 802–808.

APPENDIX A1 – NECK DISABILITY INDEX

Patient Name: _____ Age: _____

Neck Disability Index
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.

Neck Disability Index Source: Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. J Manipulative Physiol Ther. 1991 Sep;14(7):409-15.

APPENDIX A2 - RANGE OF MOTION

Patient Name : _____
Age : _____

Active and Passive Range of Motion

Flexion, extension, rotation, lateral flexion, and circumduction are the basic movements of the cervical region. Bone, muscle, tendon, ligament, and lymph node abnormalities tend to restrict motion (Schafer, Faye, 1990).

Flexion and Extension

Active cervical flexion and extension is tested by having the patient lower and raise his chin as far as possible without moving his shoulders. The smoothness of motion and degree of limitation bilaterally is noted (Schafer, Faye, 1990).

Passive cervical flexion and extension is examined by placing your hands on the sides of the patient's skull and rolling the skull anterior-inferior so that the chin approximates the sternum and posterior-superior so that the nose is perpendicular to the ceiling (Schafer, Faye, 1990).

Rotation

Active rotation is tested by having the patient move his nose as far as possible to the left and right without moving his shoulders. The smoothness of motion and degree of limitation bilaterally is noted (Schafer, Faye, 1990).

Passive rotation is examined by placing your hands on the patient's skull and turning the head first to one side and then to the other so that the chin is in line with the shoulder (Schafer, Faye, 1990).

Lateral Flexion

Active lateral flexion is tested by having the patient attempt to touch each ear on the respective shoulder without moving the shoulders. Normally, about a 45° tilt can be observed (Schafer, Faye, 1990).

Passive lateral flexion is tested by placing your hands on the patient's skull and bending the head sideward toward the shoulder on each side (Schafer, Faye ,1990).

Goniometry

The patient is placed in a neutral position, centering goniometer with its base on line with the superior border of the larynx and the goniometer arm along the mastoid process. The neutral reading is recorded (Schafer, 2011).

- **Cervical flexion and extension:** Have patient flex their head as far forward as possible, keeping goniometer arm along mastoid process, and record end of flexion motion. Then, starting from the neutral position, the patient extends their head as far back as possible, the goniometer arm is placed along the mastoid process, and then record the end of extension motion (Schafer, 2011).

- **Cervical lateral flexion:** The patient is placed in neutral position with his arms abducted to steady the shoulders. The goniometer is centered over the back of the neck with the base on the vertebra prominans and the goniometer arm extending along the midline of the neck. The neutral reading is recorded. The patient bends the neck as far to the left as possible and this reading is recorded. The end of lateral flexion motion is recorded. Then the reading for the right side in a converse manner is recorded (Schafer, 2011).

- **Cervical rotation:** The patient is placed in neutral position and the patient's shoulders are steadied with your hands. The patient is asked to rotate their head as far to the right and left as possible. The arc of motion is estimated separately for right and left motion by position of the patient's chin in relation to the shoulder. The goniometer is not used for this evaluation (Schafer, 2011).

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°)			

Adapted from Arrandale,2005

APPENDIX B

LETTER OF INFORMATION AND CONSENT

Welcome to my study! Your participation is greatly appreciated.

Title of the Research Study: The Relative effectiveness of Homoeopathic Simillimum versus oral Traumeel® in the Treatment of Acute Mechanical Neck Pain

Principal Investigator/s/researcher: Ashmitha Rajballi (BTech.Homoeopathy)

Co-Investigator/s/supervisor/s: Dr Botha (DTech:Homoeopathy**)**
Dr De Waard (MTech: Homoeopathy)

Brief Introduction and Purpose of the Study: I am a master's student at the Durban University of Technology. I am investigating two different homoeopathic treatment approaches to Acute Mechanical Neck Pain to ascertain which one is more effective. This is a double blind study, thus, 15 of the 30 participants will receive a homoeopathic Simillimum and the other 15 will receive a homoeopathic complex (oral Traumeel®). I will be unaware which participant will receive which treatment. Medication will be dispensed according to a random list by an external dispenser. The medicines that you will receive will be in a 30% medicinal alcohol base, containing the active ingredients.

Outline of the Procedures : The double blind trial will take place in the afternoons at the Homoeopathy Day Clinic at the Durban University of Technology. Treatment will be under the supervision of a qualified and registered Homoeopathic Doctor.

In order to participate in this trial, you will be screened for the following criteria:

- Patients should be between the ages of 18-55
- Patient should have acute neck pain not lasting more than two weeks
- Patients should experience pain with an acute onset and associated with asymmetrical restriction of the neck
- Patient should have a history of awkward posture or trauma
- Pain should not come with arm or leg weakness or paresthesias, changes in bowel function or bladder
- The patient should be asked the chronicity, quality and severity of the pain
- The researcher will look for visible inflammation

In order to participate in this trial, you will need to fulfil the following criteria:

- Only patients between the ages of 18 – 55 will be accepted
- Only cases of acute or sub-acute AMNP will be accepted. Thus patients will have neck pain for no more than two weeks before the start of the trial
- Patients should have neck pain Grade I and Grade II without major signs of pathology and with or without interference with daily activity
- English conversant to facilitate homoeopathic Simillimum prescription.

The following criteria would exclude you from participating in the trial:

- Patient will be excluded if they have neck pain for longer than 2 weeks.
- Presence of bone infection, spinal tumours.
- A history of Rheumatoid Arthritis or any other arthritides.
- If they showed any contraindications to Traumeel®
    - Hypersensitivity or anaphylactic reaction to any ingredient of Traumeel®
    - Presence of a progressive systemic disease such as TB, Collagen disorders, Multiple Sclerosis, HIV/AIDS infection or any other autoimmune disorders
- If the patient was on any anti-inflammatory or taking any of the following e.g.: Aspirin, Lithium, methotrexate or heparin
- If the patient was seeing any other Practioner with regard to the current acute neck pain such as a Chiropractioner or Physiotherapist throughout the duration of the study.
- If patient had any other form of treatment for acute neck pain during the duration of the study.
- If the patient is not conversant in English.

Once you have fulfilled the above, mentioned criteria you may be accepted to participate in the trial. Treatment will involve three consultations, an initial (lasting 1 hour), and two follow-up visits (30minutes each) with 3 days between each. The study in it's entirety, will last 7 days. At the first consultation a full history will be taken and a physical examination would be performed and you would also be required to complete a questionnaire. After which, you would be given medicine. All the information obtained from the consultation will be kept confidential.

This would be completed at the two follow-up visits.

Risks or Discomforts to the Participant: There are no known or potential risks

Benefits: Patients in all groups will benefit from the treatment as each will receive a different form of treatment for Acute Mechanical Neck Pain.

Reason/s why the Participant May Be Withdrawn from the Study: A participant will be removed due to non-compliance or severe illness. Participants are free to withdraw from the study at any time without risk or consequences.

Remuneration: There will be no remuneration but the participant will receive free treatment for Acute Mechanical Neck Pain for the duration of the study (7days)

Costs of the Study: All medication and consultations will be provided free of charge for the duration of the study.

Confidentiality: All information will be kept confidential at all times. Participants will be issued with a number, thus, no names or personal identifiers will be present on any data collected.

Research-related Injury: No research related injury is expected, as all treatment forms are free of side effects. In the unlikely event of an adverse effect occurring, additional treatment will be provided free of charge.

Persons to Contact in the Event of Any Problems or Queries:

Dr Izel Botha (Supervisor): Email : izelbotha@gmail.com
Dr De Waard (Co-supervisor): 0837015925
or Institutional Research Ethics administrator : 031 373 2900
or DVC: TIP, Prof F. Otieno : 031 373 2382
or dvctip@dut.ac.za.

General:

Thank you for participating in my Research. Please note, once again that participation is voluntary and if you feel you need to drop out at any time then you may. The name of the participant and information attained will be only be known by the researcher and supervisor and data collected will only be on a purely statistical basis.

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: REC 58/13,

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

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

DO YOU SUFFER FROM NECK PAIN?

HAS IT LASTED FOR LESS THAN 2 WEEKS?

THOSE WHO QUALIFY MAY RECEIVE...

FREE TREATMENT FOR 30 PEOPLE BETWEEN THE AGES OF 18 AND 55.

IF YOU ARE NOT CURRENLTY ON ANY MEDICATION AND WOULD LIKE TO PARTICIPATE IN RESEARCH BEING DONE AT DURBAN UNIVERSITY OF TECHNOLOGY DEPARTMENT OF HOMOEOPATHY OR WOULD LIKE TO KNOW MORE….

CONTACT: ASHMITHA ON 082 6919193

APPENDIX E

Institutional Research Ethics Committee
Faculty of Health Sciences
Room MS 19, Medical School Site
Steve Biko Campus
Durban University of Technology

P O Box 1334, Durban, South Africa, 4001

Tel: 031 373 2900
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3 September 2013

IREC Reference Number: REC 58/13

Ms A Rajballi
36 Greenfern Road
Moberi Heights

Dear Ms Rajballi

The relative effectiveness of homoeopathic similimum versus oral Traumeel® in the treatment of acute mechanical neck pain

I am pleased to inform you that Full Approval has been granted to your proposal REC 58/13.

The Proposal has been allocated the following Ethical Clearance number (REC 07/13). Please use this number in all communication with this office.

Approval has been granted for a period of one year, before the expiry of which you are required to apply for safety monitoring and annual recertification. Please use the Safety Monitoring and Annual Recertification Report form which can be found in the Standard Operating Procedures (SOP's) of the IREC. This form must be submitted to the IREC at least 3 months before the ethics approval for the study expires.

Any adverse events (serious or minor) which occur in connection with this study and/or which may alter its ethical consideration must be reported to the IREC according to the IREC SOP's. In addition, you will be responsible to ensure gatekeeper permission.
Please note that any deviations from the approved proposal require the approval of the IREC as outlined in the IREC SOP's.

Yours Sincerely

[redacted]
Prof J K Adam
Chairperson: IREC