The effectiveness of the Impulse Adjusting Instrument® compared to Dry Needling in the treatment of upper trapezius myofascial trigger points

By

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Dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology: Chiropractic

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I, Mandy Laing, do hereby declare that this dissertation is representative of my own work in both conception and execution (except where acknowledgements indicate to the contrary)

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DEDICATION

To my father Burt Laing and mother Kathy Laing, I appreciate your provision, sacrifices and love despite our many hardships. Thank you for giving me the opportunities to explore my potential and enabling me to complete this dissertation.

Most importantly, I thank my heavenly father for my mind to comprehend knowledge, my hands to type, my eyes to read and stamina to endure.

I dedicate this dissertation to my son Brett who was my main motivation to endure this process, I pray this serves as motivation for you to continually gain knowledge and insight.

“For wisdom will enter your heart and knowledge will be pleasant to your soul.”

- **Proverbs 2:10**

ACKNOWLEDGEMENTS

1. Firstly, to Jesus Christ, thank you for your grace, all your blessings of strength, skill and comfort. Thank you that with you, all things are possible. Thank you that the works of my hands may be a form of worship unto you.

2. To my son Brett, thank you for being such an amazing kid, for always giving me love and laughs. As I said before, you are my main motivation for everything I do, which I hope makes you as proud of me as I will be of you one day.

3. To my parents, none of this would have been possible without the two of you. I am grateful for the opportunities and sacrifices that you have both made. This includes the hours spent baby-sitting. Not one thing is taken for granted. I thank my father for being a good role model to me with your hard work and level-headed lifestyle. I pray you will see the fruits of your labour for me in your lifetime.

4. To my best friend Lyschelle, you are the best person I could get as a best friend. Thank you for your support, love, listening ear, shoulder to cry on, laugh inducing antics and words of wisdom.

5. To my Supervisor Dr. Desiree Varatharajullu, thank you for your time, efforts, help and advice that has been readily available throughout this journey

6. To my research assistant Shaylene Swanepool, thank you for your time and excellence. I appreciate it.

7. To Tonya Esterhuizen, thank you for your time and services, relating to the statistical analysis.

8. To the clinic and administrative staff, thank you for your assistance and patience. Thank you too to our friendly security guard for a smile every morning.

To all my research participants that participated in this study, I thank you with all my heart. I appreciate you all; I pray God's blessings on you. Without you, this study would not have been possible.

ABSTRACT

Aim: There is a paucity in the literature regarding the effectiveness of the Impulse Adjusting Instrument® (IAI) in treating myofascial trigger points (MFTPs) and regarding the effectiveness between dry needling and the IAI in the treatment of MFTPs. There are many limitations and an array of contraindications for dry needling. Therefore, an alternative method should be sought as this will be beneficial to the patient. Thus, the aim of this study was to determine the effectiveness of the IAI compared to dry needling in the treatment of MFTPs found in the upper trapezius muscle.

Methodology: This study was a randomised single-blinded clinical trial. This study consisted of 41 participants between the ages of 18 and 40 who were divided into two groups. The participants were randomly allocated into their respective groups using a blinded allocation method that was drawn up by the statistician. Groups were divided into dry needling (Group one (n=18)) and IAI (Group two (n=23)) treatment groups. Subjective neck pain level was determined using a numerical pain rating scale (NRS). The neck disability index (NDI) subjectively assessed the effect neck pain had on the participants' activities of daily living before and after treatment. The Patients Global Impression of Change (PGIC) tool was used to determine the participants' subjective impression of treatment outcomes since the beginning of the treatment. Objective pain pressure thresholds (PPT) were measured with an algometer. Objective cervical range of motion (CROM) in lateral flexion (LF) was measured with a goniometer. Each participant had four visits over a two week period, which included three treatments and a final visit for final measurements. Data was analysed using IBM SPSS version 23. Repeated measures ANOVA was used to examine the effect on each outcome measure. Directional trends in effectiveness were drawn up using profile plots to assess the direction and trends of the effects. A p value of < 0.05 was considered to be statistically significant.

Results: Intra-group and inter-group statistical analysis revealed all subjective measurements improved in both groups with no significant differences between the groups. With respect to objective measurements, there was no statistical improvement in LF CROM and dry needling had no improvement in PPT. Impulse Adjusting Instrument trigger point therapy showed an increase in PPT, however, when compared to dry needling there was no statistical difference in PPT.

Conclusion: The conclusion for this study states that the trends in each of the outcomes suggest that the IAI is as effective as dry needling for the treatment of MFTPs.

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LIST OF ABBREVIATIONS AND SYMBOLS

%	Percent
ACh	Acetylcholine
AL	Algometer
CDC	Chiropractic Day Clinic
CROM	Cervical Range of Motion
DUT	Durban University of Technology
IAI	Impulse Adjusting Instrument
IC	Ischaemic Compression
IREC	Institutional Research and Ethics Committee
MFTP	Myofascial Trigger Point
MPS	Myofascial Pain Syndrome
n	Sample size
N	Newtons
NDI	Neck Disability Index
NRS	Numerical Pain Rating Scale
PGIC	Patient's Global Impression of Change
PPT	Pain Pressure Threshold
RA	Research Assistant
ROM	Range of Motion
SMT	Spinal manipulative therapy
TENS	Transcutaneous Electrical Nerve Stimulation
TP	Trigger Point

CHAPTER 1 : INTRODUCTION

1.1 INTRODUCTION TO THE STUDY

Myofascial trigger points (MFTPs) are described as localised hyperirritable areas of pain within muscles or their fascia, which are extremely painful to touch, stretch or stimulation and can cause referred pain on manual compression of the MFTP (Vernon and Schneider 2009; Travell and Simons, 1983). Myofascial trigger points create motor dysfunctions in a muscle such as weakness, spasms, loss of co-ordination and decreased work tolerance of the involved muscle (Simons *et al.,* 1999)

One of the causative factors for neck pain is MFTPs. Neck pain is most commonly defined as pain located between the "occiput and the third thoracic vertebra" (Cote *et al.*, 2000). Neck pain can significantly restrict daily activity and influence work place performance (Carroll *et al.*, 1998).

When MFTPs cause autonomic, sensory and motor symptoms, it is referred to as myofascial pain syndrome (MPS) (Simons *et al.,* 1999). There is a high prevalence of pain arising from MPS (Gatterman and Goe, 1990). Although there have been many advances in modern health care, there is still a void in understanding the diagnosis and treatment of MPS (Bruce, 1995).

Myofascial pain syndrome is a very common type of muscular condition presenting to primary health care providers (Alvarez and Rockwell, 2002). It is a social and medical problem causing severe discomfort and reduced ability to work which has financial implications (Srbely, 2010). Epidemiological studies suggest that pain caused by MFTPs is an important source of morbidity in communities (Cummings and White, 2001). The pathognomonic feature of MPS is MFTPs (Dommerholt *et al.*, 2006). A diagnosis of MFTPs can be made when there is the presence of a palpable taut band in skeletal muscle, a jump sign, referred pain on manual compression and a local twitch response (Simons *et al.,* 1999).

Treatment is aimed to relieve pain and restore normal functioning, length and contractibility of the affected muscle (Simons *et al.*, 1999). There are various methods for the treatment of MFTPs, of which dry needling is one of the invasive methods utilised (Tekin *et al.,* 2013;

Lewit, 1979). Dry needling occurs with the penetration of an acupuncture needle into a MFTP (Dommerholt *et al.,* 2006). Studies have found dry needling to be more effective than non-invasive methods such as massage, exercise, stretch and spray, ultrasound, electrical stimulation such as interferential current therapy (IFC), transcutaneous electrical nerve stimulation (TENS) and psychological interventions (such as stress management and cognitive behavioural therapy) in reducing MFTP tenderness due to the intramuscular stimulation it provides (Tekin *et al.,* 2013; Cummings and White, 2001). Dry needling is a more potent and efficient technique in reducing MFTP pain in comparison to other manual therapies, therefore, it was the treatment of choice for this study (Dommerholt *et al.*, 2006)

The Impulse Adjusting Instrument® (IAI) is a lightweight stainless steel instrument with a LED indicator for preload control. The IAI is a relatively new medical device for manual therapy that is hypothesized to treat different areas of the body, including joints, muscles and nerves in the body. The IAI does this by being tuned to the specific natural frequency or resonant vibrations of units in the body (this frequency is the rate at which the tissues in the body oscillate or vibrate) (Colloca *et al.,* 2005). This allows for optimum mobility of the body, thereby, bringing about relief of pain and restoring normal functioning (Keller *et al.,* 1999). The IAI has a micro-computer circuitry inside the device which creates a controlled force which is useful in treatment programs. The IAI has different force settings which allow for gentle and comfortable treatment of different areas of the body. The IAI has been shown to be effective on spinal fixations and an array of other musculoskeletal conditions (Introducing Impulse, 2009; www.impulseseminars.com/impulse).

1.2 AIMS AND OBJECTIVES OF THE STUDY

1.2.1 The aim of the study

The aim of this study was to determine the effectiveness of the Impulse Adjusting Instrument® compared to dry needling in the treatment of MFTPs found in the upper trapezius muscle.

The study consisted of participants who resided in the eThekwini municipality. Groups were divided into dry needling (Group one) and IAI (Group two) treatment groups. Subjective and objective outcome measures were used to compare the effectiveness of treatments. Objectives of the study

1.2.2 Objectives of the study

1.2.2.1 Objective one

To determine the effectiveness of dry needling alone in the treatment of upper trapezius MFTPs in terms of subjective and objective outcome measures. The subjective outcome measures included the Numerical Pain Rating Scale (NRS) (Appendix J). The objective outcome measures were obtained using a goniometer for measuring cervical spine range of motion (CROM) and an algometer to measure pain pressure threshold (PPT).

1.2.2.2 Objective two

To determine the effectiveness of the Impulse Adjusting Instrument® alone in the treatment of upper trapezius MFTPs in terms of subjective and objective outcome measures.

1.2.2.3 Objective three

To compare objective and subjective findings including the Patient's Global Impression of Change (PGIC) (Appendix L) and the Neck Disability Index (NDI) (Appendix K) questionnaire in determining the overall effectiveness of dry needling and the Impulse Adjusting Instrument® in the treatment upper trapezius MFTPs.

1.3 HYPOTHESES OF THE STUDY

1.3.1 Null hypothesis

The null hypothesis of this study states that there will be no difference between the two independent samples being compared in terms of subjective and objective outcome measures.

1.3.2 Alternate hypothesis

The alternate hypothesis states that there will be a statistically significant difference between the Impulse Adjusting Instrument® (IAI) and dry needling sample groups when being compared in terms of subjective and objective outcome measures.

1.4 RATIONALE FOR THE STUDY

Research has shown the therapeutic effects of dry needling on MFTPs. The IAI has been shown to be effective on an array of neuromusculoskeletal conditions (Introducing Impulse, 2009). In addition to the paucity in literature demonstrating the effectiveness of the IAI in

treating MFTPs, there is also a paucity in the literature to show the effectiveness between dry needling and the IAI in the treatment of MFTPs.

There are limitations in the application of dry needling as a treatment intervention for MFTPs. These include the dependency of accurate palpatory and needle admitting skills of the physician in administration of dry needling as specificity is required, individuals having a fear of needles, the discomfort brought on by post-needling soreness which can also delay healing and recovery as well as the invasive nature of dry needling. Complications may arise if any of the many contraindications for dry needling are missed or over-looked. The contra-indications for dry needling include systemic illness, fever, high anxiety or emotional stress, feeling of faintness, bleeding disorders, diagnosed blood dyscrasias, being on any form of anti-coagulant therapy and a history of epilepsy or being prone to convulsions (Hans and Harrison, 1997).

Due to these limitations and an array of contraindications, an alternative method should be sought as this will be beneficial to the patient thus it is worthwhile exploring the IAI as an alternative. Therefore, the aim of this study was to determine the effectiveness of the IAI versus dry needling in the treatment of MFTPs found in the upper trapezius muscle.

1.5 SCOPE OF THE STUDY

The data of 41 participants with non-specific neck pain and MFTPs in the upper trapezius muscle who had the inclusion criteria for this study are documented and discussed in this partial dissertation. Participants were recruited with the aid of advertisements and word of mouth. Participants who met the inclusion criteria and agreed to participate in the study signed an informed consent form at their initial consultation. This enabled the information captured during this study to be used for the purposes of this dissertation. All information regarding the participant including their files and results from the study were only accessible by the statistician, supervisor, the research assistant and the researcher. There were two groups in this randomised single-blinded clinical trial. Group One was the dry needling group and Group Two was the IAI group. Subjective and objective outcome measures were taken pre-treatment on the first, second and fourth visits. At the initial consultation, a case history, physical examination and a cervical spine regional examination was completed. Following inclusion into the study, participants were allocated into a group using the randomisation list supplied by the statistician. Baseline subjective outcome measures were taken by the researcher and then objective outcome measures were taken by the research assistant. The relevant treatment was then conducted by the researcher. Each participant had four visits

over a two week period, which included three treatments and a final visit for final measurements. All visits were within two to five days of each other. IBM SPSS version 23 was used to analyse the data. A p value < 0.05 was considered as statistically significant.

1.6 CONCLUSION

This study was a randomised single-blinded clinical trial. This dissertation will discuss the related literature on MPS focusing more on MFTPs and the various treatment options such as dry needling. It will also discuss the IAI and why and how it has been chosen as a treatment option. Thereafter, the study's design and methodology will be explained. These results will be presented and discussed followed by the conclusions and recommendations in order to emphasize the findings and problems encountered.

CHAPTER 2 : LITERATURE REVIEW

2.1 INTRODUCTION

In this chapter, all the relevant literature regarding this study will be highlighted. The topics discussed in this chapter will be the epidemiology of neck pain and myofascial pain syndrome (MPS), the anatomy and physiology of skeletal muscle particularly the trapezius muscle, the signs and symptoms, clinical features, diagnosis and differential diagnoses of myofascial trigger points (MFTPs). The different treatment methods will also be discussed with a focus on dry needling and the Impulse Adjusting Instrument® (IAI).

2.2 EPIDEMIOLOGY

Myofascial pain syndrome is a very common type of muscular condition presenting to primary health care providers (Alvarez and Rockwell, 2002). This pain disorder is often misunderstood (Friction, 1990). Myofascial pain syndrome is a social and medical problem as it can be a cause of severe discomfort and decreased ability to work which in turn has financial implications for the individuals' concerned (Bovim *et al*., 1994). The average prevalence for MPS amongst middle-aged adults between the ages of 30 and 60 years was reported to be 37% in men and 65% in women (Drewes and Jennum, 1995). Of young people, 15% to 30% suffer weekly with neck and shoulder pain (Vikat *et al*., 2000; Niemi *et al*., 1996). In people over the age of 65, the prevalence increases to 85% (Podichetty *et al*., 2003). Due to these increases, MPS has the potential to escalate as a health problem (Giamberardino *et al*, 2011). Epidemiological studies suggest that the pain caused by MFTPs is an important source of morbidity in communities (Cummings and White, 2001).

Neck pain is commonly defined as pain felt between the "occiput and the third thoracic vertebra" (Cote *et al*., 2000). This is a public health problem as it affects the welfare and personal health of individuals (Fejer *et al*., 2005). Approximately 35% of the general population will suffer from neck pain at some point (Giles and Singer, 1998). In South African based studies, the indigenous African population had a frequency of 36.5% for neck pain (Ndlovu, 2006), the Indian population 36.8% (Muchna, 2011) and the White population 45% (Slabbert, 2010). Women generally have a higher prevalence of neck pain in comparison to men (Hoy *et al*., 2010), with 30% of men and 50% of women experiencing neck pain in their lifetime (Dziedzig *et al*., 2005). Neck pain has a higher incidence in office and computer workers (Paksaichol *et al*., 2012). Personal and environmental factors such as stress,

decreased job satisfaction, a poor working environment, sedentary working positions and a lack of emotional stability also influence the production and severity of neck pain (Hoy *et al*., 2010).

2.3 ANATOMY OF THE TRAPEZIUS MUSCLE

The trapezius muscle is a quadrilateral, diamond-shaped, large and superficial muscle (Moore *et al*., 2013) (Figure 2.1).

The origins of this muscle are from the medial third of the superior nuchal line on the occipital bone, the external occipital protuberance, the ligamentum nuchae, spinous processes of C7 down to the twelfth thoracic vertebrae. The muscle then spreads laterally and inserts to the spine of the scapula, lateral third of the clavicle posteriorly and the medial margin of the acromion (Moore *et al*., 2013).

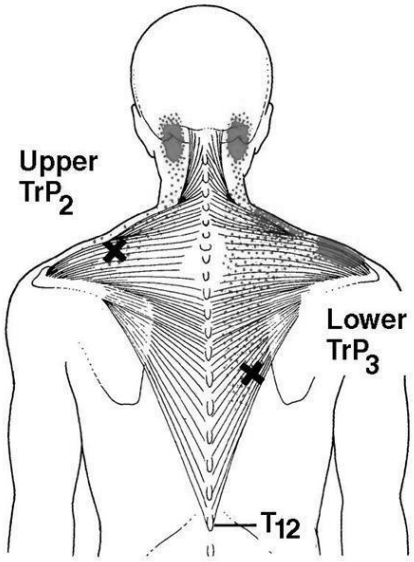


Figure 2.1: Trapezius muscle shape, origins and insertions
Source: Simons *et al*. (1999)

The muscle has three regions, namely the upper fibres of the trapezius which descends and has the function of supporting the arm as well as elevating the scapula. If this part contracts unilaterally, there will be lateral flexion or rotation of the neck on the same side (Moore *et al*., 2013; Simons *et al*., 1999; Johnson *et al*., 1994). The trapezius can also cause extension of the head and neck if it contracts bilaterally while the shoulder is stable (Simons *et al*., 1999). The other regions are the middle trapezius which extends laterally and retracts the scapula and the lower trapezius which ascends and causes depression of the scapula, medially rotates the scapula and lowers the shoulder (Moore *et al*., 2013; Simons *et al*., 1999).

The trapezius muscle is innervated by motor fibres from the spinal part of the eleventh cranial nerve known as the accessory nerve (cranial nerve XI) and by sensory fibres from the second to the fourth cervical nerve (Moore *et al*., 2013).

The blood supply for the trapezius muscle isderived from the subclavian artery which then leads to the thyrocervical trunks which have four branches; the transverse cervical, inferior thyroid, suprascapular and ascending cervical arteries. Arterial oxygenated blood is supplied to the upper trapezius muscle via the transverse cervical and suprascapular arteries bilaterally (Moore *et al*., 2013).

2.4 PHYSIOLOGY OF THE TRAPEZIUS MUSCLE

The trapezius muscle is composed of skeletal muscle which is a striated muscle controlled by the somatic nervous system and under voluntary control. Skeletal muscle is covered with connective tissue and fascia (Dally *et al*., 2010). Each muscle is covered with fascia called epimysium and each fascicle is covered with fascia called perimysium and each muscle fibre is covered with endomysium (Martini and Bartholomew, 2003; Vander, Sherman and Luciano, 2001) (Figure 2.2).

Skeletal muscle is made up of many muscle fibres (myocytes) called fascicles. Muscle fibres, in turn, are made of many myofibrils which contain repeating sarcomeres which are the basic functional contracting unit of muscle (Guo and Yin, 2012; Waterhouse, 2008; Lieber, 2002). The sarcomere is composed of many myofilaments called actin and myosin. Actin filaments are thin filaments and myosin filaments are thick filaments (Guo and Yin, 2012; Lieber, 2002) (Figure 2.3). The actin and myosin are arranged in a specific pattern. One thick filament is surrounded by six thin filaments. Two other proteins called troponin and tropomyosin, are found inside the chains of the actin proteins in a helical design (Guo and Yin, 2012; Waterhouse, 2008; Vander, Sherman and Luciano, 2001).

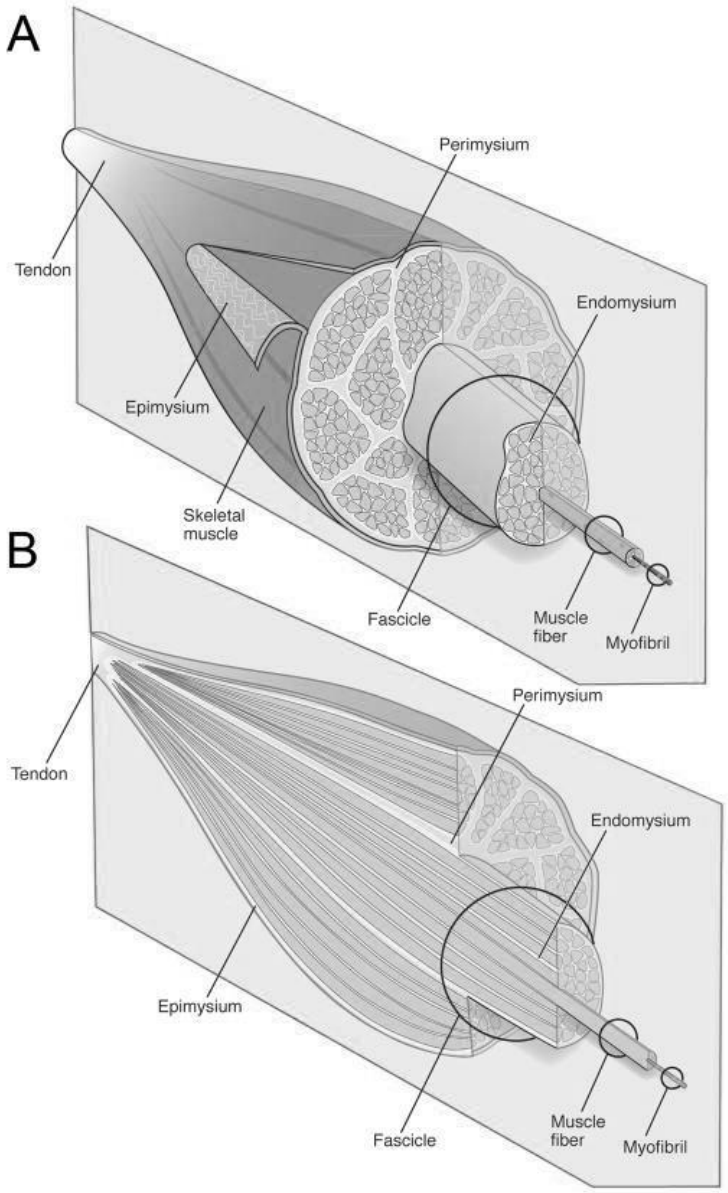


Figure 2.2: Skeletal muscle fascicle, fibre and myofibrils
Source: Gillies and Lieber (2011)

An extrafusal muscle fibre is a skeletal muscle fibre. Each muscle fiber or extrafusal muscle fibre is innervated by an alpha motor neuron which in turn branches and ends in many nerve endings. This allows many muscle fibers or an entire muscle to increase in tension and contract simultaneously which brings about movement (Guo and Yin, 2012; Waterhouse, 2008). The junction of the nerve ending and the muscle fiber is called the neuromuscular junction (Wilson and Deschenes, 2005). This junction allows for muscle contraction by allowing the synaptic transmission of signals in order for the muscle to function by maintaining muscle tone, producing contractions and preventing atrophy. The resultant

transmission allows action potentials to open calcium channels and allow calcium into the neuron (Gonzalez-Freire *et al*., 2014). In turn, the motor neuron releases acetylcholine (ACh) which is a neurotransmitter that depolarizes the muscle fiber to allow for muscle contraction (Gonzalez-Freire *et al*., 2014; Guyton and Hall, 2006).

The sliding filament theory proposed by Guyton and Hall (2006) describes how the contraction of skeletal muscle occurs using the actin and myosin filaments. The sliding filament theory states that the contraction of skeletal muscle is regulated by calcium ions, troponin and tropomyosin (Guo and Yin, 2012; Vander, Sherman and Luciano, 2001).

Muscle contraction is initiated and executed as follows (Guyton and Hall, 2006):

i. An action potential travels along a motor neuron to its neuromuscular junction on a muscle fiber.
ii. At each ending, the nerve secretes a small amount of ACh.
iii. The ACh acts on an area of the muscle fiber membrane to open multiple ion channels.
iv. Opening of the gated channels allows an influx of sodium ions into the muscle fiber through the membrane.
v. This begins another action potential at the membrane.
vi. The action potential travels along the membrane of the muscle fiber and depolarizes the membrane.
vii. A large amount of the action potential electricity flows through the centre of the muscle fiber via T-tubules. It reaches the sarcoplasmic reticulum, which is a storage site for calcium; this allows a large outflow of calcium ions into the sarcolemma.
viii. The calcium ions initiate attractive forces between the actin and myosin filaments. Troponin moves the tropomyosin away from the myosin binding sites. This allows the myosin to attach to the actin and causes them to slide alongside each other, which, when occurring over the entire muscle fiber, creates a contraction (Figure 2.3).
ix. Directly after that, the calcium ions return to the sarcoplasmic reticulum by a calcium pump and remain there until a new muscle action potential arrives.
x. The removal of calcium ions from the sarcolemma allows the muscle to relax or fall slack.
xi. Cross-bridges are the myosin-extension heads that bind to the actin protein. The tropomyosin that covers the myosin-binding site on each actin molecule prevents cross-bridges. Each tropomyosin molecule is held in this blocking position by troponin, thereby, preventing stiffness.

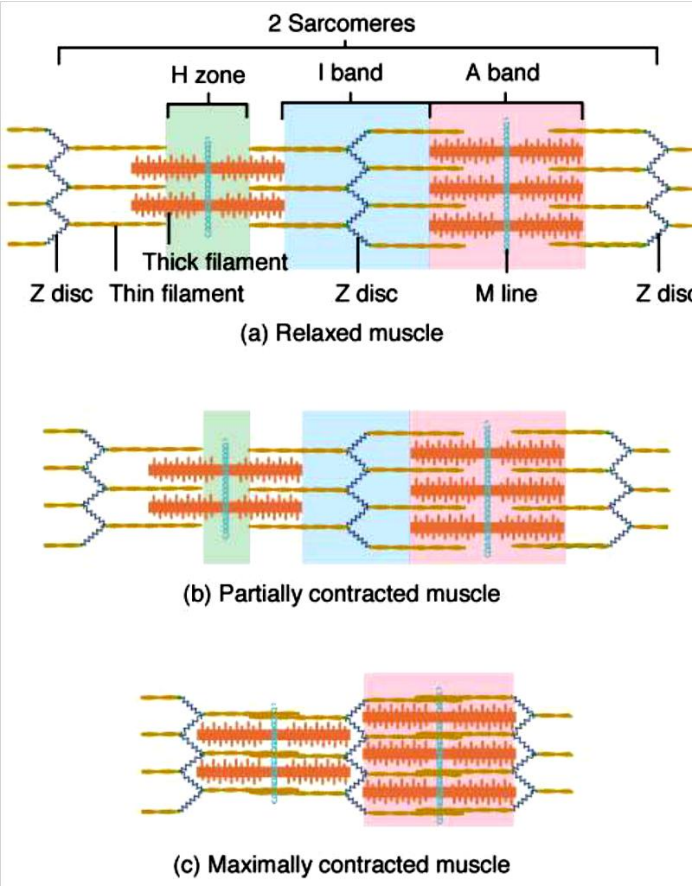


Figure 2.3: Myofilaments actin and myosin in a non-contracted, partially and maximally contracted sarcomere
Source: The Muscular System (2013)

An intrafusal muscle fiber is a skeletal muscle fiber found inside a muscle. The intrafusal fiber, however, acts as a sensory receptor which provides the central nervous system (CNS) with information regarding the length of the muscle and the rate at which it changes (proprioception) (Rumsey *et al*., 2010). There are two types of intrafusal muscle fibres and they have two types of sensory endings. Each end of these fibers can contract but the middle portion does not contract as it only stretches (Rumsey *et al*., 2010).

Groups of between three and twelve intrafusal muscle fibers form a muscle spindle, including the afferent and efferent innervation. The muscle spindle is found in the mid-portion of a muscle. These relay sensory information to the CNS regarding any change in length (Rumsey *et al*., 2010). Using the stretch reflex, this sensory information can activate motor neurons which thereby regulate muscle contraction (Rumsey *et al*., 2010). Muscle spindles also receive autonomic innervation (Rumsey *et al*., 2010).

Gamma motor neurons send signals away from the CNS (efferent innervation). This allows them to keep the intrafusal fibres (muscle spindle) taut. Gamma motor neurons activate the intrafusal muscle fibres, which change the sensitivity to stretch in the afferent innervation (Rumsey *et al*., 2010). They also allow the discharge of alpha motor neurons, which, in turn, changes its resting discharge rate and this leads to contraction of the muscle (Gladden and Matsuzaki, 2002). Beta motor neurons are the same as gamma motor neurons with the exception being that they supply both extrafusal and intrafusal muscle fibres (Gladden and Matsuzaki, 2002).

Type Ia sensory fibres are also known as primary afferent fibres as they relay information towards the CNS. These afferent fibres are sensory nerves which inform the CNS of the speed at which changes in length or stretch occur in a muscle (Rumsey *et al*., 2010). Type II sensory fibres relay information to the CNS with regard to position after movement and not rate or speed (Rumsey *et al*., 2010). Type III (also known as type A delta) sensory afferents provide pressure sensitivity and some of these fibers provide information on any chemical and temperature changes in the muscle fiber (Basbaum *et al*., 2009). Type IV (also known as type C) sensory afferents are mechanoreceptors and are pain sensitive (nociceptive) (Rotto *et al*., 1990). Afferents which contain type III and IV receptors are all pain sensitive, cold sensative, itch sensitive, muscle burn and cramping sensitive (Basbaum *et al*., 2009).

There is a system, called the fusimotor system, which can control the sensitivity of muscle spindles. This is done under the control of the CNS. The fusimotor system includes gamma and beta motor neurons (fusimotor neurons) and the muscle spindle. Fusimotor neurons provide efferent information and the muscle spindle provides afferent information regarding the muscle (Gladden and Matsuzaki, 2002).

Muscle tone is an important task maintained by the alpha and gamma motor neuron relationship. Muscle tone is a term used to describe the resting state of muscles especially the muscles related to posture such as the trapezius muscle (Masi and Hannon, 2008; Davidoff, 1992). Muscles at rest have a level of tension within the muscle fibres through the cross-bridges formed between the actin and myosin filaments (Proske and Morgan, 1999). This is allowed in order to prevent complete slacking of the muscle which will then need a high level of action potential and neuron firing to create a contraction (Masi and Hannon, 2008; Davidoff, 1992).

Different amounts of tension are needed in different muscles. This information is relayed to the CNS by the Ia spindle afferents which results in increased activity in the alpha motor

neuron. Gamma motor neurons interact with the muscle spindle. The muscle spindle controls the Ia spindle afferents, thereby regulating the steady alpha motor neuron activity via gamma motor neuron firing. All this information is relayed to the CNS. The cerebellum is the link between the alpha and gamma neuron relationship, therefore, muscle tone is relayed to the cerebellum from the muscle spindle and is maintained by the cerebellum via the alpha and gamma motor neurons (Masi and Hannon, 2008; Davidoff, 1992).

The stretch reflex (myotatic reflex) uses afferent information from Ia afferent neurons regarding the length and the speed of stretch within a muscle spindle (Shemmell, Krutky and Perreault, 2010). This information is transmitted to efferent alpha neurons which create tension by contraction within the extrafusal muscle, thereby, resisting the stretch (Shemmell, Krutky and Perreault, 2010). The opposite of the stretch reflex is the Golgi tendon reflex (inverse myotatic reflex). This reflex allows for relaxation and lengthening of the contracted muscle as alpha motor neurons are inhibited. The purpose of this reflex is to protect a muscle from excessive tension within the tendon of the contracted muscle (Jami, 1992).

After the muscle contracts, the fusimotor activity determines the length of the intrafusal fibres at rest. If the muscle is in a lengthened or stretched position at the beginning of a muscle contraction, the intrafusal fibres will remain long when the muscle is relaxed. Intrafusal fibers will fall slack if the muscle which is passive is then shortened. Spindles do not shorten but instead they fall slack, this is due to them having a resting stiffness which occurs as a result of cross-bridges between myofilaments within the sarcomere. This creates an internal stiffness as the cross-bridges are stable (Proske and Morgan, 1999).

2.5 TRIGGER POINTS OF THE TRAPEZIUS MUSCLE

2.5.1 Location

There are seven common trigger point (TP) locations found in the trapezius. These are named TP one to TP seven. Trigger point one is found in the vertical fibres anteriorly and TP two is found in the middle of the horizontal fibres, lateral to TP one (Simons *et al*., 1999). Trigger point three is found in the lower trapezius muscle fibres near the medial border of the scapula. Trigger point four is found near the insertion of the lower trapezius onto the scapula.. Trigger point five is found in the middle of the middle fibres of the trapezius. Trigger point six is found at the insertion of the middle trapezius fibres on the lateral border of the spine of the scapula. Trigger point seven is found on the upper region of the middle trapezius fibres and is often found as a skin trigger point (Simons *et al.,* 1999).

2.5.2 Common symptoms of trapezius trigger points

The upper trapezius fibres commonly cause symptoms such as tension type headaches, pain in the temple, ocular, facial or jaw region, neck pain, stiff neck, decreased range of motion, decreased weight bearing on the shoulders and dizziness or vertigo if there is involvement of the sternocleidomastoid muscle (Simons *et al.,* 1999).

The middle trapezius fibres commonly cause symptoms such as suboccipital headaches and mid-back pain. Trigger point five often refers burning pain near the spine and TP six often refers an aching pain near the top of the gleno-humeral joint. Trigger point seven often causes a “goose-flesh” type of sensation down the side of the posterior arm (Simons *et al.,* 1999).

The lower trapezius fibres commonly cause symptoms such as neck, mid-back or shoulder pain, pain on the scapular, pain down the medial arm and into the lateral two digits. Trigger point three often causes a tender ache on top of the glenohumeral joint as well as suboccipital pain (Simons *et al.,* 1999).

2.5.3 Common causes of Trapezius trigger point activation

The causes of trigger point acvtivation are plentiful. The most common causes include; fatigue, stress, large breasts, cradling a phone between the shoulder and ear, incorrect ergonomics such as arm rests which are too high or low, sitting on a chair with no back support, using a desk which is too high, no arm support when seated. Other causes include jogging, playing violin, sleeping with the head rotated to the side, one-sided sports, leg length discrepencies, short arms, bending over for long periods of time, heavy bags carried on the shoulder, tight bra straps, whiplash, incorrect posture and tight pectoral muscles (Simons *et al.,* 1999).

2.5.4 Trapezius trigger point for this study

The trapezius muscle was selected for this study due to its superficial location (Tank, 2013) and the reproducibility of locating and identifying MFTPs in this muscle (Muñoz-Muñoz *et al*., 2012). This study focused on TP one and TP two which are found in the upper muscle fibres of the trapezius. Trigger point two in the trapezius muscle has often been shown as a tender point for patients with work related muscular pain (Simons *et al*., 1999).

Research shows that the upper trapezius muscle is often found to have MFTPs (Sarrafzadeh *et al*., 2012; Gemmell and Allen, 2008; Sciotti *et al*., 2001). A study conducted by Muñoz-

Muñoz *et al*. (2012) found that the upper trapezius and levator scapulae muscles were the most common muscles found with and affected by MFTPs. Simons *et al*. (1999) stated that the trapezius muscle in relation to MPS was one of the most affected muscles.

2.6 SIGNS AND SYMPTOMS OF MYOFASCIAL TRIGGER POINTS

Myofascial trigger points are described as localised hyperirritable areas of pain within muscles or their fascia, which are extremely painful to touch, stretch or stimulation and can cause referred pain on manual compression of the TP (Vernon and Schneider 2009; Travell and Simons, 1983). The diagnosis of a MFTP can be made when there is the presence of a palpable taut band of skeletal muscle, pain and a jump sign (a jump sign occurs when a patient reacts to palpation of a TP with facial grimacing, a verbal response or by jumping or moving away from the examiner) (Tough *et al*., 2007; Simons, 2002). Muscles that do not have MFTPs are not tender and do not produce jump signs (Friction, 1990), referred pain on manual compression, a decreased range of motion for the affected muscle and a local twitch response (Vernon and Schneider 2009; Travell and Simons, 1983). The taut band is due to shortening of the muscle fibrils and therefore, the sarcomere length which causes them to increase in width. In multiple muscle fibers, this creates the nodule which is felt as the TP (Gerwin *et al*., 1997).

There are active TPs and latent TPs. An active TP can cause pain and refer pain at rest and the pain may increase with stretching or contraction of that muscle. A latent TP is a localised area of pain and tightness which does not cause pain at rest (Bennett, 2007). Clinically in symptomatic muscles, taut bands and trigger points which are active are found within the muscle (Cummings and Baldry, 2007).

Myofascial trigger points (MFTP) are a pathognomonic feature of MPS. Myofascial pain syndrome is a regional muscular disorder which involves motor, autonomic and sensory changes and its pathognomonic feature is the presence of MFTPs (Dommerholt *et al*., 2006; Simons *et al*., 1999). Myofascial pain syndrome (MPS) can occur in isolated areas of the body and can occur in any muscle or its fascia resulting in an array of symptoms; however, the pain is often described as a deep or steady ache. This often depends on the location of the MFTP, the severity of the muscular spasm and the patient's individual pain threshold. As a result of this, the intensity of the pain can vary in description from a mild or slight discomfort to a terrible excruciating and even "lightning-like" pain (Starlanyl and Copeland, 2001*).* The patient may also have work-related or functional complaints such as a decreased ability to work, weakness of the muscle or fatigue (Borg-Stein and Simons, 2002).

Therefore, to be included in this study. MFTPs needed to demonstrate characteristics as outlined by Travell *et al*. (1999) which included; a taut band of muscle fibers palpated by snapping or rolling the muscle under the finger. It also needed to include a tender nodule palpated within this taut band of muscle fibers; a local twitch response of the taut band fibers to snapping palpation; and pain referral to the referral zone specific to the muscle involved.

2.7 ETIOLOGY OF MYOFASCIAL PAIN SYNDROME

The aetiology of MFTPs varies. Chaitow and DeLany (2002) and Simons *et al*. (1999) mention the following causative factors: repetitive muscle strain, poor posture, mechanical abuse, trauma, leaving a muscle in a shortened position for a prolonged period of time, chronic overload, nerve compression, excessive cold, heat or dampness, febrile illness and systemic biochemical imbalances. Other causes include synergistic and antagonistic muscle compensation, low oxygenation of the tissues and satellite referral MFTPs that evolve within a referral zone (Baldry, 1993). Incorrect work ergonomics create musculoskeletal stress and strain (Fomby and Mellion, 1997). Myofascial pain syndrome in the shoulder and neck region is often caused by the repetitive lifting or movement required in overhead work (Henriksson *et al*., 1996). Anxiety and excessive stress can also be a cause of MPS (Cummings and Baldry, 2007).

Trigger points in the shoulder and neck region play an important role in causing neck pain (Simons *et al*., 1999). Trigger points cause neck pain by creating motor and sensory dysfunctions in a muscle; the motor dysfunction includes weakness, spasms, loss of co-ordination and decreased work tolerance. Sensory dysfunction causes local tenderness, pain referral to distant sites and peripheral and central sensitization (Simons *et al*., 1999). Referred pain elicited by active MFTPs in the neck and shoulder muscles contributes to neck pain (Muñoz-Muñoz *et al*., 2012).

The reasons for the histological changes that occur in the sarcomere were stated in a hypothesis compiled by Simons *et al*. (1999) called The Integrated Trigger Point Hypothesis.

The initial cause results in an imbalanced release of ACh from the nerve ending. This indefinite release leads to the depolarising of the muscle fiber membrane (Simons *et al*., 1999). Due to the amount of ACh released, there is also an increased calcium release. These two events result in a maximally contracted sarcomere which makes it thicken in diameter and requires an increased metabolic function (Simons and Simons, 2002). The blood supply cannot reach the sarcomere as the capillaries are cut off due to the thickening

of the sarcomere. Thirty to fifty percent of a full sarcomere contraction is enough to cut off the local blood supply, therefore, the lack of blood supply and the increased need for metabolites which are normally delivered via the blood supply creates a cycle of energy deficiency which is local but severe (Dommerholt and Bron, 2012; Simons *et al*., 1999).

With this energy deficiency cycle, adenosine triphosphate (ATP) is not available. The calcium pump which uses ATP to remove calcium from the sarcolemma to the sarcoplasmic reticulum, can no longer do so which results in the myosin heads becoming attached to the actin and the contractile elements available for attachment. This results in muscular stiffness (Gissel and Clausen, 2001). The hypoxia and energy deficiency cycle is amplified which then initiates the release of inflammatory substances which attempts to cause vasodilation in the capillaries but instead sensitises the nociceptors (Simons *et al*., 1999).

Partanen *et al*. (2010) noted that TPs in MPS were found to be related to inflamed and pain sensitised muscle spindles. Simons and Mense (1998) suggested that the pathognomonic taut band found in MFTPs was a form of rigor or contracture in beta motor neurons. This was caused by a reflex from the muscle spindle (Simons and Mense, 1998). Hong and Simons (1998) found a heavy saturation of contraction and inflammatory metabolites in the muscle which they stated was due to the fusimotor activity being held (Johansson *et al*., 1993). The Type III and IV sensory afferents within the intrafusal muscle fibers are activated and affected by the chemical changes within the intrafusal muscle fibers (Gladden and Matsuzaki, 2002). This intrafusal muscle fiber inflammation causes even more activation of the fusimotor systems (Johansson *et al*., 1993). This inflammation explains the pain and sensitivity to pressure in TPs felt by patients with MFTPs.

In contradiction to the above literature Quintner *et al*., (2014) conducted a critical review of the TP phenomenon and concluded that the literature was scientifically unreliable. This review stated that the diagnosis of TPs as the pathognomonic feature of MPS was unreliable and that the treatment of TPs could not be differentiated from the effect of placebo. This review questioned the reliability of the diagnostic criteria and stated that a physical examination is unreliable to diagnose MPS. However physical examination is the criteria for the diagnosis.

Quinter et al (2014) also stated that there was no experimental evidence to support the integrated hypothesis and states that it is an opinion based on incomplete evidence. However it is also stated in the review that it is still highly accepted by physicians and therapists. This left the researchers with the question of why clinicians insist on these treatments. This is because despite a lack of scientific evidence the treatments performed

still have a therapeutic effect. The researchers explained this effect as a result of placebo, counterirritation (which is when a painful stimulis is applied to an existing painful site resulting in “anti-nociception” (Piche *et al*., 2009)), or because these treatments are often accompanied by other manual therapies (Quinter *et al*., (2014).

2.8 DIAGNOSIS AND DIFFERENTIAL DIAGNOSIS OF MYOFASCIAL PAIN SYNDROME

The diagnosis of MPS and MFTPs mostly requires precise manual palpation as well as patient symptoms and feedback (Sciotti *et al*., 2001). To diagnose MPS correctly, other sources of myofascial pain such as Fibromyalgia Syndrome, connective tissue disorders, articular dysfunction and non-myofascial trigger points, such as fascial or connective tissue TPs, need to be eliminated as differential diagnoses (Fomby and Mellion, 1997). Fibromyalgia syndrome is very similar to MPS due to similar signs and symptoms. Fibromyalgia is as a result of a systemic disorder which has generalised muscle pain, it can occur with MPS; however, MPS can occur without fibromyalgia (Starlanyl and Copeland 2001).

The diagnosis of MFTP requires a palpatory examination performed by an experienced clinician. This allows for interrater reliability; however, the examination cannot be rushed if this is to be achieved. This is because referred pain and twitch responses are easily missed; the referred pain may take up to 10 or 15 seconds of continual pressure on the TP for it to become noticeable (Gerwin *et al*., 1997). However, MFTP palpation was shown to be reliable as a diagnostic tool for identifying MFTPs in a study conducted by Moodley (2011). This was also stated by Simons *et al*. (1999). Cagnie (2012) suggested palpation and clinical signs and symptoms be used in clinical practice to determine dry needling sites. Algometry outcome measures may be used to objectively differentiate between tender spots and unaffected muscle tissue, and may be used to quantitatively measure tender spots over time objectively with high sensitivity (Fischer, 1998).

2.9 TREATMENT FOR MYOFASCIAL PAIN SYNDROME

The aim of treatment for MPS is aimed to relieve pain and to restore normal functioning, length and contractibility of the affected muscle (Simons *et al.*, 1999). There are various methods for the treatment of MFTPs. To treat MPS effectively, the MFTP needs to subside and the likelihood of it reoccurring to be prevented (Gerwin *et al*., 1997). Therefore, psychosocial and physiological stresses must be addressed (Han and Harrison, 1997).

Lifestyle modification and long-term management is important in order to prevent reoccurrences (Auleciems, 1995).

Myofascial pain syndrome can be treated with many different therapies e.g. manual therapy, electrotherapy, needling therapy, pharmacological intervention and psychological therapy.

2.9.1 Manual therapies

Manual therapies have shown evidence which is moderate to moderately strong in support of providing immediate and short-term relief of pain associated with MFTPs. However, the evidence is not as strong and is limited for long-term treatment. These manual therapies include cryotherapy, heat, stretching, massage, ischaemic compression, trigger point release and post-isometric relaxation.

a. Cryotherapy is the use of ice or cold. It results in the inhibition of pain transmission, decreases muscle spasm, decreases inflammation and spinal inhibition mechanisms (Simons *et al*., 1999). In order to achieve this, it causes vasoconstriction of blood vessels which decreases blood flow and therefore slows down metabolism in the area. Histamine levels in the blood decrease and the excitability of the nerve endings decreases (Schafer and Faye, 1990).
b. Heat increases tissue flexibility and blood flow as well as decreases pain and muscle spasm (Simons *et al*., 1999). It does this by causing vasodilation which increases oxygenation and delivery of nutrients. This also aids in the removal of waste metabolites. Heat increases cell metabolism which promotes healing (Nadler *et al*., 2004). Heat can be applied with the use of heat packs, infrared radiation and fluidotherapy (Hecox *et al*., 1994)
c. Stretching restores muscle flexibility and length (Yap, 2007). By stretching a muscle, stretching of the affected sarcomeres within the muscle occurs; this increases its length which helps decrease the energy deficiency cycle (Bennet, 2007). There are different stretching therapies such as active, passive and spray and stretch.
d. Massage stretches the muscle passively and gradually which decreases pain and blocks any reflexive spasms which can inactivate MFTPs (Auleciems, 1995). It does this by breaking fibrous bands that can form when a muscle is in spasm; it also increases circulation to the area which allows pain mediators to escape the area (Travell *et al*., 1999). Massage also releases endorphins which gives the patient a sense of well-being (Yap, 2007).
e. Ischemic compression uses a firm pressure (often applied with the thumb), which is firm enough to cause skin blanching (Gemmell and Mellion, 2007; Travell and

Simons, 1983). This causes ischaemia in the local area which reflexively improves the circulation to the affected area (Auleciems, 1995). Moderate evidence supports ischemic compression for immediate pain relief of MTFPs (Vernon and Schneider, 2009).

f. Trigger point release makes use of a moderate compression with a massage technique (often applied with the fingers) to a MFTP (Kostopoulos *et al*., 2008). This increases lymph drainage and circulation which also helps venous drainage and activates the stretch reflex. These factors help relax muscles in spasm as a result of TP release (Travell *et al.,* 1999).

g. Post-isometric relaxation is a type of stretch done by stretching the affected muscle then isometrically contracting the muscle with slight resistance followed by relaxation and then a further gentle stretch. It is used to decrease tension within a muscle and restore dysfunction of the involved joint in MPS, therefore, increasing range of motion (Sharma *et al*., 2010; Emary, 2012).

2.9.2 Electrotherapies

These include transcutaneous electrical nerve stimulation (TENS), ultrasound, interferential current therapy (IFC) and light amplification by stimulated emission of radiation (LASER). Electrotherapies were shown to have conflicting or limited evidence for the relief of pain in the treatment of mechanical neck pain (Kroeling *et al*., 2005). Some electrotherapies have moderate evidence, others have limited evidence while some electrotherapies have moderate to strong evidence for the immediate relief of MFTPs (Rickards, 2006).

a. Transcutaneous electrical nerve stimulation helps decrease pain, increase range of motion and lengthen the muscle. It creates contractions between agonist and antagonistic muscles against resistance (Melzack and Wall, 1988). A review conducted by Vernon and Schneider (2009) suggests moderate evidence for TENS in the treatment for MFTP and MPS although the duration of relief varies. Rickards (2006) compared non-invasive interventions namely electrotherapies, LASER, ultrasound, magnetic and manual therapies for MFTPs in the upper trapezius region. The therapies reviewed included TENS which only showed an immediate decrease in pain intensity and did not exceed a moderate level of evidence; no long-term outcomes and no outcomes exceeding the effect of placebo were noted (Rickards, 2006).

b. Ultrasound increases blood flow which helps decrease pain by diluting pain mediators. This decreases muscular pain, spasm, decreases joint stiffness and

encourages repair and regeneration of soft tissue. Ultrasound has been reported to have no more effect than placebo and only a moderate level of evidence has been provided (Rickards, 2006).

c. Interferential current therapy passes two medium frequencies through the affected tissues. At the point where the two frequencies meet, a frequency from beneath the skin is given off. This prevents the discomfort of the frequency passing through the skin; this makes IFC more beneficial than other electrotherapies (Martin, 1996). Interferential current therapy causes an increase in blood flow, decrease in oedema, pain relief and muscle stimulation. It does this by stimulating the pain gate mechanisms which at higher frequencies masks the symptoms of pain and opioid mechanisms at lower frequencies; both these mechanisms show limited durations of effectiveness (Almeida *et al*., 2003). Pain relief also occurs by blocking C fiber transmission of pain and by suppressing the effect of the sympathetic reaction. This improves blood supply and oxygenation and promotes the removal of metabolic waste (Hou, *et al*., 2002). Empirical evidence within the literature determining the efficacy of IFC is sparce (Rickards *et al*., 2006). Rickards *et al*. (2006) compared non-invasive interventions for MFTPs. One of the therapies reviewed was IFC which showed limited evidence and required further investigation.

d. Light amplification by stimulated emission of radiation namely low-level laser therapy (LLLT) helps stimulate tissue healing or acupuncture points and decreases pain (Woodruff *et al*., 2004) by emitting light in single wavelengths of coherent beams in the visible to infrared spectrum. Light amplification by stimulated emission of radiation is painless, non-invasive and is easy to administer. Pain relief is most likely due to anti-inflammatory effects; however, there is a lack of concrete evidence and supporting literature. It has been shown to decrease MFTP tenderness within 15 minutes of its application (Baxter *et al*., 1994). This is accomplished by inhibiting the transmission at the neuromuscular junction or by blocking C fibers' transmission of pain (Chow *et al*., 2007). A review conducted by Vernon and Schneider (2009) suggests strong evidence which supported LASER therapy for MFTP treatment although the duration of relief varies. Rickards *et al*. (2006) compared non-invasive interventions for MFTPs including laser, which showed significant short-term effectiveness only.

2.9.3 Psychological therapies

These are used when practitioners take into account the multifaceted phenomenon of chronic pain, instead of viewing and treating it as being a neurophysiological state only. This approach assumes that there is also a psychological aspect to chronic pain. These aspects can lead to aberrant thinking patterns, functional disabilities and poor coping mechanisms (Basler *et al*., 1997). Psychological therapies include stress management, cognitive behavioural therapy and electromyography biofeedback.

a. Chronic tension and subconscious muscular contraction expedite and amplify pain. Stress management removes or decreases external or environmental stressors decreasing tension and associated muscular contraction (Hans and Harrison, 1997).
b. Cognitive behavioural therapy (CBT) decreases the neural circuitry involved in inappropriate emotional responses to pain and other symptoms. The goal of CBT is to increase a patient's sense of control over their pain (Bennet and Nelson, 2006).

2.9.4 Pharmacological intervention

This uses drug therapy to decrease pain, inflammation and muscle spasms. Care must be taken to prevent severe sedatory effects (Rives and Douglass, 2003). The most commonly used drugs by patients are nonsteroidal anti-inflammatory drugs (NSAIDs) (Ibraimi *et al*., 2013). Pharmacological interventions are not to be used for prolonged periods of time. If this is done, they are not effective and they can have fatal or toxic effects resulting in drug dependencies (Kvien and Viktil, 2003). However, in acute pain, pharmacological therapy may decrease pain for a short period (Von Feldt and Ehrlich, 1998). Pharmacological interventions include NSAIDs, analgesics, anti-depressants and muscular relaxants or spasmolytics.

a. Nonsteroidal anti-inflammatory drugs have been prescribed to decrease inflammation, thereby, relieving pain (Wheeler, 2004).
b. Opioid analgesics are for severe pain as they result in fast acting relief of pain (Wheeler, 2004).
c. Muscle spasmolytics bring about muscular relaxation (Wheeler, 2004).
d. Anti-depressants help with external stressors as well as help with sleep and are also used to treat chronic pain and dysthesia (Wheeler, 2004).

2.9.5 Needling therapies

These include dry needling and MFTP injection. With MFTP injections, the needle disrupts the nerve endings and the muscle fibers mechanically which then interrupts the feedback mechanism towards the CNS. Intracellular potassium is released as depolarization occurs. A

saline solution or a local anaesthetic is injected which dilutes the substances within the MFTP and sarcomere, thereby, causing nociception. This, in turn, causes local vasodilation and with the accompanying local micro-trauma and bleed caused by the needle insertion, these substances are removed by the blood supply. This in turn relieves pressure and pain (Han and Harrison, 1997 and Travell *et al*., 1999).

2.10 DRY NEEDLING

Dry needling is an invasive method used for the treatment of MFTPs (Ziaeifar *et al*., 2014; Tekin *et al.,* 2013) and has been found to be more effective than other superficial methods in reducing MFTP tenderness due to the intramuscular stimulation it provides (Tekin *et al*., 2013; Cummings and White, 2001). Wilks (2003) found dry needling to be effective in the treatment of MPS in terms of subjective and objective clinical findings, using the Numerical Pain Rating scale as a subjective measure and pressure algometry and Myofascial Diagnostic Rating Scale as objective measures. However, Wilks (2003) further stated that dry needling is not more effective than placebo (the placebo intervention used was a sham dry needle designed by Steitberger and Kleinhenz [1998] where the skin is not penetrated but a pricking sensation is felt). Dry needling was shown to be an effective treatment intervention for MPS of the biceps muscle involving active TPs (Cowie, 2003). Dry needling is a more potent and efficient technique in reducing MFTP pain than other manual therapies (Dommerholt *et al.*, 2006), therefore, this was the treatment of choice for this study.

Two types of dry needling exist i.e. superficial and deep dry needling (which is penetration into a MFTP). Both were reported to be effective (Ceccherelli *et al.,* 2002). They were compared in terms of their pain relieving effects and it was concluded that deep dry needling was more effective (Ceccherelli *et al*., 2002). It was shown that these effects lasted and quality of life was improved after 11 weeks of treatment which included a three week interval within the 11 weeks (Itoh *et al*., 2007).

Dry needling is defined as the penetration of an acupuncture needle into a MFTP (Dommerholt *et al.,* 2006). The fanning method is where the needle is then removed from the TP but not the skin and it is then reinserted into the TP from different points while the original entry into the skin is kept (Dommerholt *et al*., 2006). The static or single insertion method is when the needle is inserted in one precise insertion (Rowley, 2000). The single insertion method has a lesser chance of haemorrhage, therefore, there is less probability of post-needling soreness; however, the fanning method has a greater chance of stimulating the MFTP and exhausting the twitch response of the MFTP (Cotchett *et al.,* 2010; Manga,

2008). Therefore, the fanning technique was used in this study as it was more likely to be effective.

The twitch response which occurs in dry needling is a spinal cord reflex which occurs involuntarily within the muscle fibers of the taut band found in a MFTP (Dommerholt *et al*., 2006). It is important to attain this response when dry needling as it improves treatment outcomes, decreasing the abnormally high spontaneous electrical activity (Chen *et al*., 2000) and confirms the correct insertion of the needle (Hong, 1994).

Dry needling has mechanical and metabolic effects. The disruption of TPs (Koritnik *et al*., 2001) and local stretch of the sarcomere occur mechanically and influences microcirculation and metabolic mediators and microcirculation (Dommerholt *et al*., 2006). Mechanical disruption occurs when the shortened contractile elements of the muscle or nerve ending disrupt or break the feedback loop responsible for sustaining the MFTP (Travell and Simons, 1983). Studies have repeatedly shown that there is an increase in blood flow to the skin and musculature after being needled (Sandberg *et al*., 2004; Kubo *et al*., 2010). This may be due to increased sympathetic nerve activity from a sympathetic stress response which is short lasting (Sandberg *et al.,* 2005).

There are numerous mechanisms which have been suggested which explain why dry needling may be effective in the treatment of MFTPs (Travell *et al*., 1999; Hong, 1994). A summary of the proposed mechanisms follows:

I. Dry needling causes micro-trauma which disrupts motor endplates of distal axons resulting in denervation (Travell *et al*., 1999). This disruption also causes hyper-stimulation leading to analgesia which stops the cycle of pain caused by the positive feedback loop that was created (Gatterman and Goe, 1990).
II. Dry needling causes a disruption of the taut band in the muscle which makes the local nerve endings less sensitive. This brings about inflammation and a local bleed which in turn allows nociceptive substances to be diluted and removed from the area (Simons *et al*., 1999). There is decrease in pain and a resultant resolution of the MFTP (Kalichman and Vulfsons, 2010).
III. The mechanical disruption caused by dry needling occurs in the nerve fiber or muscle fibers. This allows potassium to escape into the extracellular fluid which allows the muscle fiber and nerve fibers to depolarise (Han and Harrison, 1997). This causes the myosin and actin cross-bridges to detach and the muscle to relax (Srbely *et al*., 2010; Kalichman and Vulfsons, 2010).

IV. The insertion of the needle also has bio-electric properties (Hsieh *et al*., 2007; Baldry, 1995). This increases blood flow which dilutes nociceptive substances and allows for their removal, thereby, helping to resolve the MFTP (Kubo *et al*., 2010).

Dry needling contra-indications as stated in Chapter 1 include systemic illness*,* fever, high anxiety or emotional stress, feeling of faintness, bleeding disorders, diagnosed blood dyscrasias*,* being on any form of anti-coagulant therapy and a history of epilepsy or being prone to convulsions (Hans and Harrison, 1997). Disregard for these contra-indications can lead to complications such as vasovagal syncope, hematomas and pneumothorax is a risk if the lungs are pierced through an intercostal space (Alvarez and Rockwell, 2002).

2.11 THE IMPULSE ADJUSTING INSTRUMENT® (IAI)

2.11.1 Properties

Figure:2.4 The Impulse Adjusting Instrument
Source: Colloca et al. (2005)

The IAI is a relatively new medical device for manual therapy. The IAI is a lightweight stainless steel instrument with a LED indicator for preload control as seen in figure 2.4. The IAI has been hypothesised to treat different areas of the body by having three different force settings for the cervical, thoracic and lumbar regions. These force settings are delivered as 12 pulses of 6Hz in 2 seconds. The highest setting is at 400N, medium at 200N and low at 100N in a rapid pulse motion (Colloca and Keller, Impulse Adjusting Instrument Operations manual, 2009). Other areas can be treated, these include joints, muscles and nerves which can be treated by the instrument being tuned to and responding to the specific natural frequency of the body (this is the natural rate at which tissues oscillate, this determines stiffness and the body's response to external forces (Fuhr and Menke, 2005)). This thereby,

brings about relief of pain and restoring normal function (www.impulseseminars.com/impulse; Introducing Impulse, 2009). The IAI has a micro-computer circuitry inside the device that creates a controlled force which is useful in treatment programs. The IAI different force settings allow for gentle and comfortable treatment of different areas of the body. The IAI has received FDA approval, indicating that it is safe.

2.11.2 Review of the literature

Using the instrument has been proven to be more effective on spinal fixations when compared to various other adjusting instruments such as the Chiropractic Adjusting Tool (CAT) and the Activator Adjusting Instrument IV (Activator IV). Keller *et al.* (2006) conducted a study using six sheep, where they attached an accelerometer to their L1 and L2 spinous processes, thereby monitoring the acceleratory and displacing responses after a T12 manipulative thrust. This was done for each force setting. The results of this study revealed axial and posterior-anterior (PA) displacement to improve the most. The IAI showed the highest intersegmental displacement and the greatest force production especially in the PA direction (Keller *et al*., 2006).

Another study comparing adjusting instruments was done by Colloca *et al* (2005). This study compared the spring-loaded Activator Adjusting Instruments (I, II, III and IV) and two electromechanical instruments namely the Impulse Adjusting Instrument and Harrison Handheld Adjusting Instrument. The mechanical characteristics of these devices were tested and compared using a flight experiment with a shuttlecock (the instrument was used to fire a shuttlecock into the air, videography was used to record flight height and times) and a force calibration test (bench tests were used by pulsing the device onto a dynamic load cell to record force-time profiles). The results showed that the IAI produced a frequency area ratio that was greater than the other five devices. It also had the highest peak force transmission, which is hypothesised to have greater vertebral movement during a chiropractic adjustment (Keller and Colloca, 2002)

2.11.3 Concepts regarding the IAI

The IAI is hypothesised to be effective in the treatment of muscular conditions because of the link between manual therapy and the neurophysiological reflex (Keller *et al*., 2006). The neurophysiological reflex is a concept which states that a painful lesion in a muscle leads to an increase in action potentials, therefore, increasing tension within the muscle by activating gamma motor neurons in the affected region (Mense and Skeppar, 1991).

Research conducted by Mclain (1994) depicted the presence of mechanosensitive and pain receptive afferent fibers in tissues such as the intervertebral disc, facets, ligaments and muscles. Cavanaugh *et al*. (1996) conducted the relevant neurophysiological research which demonstrated the role of afferent stimulation in the production of pain. Stubbs *et al*. (1998) depicted the co-ordinated neuromuscular stabilisation of the spine that follows afferent stimulation. The work of Stubbs *et al*. (1998), Cavanaugh *et al*. (1996) and Mclain (1994), provide a framework where the mechanisms of chiropractic adjustments, spinal manipulation and manual therapy can be investigated (Colloca *et al*., 2004). Manual therapy has been shown through clinical studies to decrease muscle inhibition and electromyography (EMG) activity in the superficial neck flexors (Sterling *et al*., 2001; Suter *et al*., 1999). This shows that manual therapy results in decreased pain, muscle spasm and improved motor functioning mediated through the spinal cord (Bialosky *et al.,* 2008).

The sensation felt by the IAI treatment is described as a “gentle tapping sensation” when perceived by the patient (www.impulseseminars.com/impulse). It is known that a specific pattern of events occur when a muscle is tapped or stretched during treatment with the IAI. In the studies conducted by Tani *et al.* (1997) and Dimitrijevic *et al*. (1980), the pattern of events occurs in the following manner: initially on an EMG reading, there is a short wave of activity (named R1) followed by a period of silence and then a repeated longer period of activity (named R2). The short R1 activity provides evidence of a segmental reflex loop, whereas, the longer R2 activity has been attributed to reflexes indicating the involvement of supraspinal influences, the former being a spinal segmental reflex (Tani *et al*., 1997). Under the influence of the theory of the muscle spindle proposed by Korr (1975), the application of the IAI treatment consists of significant impulses which silence the increased activity of the gamma motor neurons, thereby decreasing the alpha motor neuron activity. This then leads to hypotonicity or a decrease in tension or the presence of cross-bridges of a currently hypertonic MFTP within a taut band (Potter *et al*., 2005). Alpha motor neurons provide nerve supply to extrafusal muscle fibers of skeletal muscle and are responsible for initiating and perpetuating its contraction. Therefore, eliciting of the neurophysiological reflexes with the IAI is expected to decrease muscle spasm, decrease pain and decrease muscle inhibition.

Another study in relation to the use of the IAI on MFTP was conducted by Gemmell and Allen (2008). This clinical trial determined the immediate effectiveness of an activator adjusting instrument (using thrusts which were mechanically assisted) and ischaemic compression when treating active MFTPs in the upper trapezius muscle. The study showed a dramatic decrease in pain in both groups. The decrease in pain was significantly greater than the sham ultrasound ($p > 0.05$) which was conducted in a previous study by Gemmell *et*

al. (2008). An Activator Adjusting Instrument (AAI), which is similar to the IAI, as it is also used for handheld instrument manipulation; however, the AAI is spring loaded whereas the IAI is electromechanical. The study conducted by Gemmell and Allen (2008), and the studies conducted by Tani *et al*. (1997) and Dimitrijevic *et al*. (1980), opens up a framework for research where the IAI can be hypothesized to be effective in the treatment of MFTP and MPS.

2.12 CONCLUSION

Clinical studies have only been conducted on the activator adjusting instrument and no similar research has been conducted on the IAI, so it has not been shown whether the IAI is effective in the treatment of muscular conditions such as MFTPs or not. The IAI is a non-invasive and more comfortable form of therapy compared to dry needling. Research has shown the therapeutic effects of dry needling on MFTPs; however, due to post-needling soreness, some people having a fear of needles, and due to the invasive nature of dry needling, an alternative method should be sought. In order to address the gap in the literature which exists due to the paucity in the relevant literature, the aim of this study was to determine the effectiveness of the IAI versus dry needling in the treatment of MFTPs.

CHAPTER 3 : METHODOLOGY

3.1 INTRODUCTION

This chapter discusses the design of the study, the sample population and recruitment process, the criteria for inclusion and exclusion as well as the group allocation and randomization. It also outlines the research procedure and protocol which was followed and the measurement tools utilised in the study. The intervening treatments, process of statistical data analysis and ethical considerations are discussed.

3.2 STUDY DESIGN AND LOCATION

This study was in the quantitative paradigm and designed as a randomised, single-blinded clinical trial. The study was conducted at Durban University of Technology (DUT) Chiropractic Day Clinic (CDC). Permission to use the DUT CDC for the duration of this study was obtained (Appendix A).

3.3 ETHICAL CONSIDERATION

This study was approved by the Institutional Research and Ethics Committee (IREC) (Ethics clearance number 070/15) (Appendix B).

3.4 SAMPLE POPULATION

The study consisted of a total of 41 participants who resided in the eThekwini municipality. This number was selected as it reflected the minimum sample required for effects to be noticeable. This allowed for two groups, one of 18 and another of 23 participants.

3.5 RECRUITMENT

Permission to advertise to recruit participants for the study was sought from the relevant authorities at the DUT and shops in the vicinity (Appendix C). Thereafter, advertisements (Appendix D) were placed on the notice boards at the DUT, DUT CDC and shops which had free advertisement boards. All prospective participants were requested to contact the researcher telephonically for further information.

Table 3.1 lists the questions that prospective participants who contacted the researcher telephonically were asked to determine their eligibility for the study.

Table 3.1: Qualifying telephonic questions and required answers for inclusion into the study

Qualifying telephonic questions	Required answers for inclusion into the study
1. "May I ask you some questions which will help me to determine if you are eligible to participate in this study?"	Yes
2. "How old are you?"	Between the ages of 18 and 45
3. "Are you experiencing any pain or discomfort in the lower neck or upper back region?"	Yes
4. "Do you have a fever or a fear of needles"	No
5. "Do you have any recent history of trauma?"	No
6. "Are you currently taking any muscle relaxants, Non-Steroidal Anti-Inflammatory Drugs, pain medication or steroids including over the counter medication?"	No
7. "Are you taking any blood thinning medication such as Aspirin, Alteplase, Ardeparin, Dalteparin, Danaparoid, Enoxaparin, Fondaparinux, Lepirudin, Urokinase or Warfarin or do you have any bleeding disorders that you are aware off?"	No

If the answer given was not in alignment with the answer required to be included in the study, then the person was thanked for calling and the call terminated.

3.6 INCLUSION AND EXCLUSION CRITERIA

3.6.1 Inclusion criteria

- Participants between the ages of 18 and 45 years as a relatively young population of participants was needed in order to minimise pain that can be caused by accompanying degenerative disc or joint diseases (Harrop *et al*., 2007). This criterion was determined during the telephonic interview.
- Participants diagnosed with active TPs, one and/or two in the trapezius muscle, which was determined at the initial consultation and those which demonstrated the characteristics as outlined by Travell *et al*. (1999) which included the following:

- Taut band of muscle fibers palpated by snapping or rolling the muscle under the finger;
- A tender nodule palpated within this taut band of muscle fibers;
- A local twitch response of the taut band fibers to snapping palpation; and
- Pain referral to the referral zone specific to the muscle involved.

- Participants had to be fluent in written or spoken English, this was determined during the telephonic interview.
- Non-specific neck pain between three and eight on the Numerical Pain Rating Scale 101 (NRS 101) with MPS of the upper trapezius muscle, this was determined at the initial consultation. The specific pain rating was chosen to maintain sample homogeneity.

3.6.2 Exclusion criteria

- History of physical trauma to the associated neck region which was determined during the telephonic interview.
- Participants who had symptoms of Fibromyalgia Syndrome (Schneider, 1995). These symptoms include fatigue, somatic symptoms, unrefreshing sleeps and impaired cognition (Wolfe *et al*., 2010). This was determined at the initial consultation.
- Participants who had a fear of needles, this was determined during the telephonic interview.
- Participants who had any contra-indications to dry needling, this was determined during the initial consultation , including:
    - systemic illness or fever
    - high anxiety or emotional stress;
    - feeling of faintness;
    - bleeding disorders (Hans and Harrison, 1997);
    - diagnosed blood dyscrasias;
    - on any form of anti- coagulant therapy (Hans and Harrison, 1997); and
    - history of epilepsy or susceptibility to convulsions (Forster and Palastanga, 1985)
- Patients who were taking any form of medication that would influence the results of the study i.e. analgesics, muscle relaxants, NSAIDS or steroids (Poul *et al*., 1993), this was determined during the telephonic interview.
- Participants refusing to sign the informed consent form (Appendix E), this was determined at the initial consultation.

- Participants who presented with TPs in the neck region, other than those included in the study, this was determined at the initial consultation.

3.7 GROUP ALLOCATION AND RANDOMIZATION

Once accepted into the study, participants were then randomly assigned to one of two treatment groups i.e. Group One being the dry needling group and Group Two being the IAI group. Assignment was by means of a computer generated list which was drawn up by the statistician and not seen by the researcher. This list was kept at the clinic reception, in line with the blinding process. The clinic receptionist or student administrator at the clinic handed out the interventions to the researcher via sealed envelopes marked according to the allocation schedule. Therefore, each participant had a fair chance of being in either group.

- Group One received treatment of the upper trapezius MFTP using dry needling. The area to be treated was sterilised with alcohol prior to treatment. The dry needling was done using a 25 mm, 0.25 g acupuncture needle. The invasive needling technique that was used in this study was done as follows: the MFTP was located by palpation and a taut muscle band was found. The needle was then inserted between the fingers that located the MFTP. The needle was inserted 1 cm to 2 cm away from the MFTP so that the needle entered the MFTP at an angle of about 30 degrees to the surface of the skin. The fanning technique was used; this was done by drawing the needle out of the MFTP and then re-inserting the needle repeatedly to penetrate a new part of the TP (Cotchett *et al.,* 2010; Dommerholt *et al*., 2006).
- Group Two received treatment of the upper trapezius MFTP using the IAI. The IAI group had the same treatment frequency and duration as that of the dry needling group. The IAI was placed directly over the TP and when applied, a gentle tapping sensation was felt by the participant (www.impulseseminars.com/impulse).

3.8 MEASUREMENT TOOLS

Participants were monitored and assessed in terms of subjective and objective data. Subjective outcome measures included the Numerical Pain Rating Scale (NRS), Neck Disability Index (NDI) and Patient's Global Impression of Change (PGIC). Objective outcome measures included the Algometer and cervical range of motion (CROM) goniometer. Subjective measures were measures which were reported by the research participant. Objective measures were measured by the research assistant. Table 3.2 summarizes the series of events for outcome measures and the approximate time taken with each visit.

Table 3.2: Summary of series and timing of events at each visit

Visit number	Outcome measures taken		Approximate
	Subjective	Objective	duration of visits
1	NRS, NDI	CROM, Algometer	1 hour
2	NRS	CROM, Algometer	30 minutes
3	None, treatment only	None, treatment only	15 minutes
4	NRS, NDI, PGIC	CROM, Algometer	30 minutes

NRS = Numerical Rating Scale; Al = algometery; CROM = Cervical Range of Motion; NDI= Neck disability Index PGIC= patients global impression of change

3.8.1 Subjective measures

3.8.1.1 Numerical Rating Scale (NRS)

This is a subjective form of information whereby the participant estimated their level of pain before each treatment by choosing a number on a scale between zero and 10 where zero is no pain and 10 being the most unbearable pain (Ferreira-Valente *et al*., 2011). This scale showed if there was any progression or regression of the participant's level of pain during the study. The NRS has been shown to be valid and reliable by Jenson *et al*. (1986) in a study using 75 patients who rated their pain using six different scales. Each of the scales met the five criteria to judge intensity scales. The scales all correctly had similar results in terms of predictability, however, the NRS was said to be the most predictable which yields it valid and reliable (Jenson *et al*., 1986). This scale was said to be a practical and easy to use scale (Jensen *et al*., 1986). Sallafi *et al*. (2004) showed a decrease of two points on the NRS to be indicative of improvement in the clinical setting. This measurement was taken at the first, second and final consultations.

3.8.1.2 Patient's Global Impression of Change (PGIC)

This questionnaire (Appendix L) was easy to understand and quick to use. It provided information on activity limitations, symptoms, emotions and the participant's overall quality of life (Middel *et al*., 2001). For clinical research, this questionnaire was found to have strong face validity, reliability and feasibility (Studenski *et al*., 2004). Studenski *et al*. (2004) determined the feasibility, relevance, validity and reliability of this scale by structuring interviews with experts, web-based studies and a pilot study. This questionnaire was completed on the final consultation. Kamper *et al*. (2009) agreed that this scale had a high face validity. The study shows face validity to be the degree that a measure makes sense to a reader and by indicating a change along the scale did represent a meaningful clinical

change according to the patient. The minimum detectable change for the PGIC is 0.45 points on the scale. The minimally clinically important change for the PGIC is 2 points on the scale (Kamper *et al*., 2009; Costa *et al*., 2008). Six or more is needed on a seven point scale to show meaningful improvement (Van der Roer *et al*., 2006)

3.8.1.3 Neck Disability Index (NDI)

This questionnaire (Appendix K) was created by Vernon and Mior (1991) to assess the impact of neck pain on the daily activities of an individual. Permission was granted for the use of this questionnaire (Appendix F). The NDI consists of 10 questions which include topics regarding activities of daily living, pain intensity, concentration and headache symptoms (Vernon and Mior, 1991). Each question is measured on a scale, where zero is no disability and five is maximum disability. A score out of 100 is calculated by totalling the score and doubling it. The higher the participants NDI score, the greater a patient's subjective disability due to neck pain (Vernon and Mior, 1991). The NDI had high reliability and validity (Howell, 2011). Howell (2011) determined the reliability and validity by conducting a literature review in five databases and hand searching articles; 23 were found which met the study criteria. The study showed the NDI to have high validity and reliability for neck pain and whiplash patients especially when compared to other questionnaires. The minimally clinically significant change is 5 points or 10% on the NDI (Howell, 2011). This questionnaire was completed during the initial and final consultations.

3.8.2 Objective measures

3.8.2.1 Cervical Range of Motion (CROM) II Goniometer

This tool was used to measure the cervical range of motion. The goniometer was found to have good intra-examiner and inter-examiner reliability in measuring CROM (Youdas *et al*., 1991). To show this Youdas *et al*. (1991) measured 60 patients with orthopaedic cervical spine disorders, after being divided into standardised groups where CROM was measured using three methods of measuring CROM (CROM II goniometer, the Universal goniometer and visual estimation). Inter- and intra-examiner reliability was tested for all three groups and the correlation was best in the group measured with the CROM device, as there were interclass correlation coefficients of more than 80.

The tool was placed on the participant's nasal bridge and ears and fastened with straps to the back of the participant's head. For this study, the CROM II goniometer was used to measure the active CROM in left and right lateral flexion only as the trapezius muscle

primarily controls the movement of lateral flexion of the neck (Blikstad and Gamelli, 2008). Each movement continued until the participant stopped the motion due to pain. Good posture was maintained while the participant was seated facing forward on the chiropractic treatment table. This measurement was taken at the first, second and final visits.

3.8.2.2 Algometer

This measurement tool was used to measure the sensitivity of the MFTPs by measuring the pain pressure threshold (PPT) over the MFTP. This is done by pressure algometry. The algometer was said to be a reliable diagnostic tool to quantitatively document the sensitivity of MFTPs (Hans and Harrison, 1997). The algometer was used to measure and quantify sensitivity to painful stimuli (Kruse and Christiansen, 1992). The algometer as an index of MFTP sensitivity was found to be valid and reliable and it was demonstrated to have high inter- and intra-examiner reliability in measuring marked MFTPs (Kinser *et al*., 2009). The study conducted by Kinser *et al*. (2009) had an investigator apply set controlled forces onto a force plate using an algometer, thereby, testing the investigators application on to the force plate as well as the algometer readings of the force as it correlated with the reading on the force plate. The algometry readings were measured in kg/cm^2, therefore, the more sensitive the TP, the smaller the reading. The procedure for algometer reading proceeded as follows: the dial was set to zero and the algometer was placed over the chosen TP with the metal rod being perpendicular to the surface of the skin. The participant was instructed to express the point at which an unpleasant physical sensation of pain was first felt. Then pressure was slowly applied, increasing at a rate of 1 kg/second as is recommended by Fischer (1986) and confirmed by Kinser *et al*. (2009). Once the pain threshold was reached, the procedure was stopped and the reading was taken in kg/cm^2. This measurement was taken at the first, second and final visits. This form of measurement has been proven to be useful for the assessment of treatment results (Kinser *et al*., 2009). The minimally clinically important change for PPT is 14.71 (Chesterton *et al*., 2009)

Figure 3.1 The Algomoter
Source: Potter *et al*. (2006)

3.9 PROCEDURE

Following the telephonic interview, all participants meeting the inclusion criteria were invited to an appointment at the DUT CDC. The participants recruited in this study were advised that they would be required to attend four appointments within two weeks, not on consecutive days and not leaving more than five working days between each visit. They were also informed that they were to receive either dry needling or treatment with an adjusting instrument which would not result in any long lasting side effects. The name of the adjusting instrument was not divulged to the participant at any point in time.

3.9.1 Initial consultation

Upon arriving at the DUT CDC appointment, the participant was given a brief verbal explanation of the research procedure together with a letter of information and informed consent (Appendix E) which they were required to read and sign. The participant was then allowed to ask any questions pertaining to the research. The researcher then completed a case history (Appendix G), a physical examination (Appendix H) and a cervical spine orthopedic examination (Appendix I) for each participant. It was important to undergo these examinations to ensure the exclusion criteria were met, as the researcher could not assume

that the participants were aware of their current health status. It is also important in cases where referrals are needed. This is needed in cases such as diabetes and peripheral neuropathy which are often found due to the type of patients who report to the clinic. The participant was then required to complete a pain questionnaire (Appendix J) which required the participant to state the rating of their pain via the NRS, and the NDI questionnaire (Appendix K).

The trapezius muscle was selected for this study due to its superficial location (Tank, 2013) and based on previous studies that have used this muscle successfully (Cagnie *et al*., 2012; Wilks, 2003). Trigger points one and two were assessed in this study, if only one was present only that specific one was treated. If both were present, the most painful TP was treated as the other would be referred to as a secondary TP, as these TPs are in close proximity with similar referral patterns.

A diagnosis of a MFTP was confirmed after manual palpation making use of pincer and flat palpation (this occurred with the participant both seated and prone) of the trapezius muscle and participant feedback (Chaitow and DeLany, 2002). An initial CROM measurement was taken using the goniometer. This was followed by algometry measurements for MFTP sensitivity by measuring the pressure threshold over the MFTP.

To keep in line with the blinding procedure, a research assistant (RA) was utilised, who had been sufficiently trained in algometry and CROM recordings prior to the study. The RA signed an RA agreement (Appendix M). The RA had been trained by a clinician and competency was ensured by means of the RA practicing on the researcher under observation of the clinician. The RA had an equal training to the researcher having completed a Bachelor in Technology: Chiropractic and was in the process of completing a Masters in Technology: Chiropractic. The RA was unpaid and was recruited to take the algometry and CROM outcome measures at the first, second and forth visits. All the objective outcome measures were recorded by the RA on a data collection sheet (Appendix N).

The participant was then asked to remove any clothing covering the neck to shoulder area (if they required a clinic gown, one was provided for them). The area to be treated by the researcher was marked with a spot of henna. Henna is a reddish-brown dye obtained from leaves of the henna plant and used as a dye mainly on hair and skin, and fades in due course leaving no permanent mark (www.merriam-webster.com). The henna was used in this study to ensure that the same spot was treated at each visit as the dye is not readily removed; however, it was reapplied if any sign of fading was noted. The researcher then

checked which group the participant was allocated to and the relevant treatment method was performed. After the initial consultation, the next appointment was made. The participant was thanked for their time and they were allowed to leave.

3.9.2 Second consultation

Upon arrival for the second consultation, the subjective NRS measurement obtained from the participant followed by the objective outcome measures taken by the research assistant. The participant was then asked to remove any clothing covering the neck to shoulder area (if they required a clinic gown, one was provided for them) and the appropriate treatment was administered by the researcher according to their allocated group. After the treatment, the next appointment was made. The participant was thanked for their time and allowed to leave.

3.9.3 Third consultation

At the third consultation, no subjective or objective outcome measures were taken. Only the appropriate treatment was given according to their allocated group. After the treatment, the next appointment was made. The participant was thanked for their time and allowed to leave.

3.9.4 Fourth consultation

At the fourth and final consultation, only subjective outcome measures including the patients' global impression of change (PGIC) (Appendix L) and objective outcome measures were taken as part of the research procedure. The treatment given on this visit was an optional free treatment given after the outcome measures were taken and so had no impact on the research study itself. The participants were thanked for their time and commitment to the research procedure and were allowed to leave. Table 3.2 contains a summary of these consults including outcome measures, and the average timing of each visit

3.10 ETHICAL CONSIDERATIONS

i. The participant's name was not captured onto the data capturing sheets which were sent to the statistician; each participant was given a file number. The research data will be safely stored in the Chiropractic programme for a period of five years, after which it will be shredded.

ii. Informed consent (Appendix E) was obtained from each participant; all participants were informed that they were free to leave the study at any time should they wish to do so without prejudice, ensuring autonomy.
iii. There was no pressure from the company Neuromechanical Innovations to produce favorable results for the IAI. The company did not and will not receive any information until completion of the research.
iv. A Memorandum of Understanding (MOU) (Appendix O) had been drawn up between: the research institution Durban University of Technology and the 'manufacturer'. Neuromechanical Innovations. The MOU stated that the institution had no financial obligations or commitments to the 'manufacturer' as a result of conducting this study and the 'manufacturer' may not award or incentivize the study or its related parties in any manner whatsoever, nor remunerate, award or offer any financial or other donation or gift to any of those involved with the study
v. The registered trademark of the product was included in the title. This could have biased the participants as they may assume there may be a conflict of interest. However, to avoid such bias the consent form contains the ethical clearance number given for this study. This shows the participant that any conflict of interest would have been picked up by the ethics committee, this includes any conflict of interest. It was also stated; that this device is for spinal adjustments and this research aims to find an alternative therapy for trigger points found in muscle.

vi. Participation was voluntary and did not involve financial benefits. However, a free treatment was given at the last consult after final readings were taken to ensure participants returned for the final readings.
vii. Non-maleficence was ensured as dry needling is known as an effective form of therapy and the IAI was hypothesised to be effective with concrete literature grounding.

3.11 DATA ANALYSIS

Descriptive statistics such as age and gender were presented as age distribution, mean age, standard deviation and gender distribution in each group and with the two groups combined.

IBM SPSS version 23 was used to analyse the data. A *p* value of <0.05 was considered as statistically significant. A *p* value of <0.05 gives a confidence interval of 95%. Repeated measures ANOVA was used to examine the effect on each outcome measure separately of time and treatment group interaction. Wilks Lamda was used to test the effect of size. Table

3.3 shows a listing of each objective, their statistical tests and the normality testing used for eachProfile plots were generated in order to assess direction and trend of the effect of the treatment (Esterhuizen, email communication with the statistician, 2015).

Table 3.3: List of the statistical tests and normality testing for each objective

Objective	Statistical test	Normality testing
To compare the baseline measurements between groups	Independent samples t-test (parametric test)	1. Rule of thumb test: two standard deviations subtracted from the mean does not yield an impossible or negative value. 2. Histogram to visualise the distributions 3. Kolmogorov-Smirnov test
Within-group changes over time	Repeated measures ANOVA testing (Wilk's lambda for the time effect) (parametric test)	1. Rule of thumb test: two standard deviations subtracted from the mean does not yield an impossible or negative value. 2. Histogram to visualise the distributions 3. Kolmogorov-Smirnov test
Within and between group changes to assess the treatment effect	Repeated measures ANOVA testing (Wilk's lambda for the time x group effect) (parametric test)	1. Rule of thumb test: two standard deviations subtracted from the mean does not yield an impossible or negative value. 2. Histogram to visualise the distributions 3. Kolmogorov-Smirnov test
To compare the Patients Global Impression of Change scale after treatment between the groups	Mann Whitney U test (non-parametric)	1. Rule of thumb test: two standard deviations subtracted from the mean does not yield an impossible or negative value. 2. Histogram to visualise the distributions 3. Kolmogorov-Smirnov test

CHAPTER 4 : STUDY RESULTS

4.1 INTRODUCTION

Analysis of the subjective and objective data which was retrieved from each participant will be shown in this chapter. This data was analysed by IBM SPSS version 23 as mentioned in Chapter 3. The value of < 0.05 was set as the *p* value (which has a confidence level of 95%); this determined if the data results were considered statistically significant. To compare the changes over time within and between treatment groups, repeated measures ANOVA within and between groups analysis was used. A method using time x group interactions indicated any significant differences in treatment effect over time between the two groups. The following flow diagram (Figure 4.1) shows the number of people recruited, how many participants dropped out and at which stage of the study.

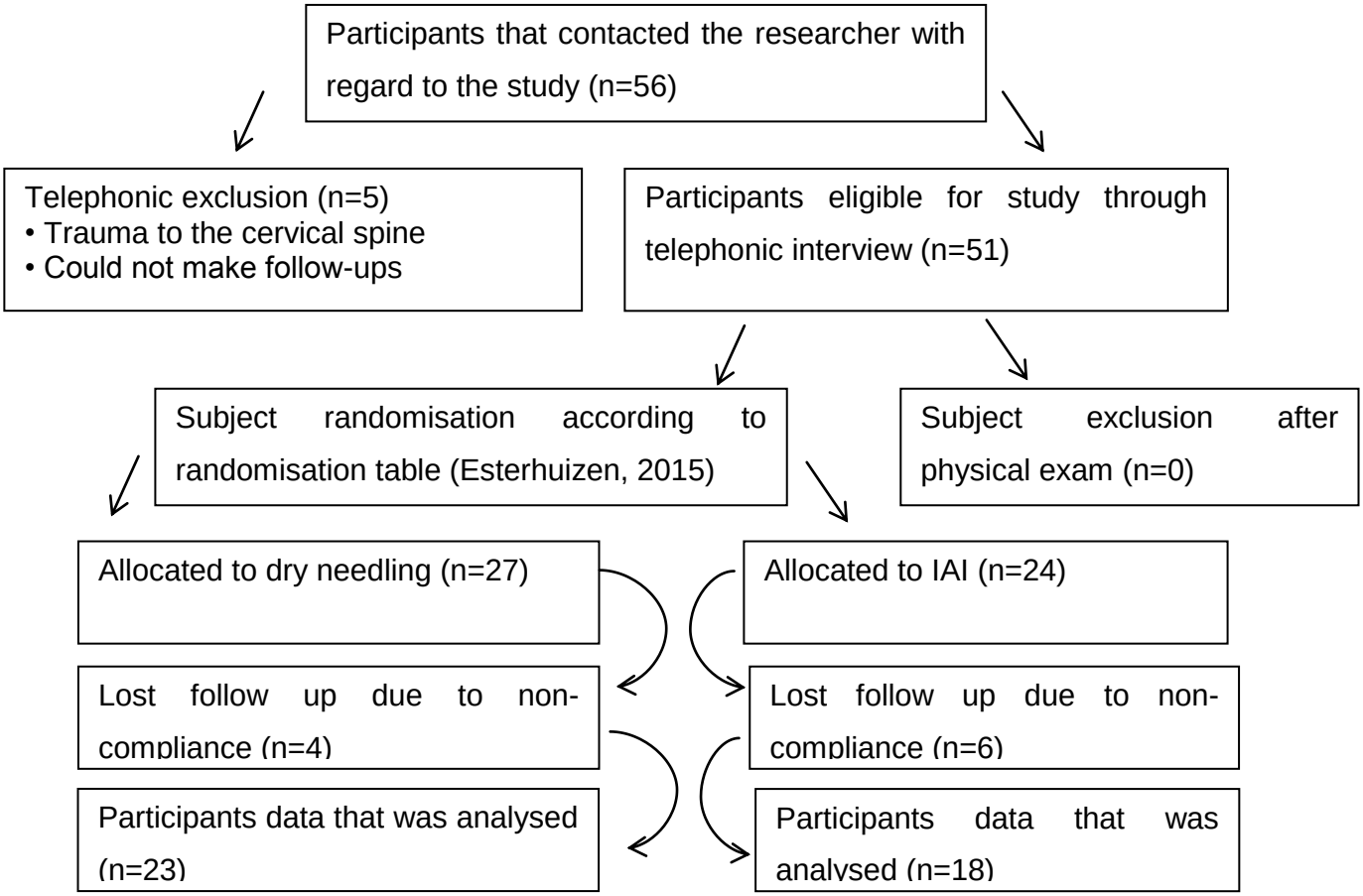


Figure 4.1: Consort flow chart showing number of recruitments and drop outs

The data analysed included the following:

i. Demographics including gender and age.
ii. Subjective outcome measures using the NRS, NDI questionnaire and PGIC. A non-parametric Mann Whitney test was used to compare the PGIC between the groups.
iii. Objective outcome measures comprising of the algometer and CROM goniometer device.
iv. Comparison between groups in terms of subjective and objective outcome measures.

4.1 DEMOGRAPHICS

The sample consisted of 41 participants who were between 18 and 40 years of age with a mean age of 29. Participants in Group One had a mean age of 29.9 years, whereas participants in Group Two had a mean age of 26.7 years (Table 4.1). The population consisted of 58.5% of males and 41.5% of females.

Table 4.1: Demographic data analysis of age and gender

Data	Group One	Group Two	Combined Total
Age distribution (years)	18-37	18-40	18-40
Mean age (years)	29.9	26.7	29
Std Deviation	2.4	2.3	0.0
Gender Distribution	10 Females 13 Males	7 Females 11 Males	17 Females 24 Males

4.2 MEASUREMENTS AT BASELINE

There was no statistically significant difference at baseline measurements for the CROM values, NRS, algometer (Al), and NDI scores between the two groups (Table 4.2). At baseline the *p* value was shown as follows: NRS $p = 0.823$; Al $p = 0.993$; CROM left $p = 0.588$; CROM right $p = 0.734$; and, NDI $p = 0.119$. Therefore, the groups were statistically equal.

Table 4.2: Comparison of baseline measurements between each group

	GROUP				*p* value
	Dry needling		Impulse Adjusting instrument		
	Mean	Standard Deviation	Mean	Standard Deviation	
NRS -1	5.4	1.5	5.5	1.6	0.823
AI -1 (KG/CM²)	7.0	3.0	7.0	2.3	0.993
CROM -1 Left	42.4	6.8	41.2	6.8	0.588
CROM -1 Right	38.0	7.3	37.3	6.7	0.734
NDI	9.1	6.2	6.4	4.4	0.119

NRS = Numerical Rating Scale; AI = algometery; CROM = Cervical Range of Motion; NDI= Neck disability Index

4.3 OBJECTIVE ONE

The first objective was to determine the effectiveness of dry needling alone in the treatment of upper trapezius MFTPs using subjective and objective outcome measures.

4.3.1 NRS

The change in subjective pain showed a highly significant decrease in pain over the three time points according to the NRS ($p < 0.001$; repeated measures ANOVA); this is especially true between treatment number 2 and treatment number 3 (which is visit four) in Group One (Figure 4.2).

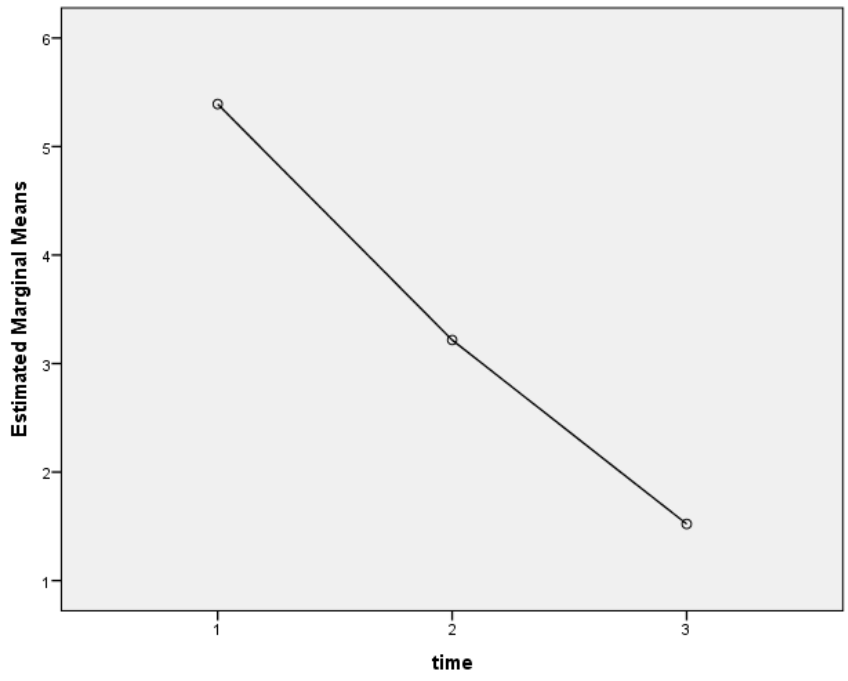


Figure 4.2: Mean NRS over time in Group One

4.3.2 Algometer

There was no statistically significant change in the algometer readings over the treatments in Group One. This indicates no change in objective pain sensitivity (p = 0.348; repeated measures ANOVA) (Figure 4.3).

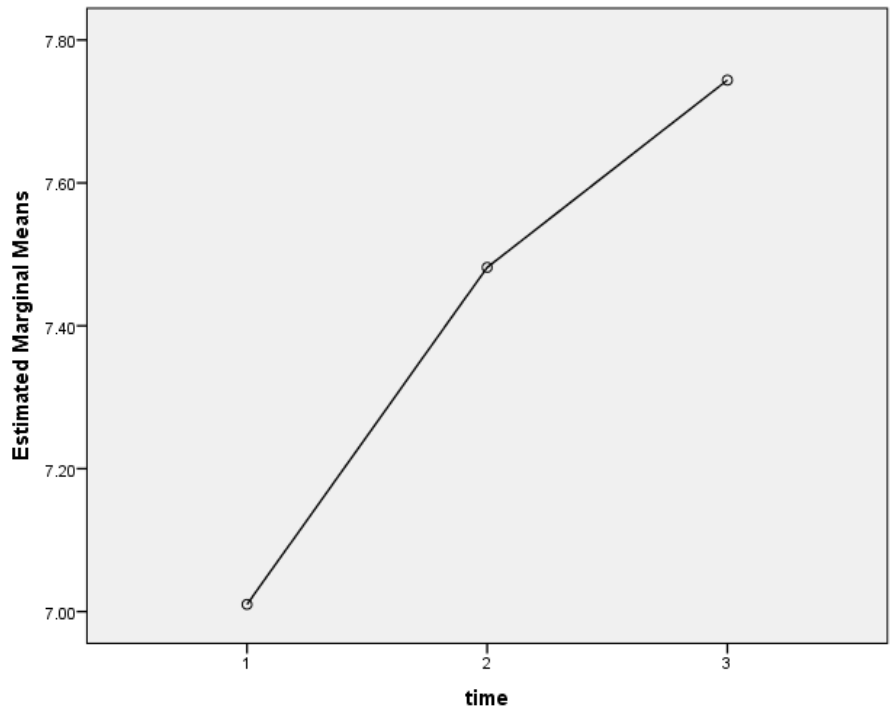


Figure 4.3: Algometer readings over time in Group One

4.3.3 CROM Left Lateral Flexion

There was a marginal but insignificant change in CROM left measurements over time in Group One. There was an initial decrease between treatment number 1 and treatment number 2 followed by an increase between treatment number 2 and treatment number 3 (Figure 4.4) (p = 0.081; repeated measures ANOVA).

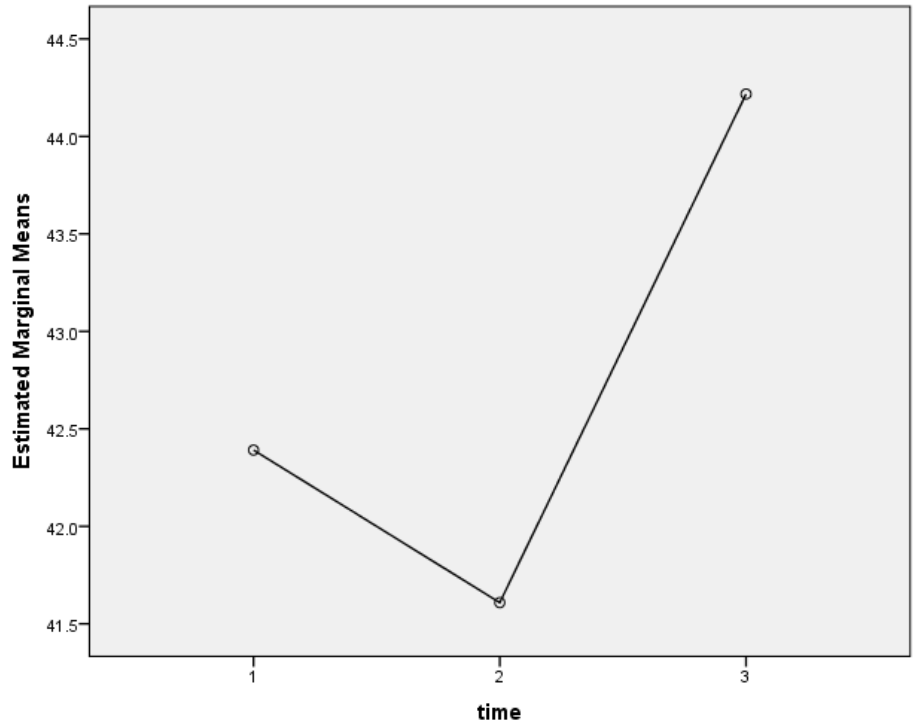


Figure 4.4: CROM left lateral flexion outcome measures over time in Group One

4.3.4 CROM Right Lateral Flexion

There was no significant change in outcome measures for CROM on the right for Group One (p = 0.335; repeated measures ANOVA). There was an initial increase between treatment number 1 and treatment number 2 followed by a steady continuation in CROM measurements between treatment number 2 and treatment number 3 (Figure 4.5)

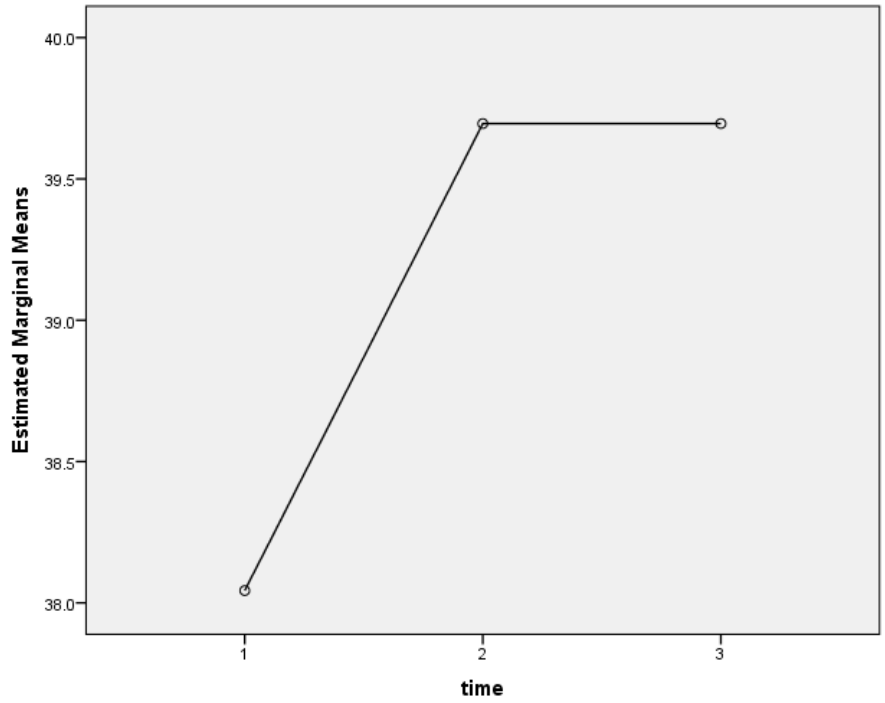


Figure 4.5: CROM right lateral flexion outcome measures over time in Group One

4.4 OBJECTIVE TWO

The second objective was to determine the effectiveness of the IAI alone in the treatment of upper trapezius MFTPs using subjective and objective outcome measures.

4.4.1 NRS

There was a statistically significant decrease in NRS over time in Group Two ($p < 0.001$; repeated measure ANOVA). A steady decrease in pain intensity can be seen over the three points (Figure 4.6). This indicates that there was a significant decrease in patients' subjective feeling of pain.

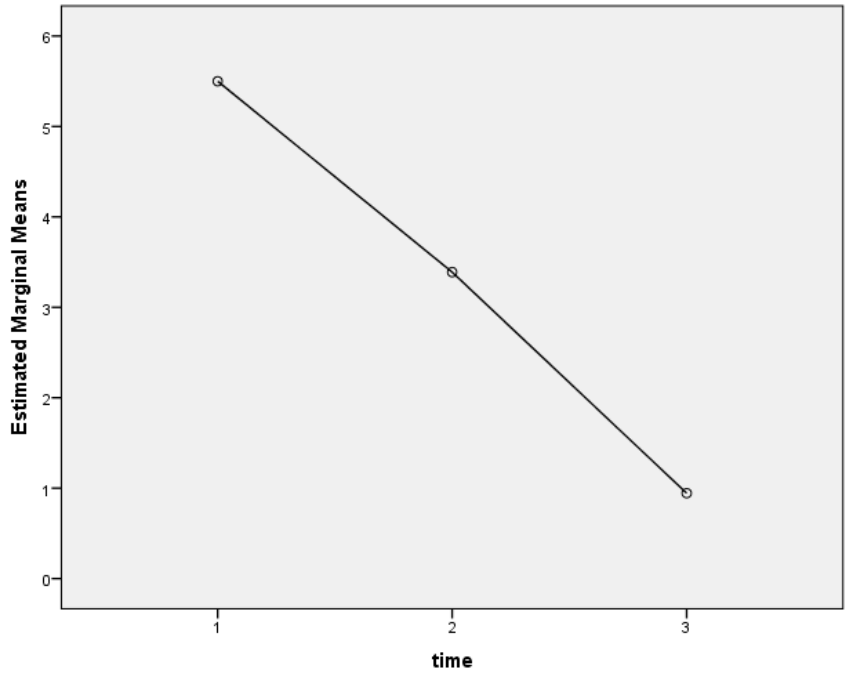


Figure 4.6: Mean NRS over time in Group Two

4.4.2 Algometer Readings

There was a statistically significant increase in algometer readings over the three time points (p = 0.020; repeated measures ANOVA) (Figure 4.7). An increase in pain threshold can be seen over the three points (Figure 4.7).

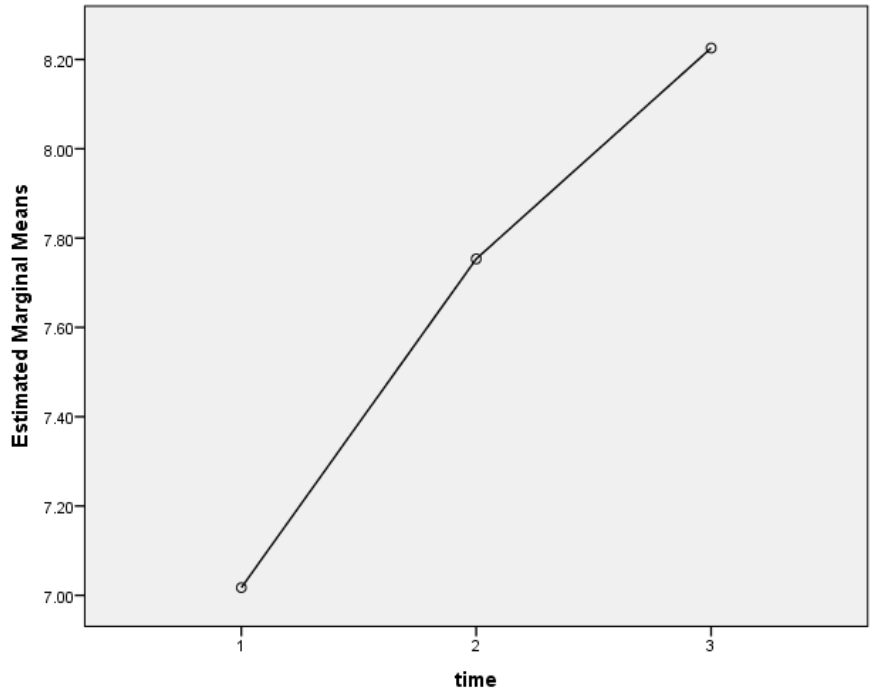


Figure 4.7: Algometer readings over time in Group One

4.4.3 CROM Left Lateral Flexion

There was no statistically significant change in CROM left lateral flexion over time in Group Two even with the slight initial decrease in CROM measurements between treatment number 1 and treatment number 2 and an increase in CROM measurements between treatment number 2 and treatment number 3 (Figure 4.8) (p = 0.258; repeated measures ANOVA).

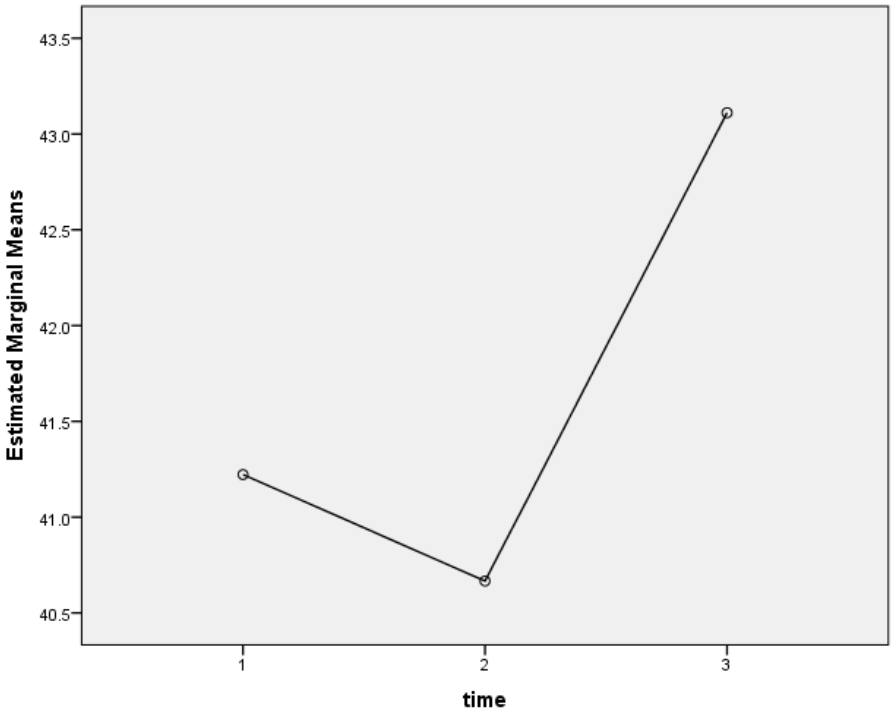


Figure 4.8: CROM left lateral flexion outcome measures over time in Group Two

4.5.4 CROM Right Lateral Flexion

There was no statistically significant change in CROM right lateral flexion over time in Group Two even though there was a progressive increase in CROM outcome measures between treatment number 1 and treatment number 2 and a steep increase in CROM measurements between treatment number 2 and treatment number 3 (p = 0.127; repeated measures ANOVA) (Figure 4.9).

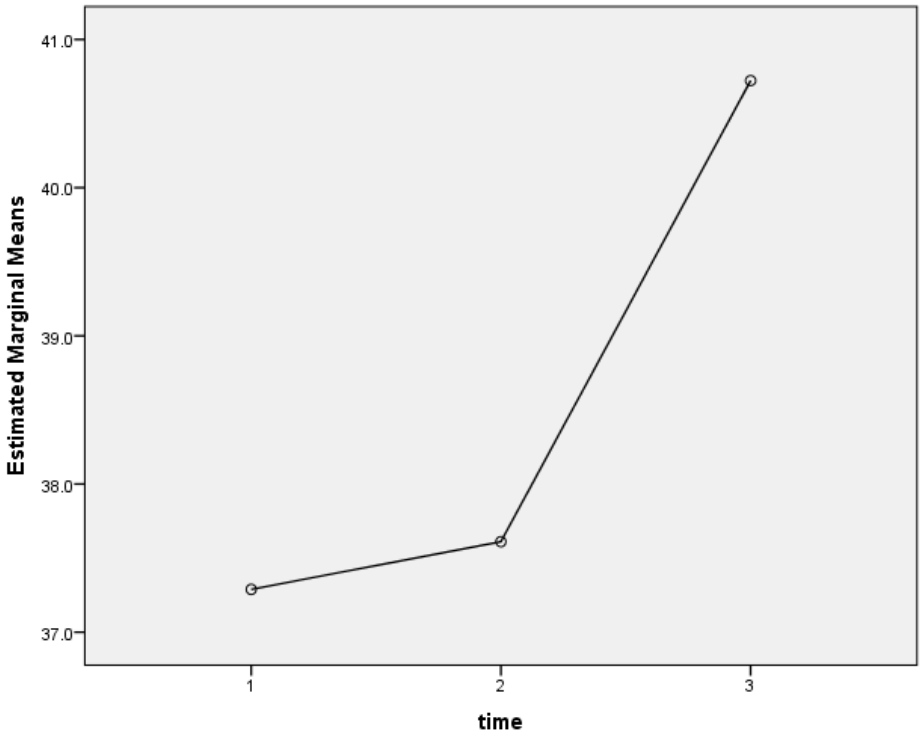


Figure 4.9: CROM right lateral flexion outcome measures over time in Group Two

4.5 OBJECTIVE THREE

The third objective was to compare the overall effectiveness of the IAI and dry needling in the treatment of upper MFTPs. This was determined by comparing the subjective and objective findings.

4.5.1 NRS

There was no statistically significant difference between groups in the effect of treatment for NRS, as both groups decreased at the same rate (p = 0.362; repeated measures ANOVA) (Table 4.3), although the effect of time was statistically significant (p < 0.001).

Table 4.3: Effects for NRS in both groups' within-subjects

Effect	Statistic	*p*-value
Time	Wilk's lambda = 0.114	<0.001
Time x group	Wilk's lambda = 0.948	0.362
Group	F = 1.044	0.362

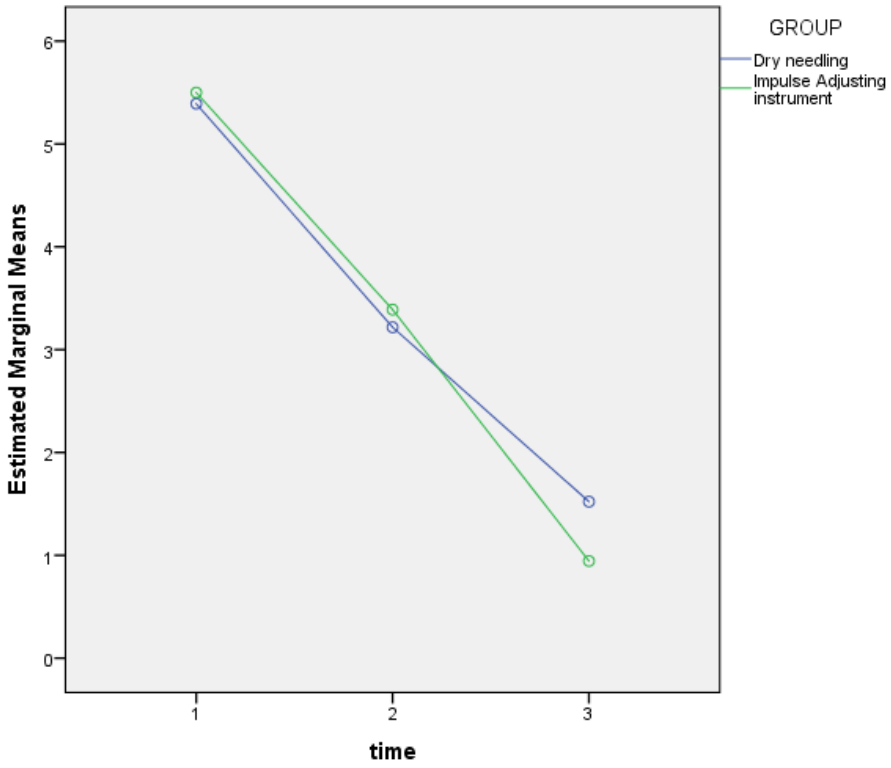


Figure 4.10: NRS outcome measures comparison over time between Group One and Group Two

Figure 4.10 shows significant changes in the two groups. The two groups were very similar in terms of statistically significant effectiveness. However, Group Two had a higher initial and lower final pain score compared to Group One. Both groups had significant decrease in subjective pain intensity.

4.5.2 NDI

The effect of time was statistically significant ($p < 0.001$); however, there was no statistically significant difference between groups in the effect of treatment for NDI. Both groups decreased at the same rate ($p = 0.925$; repeated measures ANOVA) (Table 4.4).

Table 4.4: Affects for NDI in both groups within-subjects

Effect	Statistic	*p*-value
Time	Wilk's lambda = 0.430	<0.001
Time x group	Wilk's lambda = 1.000	0.925
Group	F = 0.009	0.925

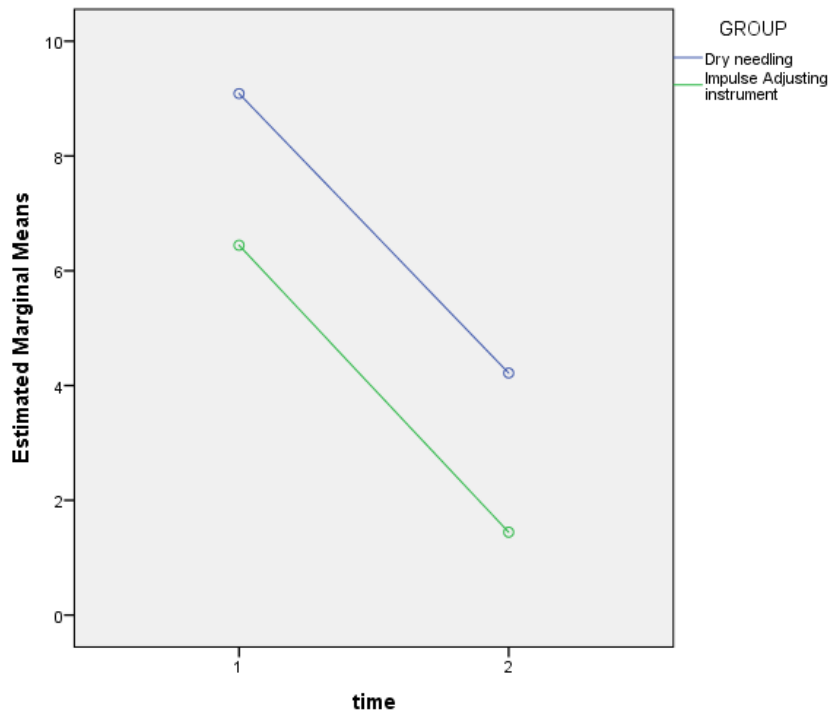


Figure 4.11: NDI outcome measures comparison over time between Group One and Group Two

Figure 4.11 shows a statistically significant parallel change between Group One and Group Two as they decrease at the same rate.

4.5.3 Algometer

The effect of time was statistically significant (p = 0.020 repeated measures ANOVA) for algometry outcome measures. There is no statistically significant difference in time-group correlation (p = 0.780) (Table 4.5). This indicates that both treatment groups increased over the time period in relation to algometer outcome measures.

Table 4.5: Within-subjects and between-subjects effects for algometer

Effect	Statistic	*p*-value
Time	Wilk's lambda = 0.813	0.020
Time x group	Wilk's lambda = 0.987	0.780
Group	F = 0.250	0.780

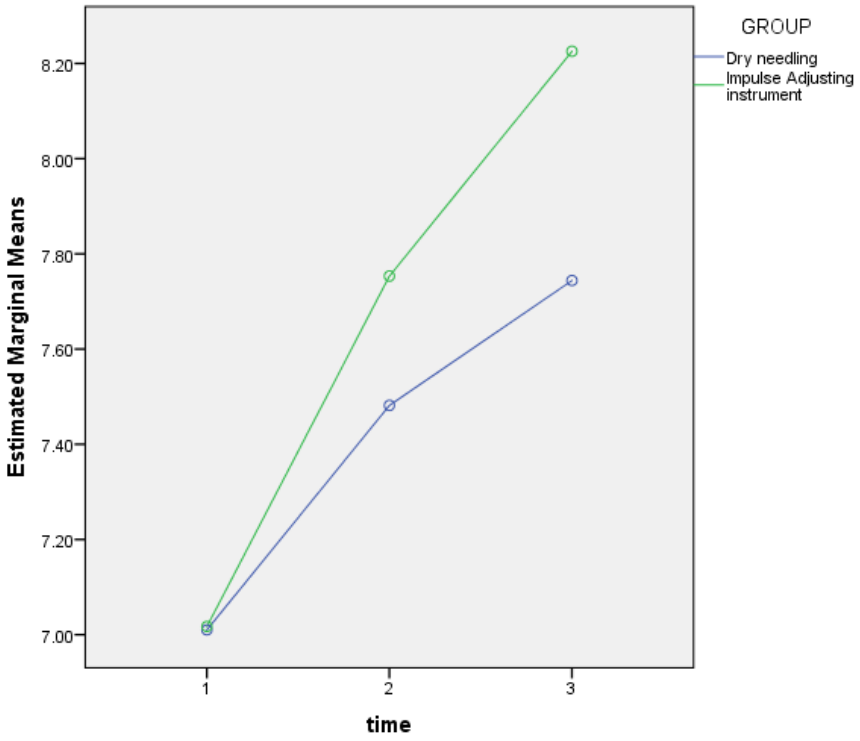


Figure 4.12: Effects for algometer within-subjects and between-subjects

Figure 4.12 shows profiles of the two groups. There was a steady increase for both groups; however, more so for Group Two when compared to Group One. The trend in the graph suggests that the rate of increase is higher in Group Two which is the IAI although there was no difference in treatment. The increase slightly decreases in both Groups between treatment number 2 and treatment number 3.

4.5.4 CROM Left Lateral Flexion

There was no statistically significant difference in treatment effects (p = 0.990; repeated measures ANOVA) for CROM left lateral flexion (Table 4.6). There was a statistical difference on the effect of time between the two groups (p = 0.022).

Table 4.6: Within-subjects and between-subjects effects for CROM Left

Effect	Statistic	*p*-value
Time	Wilk's lambda = 0.818	0.022
Time x group	Wilk's lambda = 0.999	0.990
Group	F = 0.10	0.990

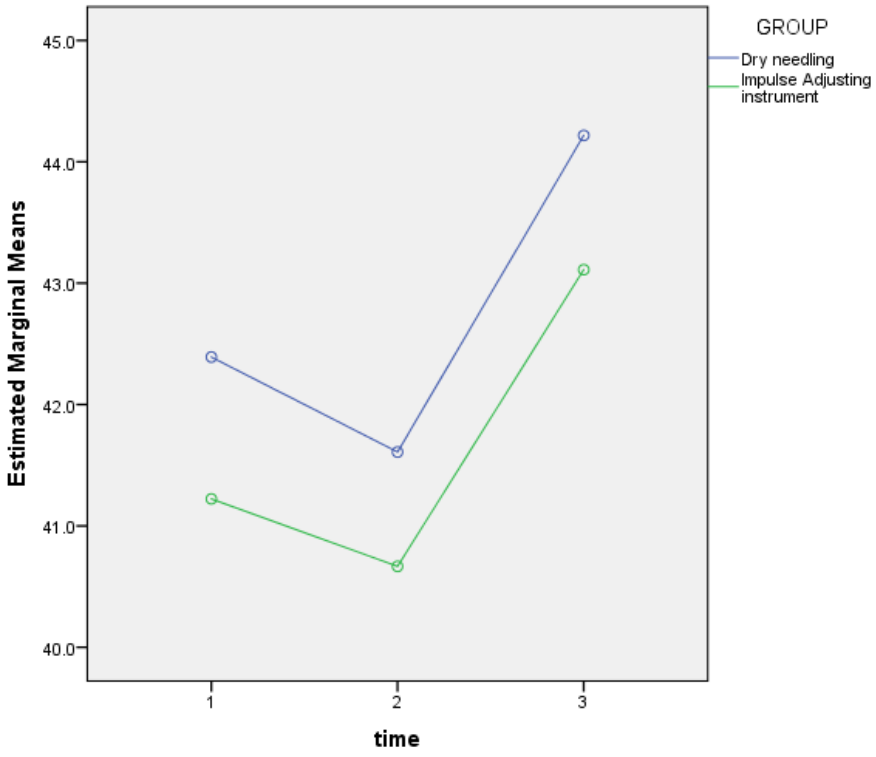


Figure 4.13: Within-subjects and between-subjects effects for CROM left

Figure 4.13 shows profiles of the two groups. There was a slight decrease between treatment number 1 and treatment number 2 and an increase in both groups between treatment number 2 and treatment number. Trend in the graph suggests that the rate of increase is similar in both Groups.

4.5.5 CROM Right Lateral Flexion

There was a difference on the effect of time between the two groups (p = 0.038) (Table 4.7). However, there was no statistically significant difference in the effect of treatment between the groups (*p* = 0.384; repeated measures ANOVA).

Table 4.7: Within-subjects effects and between-subjects effects for CROM right

Effect	Statistic	*p*-value
Time	Wilk's lambda = 0.842	0.038
Time x group	Wilk's lambda = 0.951	0.384
Group	F = 0.982	0.384

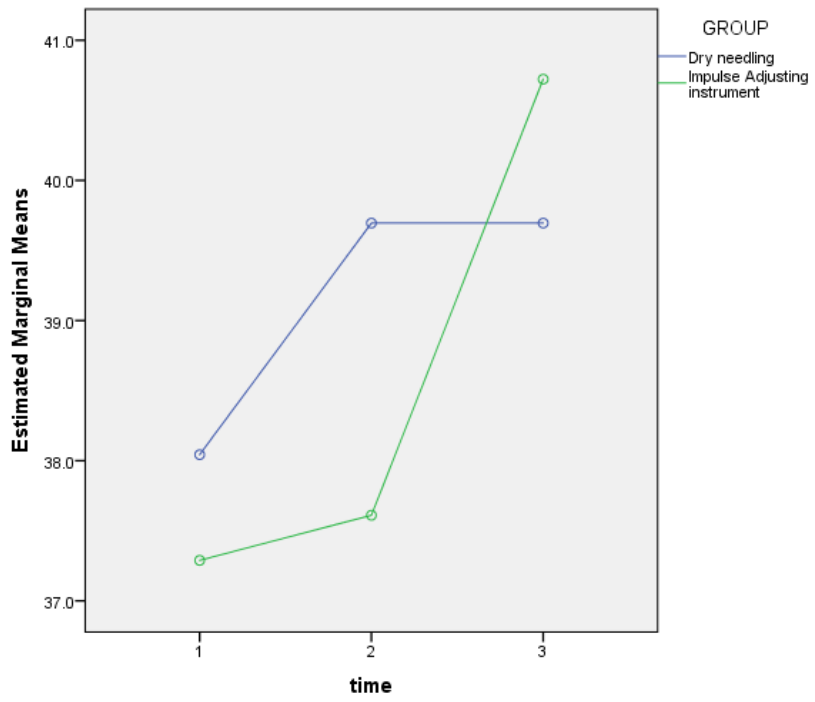


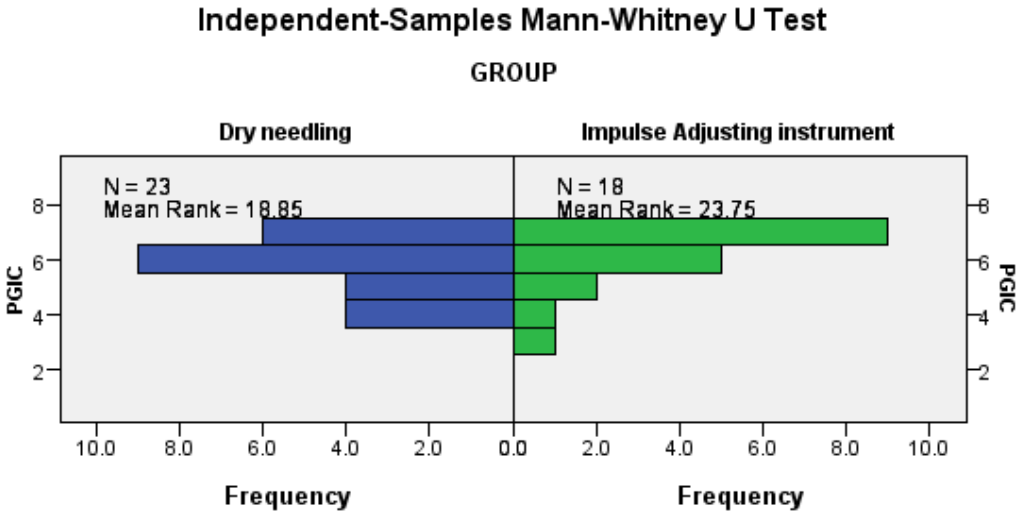
Figure 4.14: Within-subjects and between-subjects effects for CROM right

Figure 4.14 shows no significant relationship between the two profiles. The increase was steady between treatment number 1 and treatment number 2 in Group One. There was a significant increase between treatment number 2 and treatment number 3 in Group Two while in Group One there was no significant change over the same time period. There is a higher increase in Group Two as suggested by the trend in the graph although the effect of the treatment between the two groups, statistically, had no significant difference.

4.5.6 Patients Global Impression of Change Scale

The PGIC scale was the final subjective measurement obtained. The PGIC scale scores were retrieved at the final appointment, after the final treatment of each participant to quantify the participant's improvement over time. The scores were compiled and compared between the groups using a non-parametric Mann Whitney test.

Figure 4.15 illustrates that Group One had 23 participants and the mean rank was 18.85. Group Two had 18 participants and the mean rank was 23.75. The most frequent for Group One was six and the least frequency was four, with the most common frequency in Group One being six. In Group Two, the most frequent was seven and the least frequent was one, the most common frequency in Group Two was seven. There was no statistically significant difference between Group One and Group Two (p = < 0.172).



Total N	41
Mann-Whitney U	256.500
Wilcoxon W	427.500
Test Statistic	256.500
Standard Error	36.248
Standardized Test Statistic	1.366
Asymptotic Sig. (2-sided test)	.172

Figure 4.15: The effects for PGIC within-subjects and between-subjects

CHAPTER 5 : DISCUSSION

5.1 INTRODUCTION

Chapter 4 presented the results and statistics of this study. This chapter will discuss those results in terms of demographic data which will show the homogeneity of the participants within the groups. This chapter will also discuss the results in terms of the statistical analysis of objective data and subjective data within the groups and between the groups.

5.2 DEMOGRAPHIC DATA

This study had a total sample size of 51 participants; however, of those 51 participants 10 dropped out of the study – six dropped out of Group Two and four from Group One. The reasons for the dropouts was due to the inability to return for follow-up treatments often because of work commitments, transport issues or travel. None were due to the effects of the treatments. This left a total number of 41 participants, 23 in Group One and 18 in Group Two which was a similar number to that of the study done by Tekin *et al*., (2013) who had n = 17 in the sham intervention group and n = 23 in the dry needling intervention group.

The ages of the participants ranged from 18 to 40 years of age with a mean age of 29 years. Group One had an age range of 18 to 37 with a mean age of 29.9 and Group Two had an age range of 18 to 40 with a mean age of 26.7 (Tale 4.1). This result shows a relevantly young population was used for the study. Possible reasons for the young population may be due to word of mouth spread among similarly aged social groups and the location of the study being at a university. The average age group for this study, although being young, was similar to a study conducted by Ziaeifar *et al*. (2014) who had a mean age of 26.5 ± 8.57 in their standard group (n = 17) and a mean age of 30.06 ± 9.87 in their experimental group (n = 16). Another study conducted by Van Der Westhuizen (2012) had a younger population with a mean age of 27.7 ± 6.1 years and recommended that the outcomes for the study be applicable to younger patients. Therefore, the outcomes of this study may only be applicable to younger to middle aged patients. This is relevant as 15% to 30% of young people suffer weekly with neck and shoulder pain (Vikat *et al*., 2000; Niemi *et al*., 1996). A longitudinal study conducted by Siivola *et al*. (2004) surveyed young people regarding neck and shoulder pain and resurveyed them again after a period of seven years. The results of this study showed neck pain in young adolescents to increase from 17% to 28% in young adults and it was also revealed in this study that neck and shoulder pain is multifactorial in younger

people. From this knowledge, it would prove important to introduce treatment to this age group before it progresses and worsens in adulthood.

Of the 41 participants, 17 (58.5%) were female and 24 (41.5%) were male. There were 10 females in Group One and seven in Group Two. There were 13 males in Group One and 11 in Group Two (Table 4.1). This shows a fairly even distribution in terms of gender, however, males were higher in number in both groups. This is not consistent with epidemiological studies which found the prevalence of neck pain to be higher in females than in males (Hoy *et al*., 2010; Manchikanti *et al*., 2009). This is because females are more likely to have a history of low back pain or neck pain, a poorer psychological state, headaches, sedentary work style and low job satisfaction (Carroll *et al*., 2009). Between males and females, 30% of men and 50% of women experience neck pain in their lifetime (Dziedzig, 2005). This study is similar to the study conducted by Ferna´ndez-de-las-Pen˜as *et al*. (2006) who also had a higher number of males (57.5 %) than females in their study. Burström *et al*. (2013) conducted a study on Swedish construction workers. The aim of the study was to determine the prevalence of neck and lower back pain in construction workers and to determine if working outdoors in the cold increased the risk of symptoms. The study was a questionnaire but also involved regular health examinations. It surveyed male workers only as there were not enough females in the construction field. Most females were found in the indoor, office environment and did not do manual work. The nature of manual work can lead to pain and impairment in normal functioning of muscles and joints. This is due to prolonged or excessive biomechanical stress on the neuromusculoskeletal system in the form of repetitive heavy loading and monotonous awkward postures (Johansson *et al*., 2003). In such cases, there would be more males than females, as females tend to have less biomechanically stressful occupations.

5.3 SUBJECTIVE DATA

5.3.1 Numerical Pain Rating Scale (NRS)

This scale shows if there was any progression or regression of participants' level of pain during the study (Jenson *et al*., 1986). In this study, the inclusion criteria required the NRS to be between three and eight to maintain sample homogeneity. Sallafi *et al*. (2004) showed a decrease of two points on the NRS to be indicative of improvement in the clinical setting.

In the intra-group analysis for the first objective, the Group One treatment (dry needling) was shown to be highly effective in decreasing pain according to the subjective data obtained from NRS readings over the three time points ($p < 0.001$; repeated measures ANOVA)

(Figure 4.2). The data from Group One revealed the mean NRS was 5.4 for the initial visit, 3.2 for the second visit and 1.5 for the last visit. The improvements shown were statistically significant (p = 0.001) and according to Sallafi *et al*. (2004), this was clinically significant as well.

This result concurs with the many clinical trials (Ferreira, 2006; Wilks, 2003) and review articles (Cummings and White, 2001) which show dry needling to be an effective form of subjective pain relief in patients with neck pain and MFTPs in the upper trapezius muscles. The review conducted by Cummings and White (2001) did not include clinical trials using the NRS. The clinical trial conducted by Wilks (2003) did make use of the NRS to determine the subjective pain rating of patients after dry needling of latent trigger points in TP one or TP two of the trapezius muscle. Dommerholt (2011) reported the decrease in pain to be caused by neurophysiological, mechanical and chemical changes. In accordance with this, a study conducted by Ziaeifar *et al*. (2014) suggested that the pain relief experienced was due to the increased blood flow and oxygenation in the area of the TP. However, in this study, as in the study conducted by Ziaeifar *et al*. (2014), chemical or neurophysiological changes were not measured.

Intra-group analysis for the second objective revealed that the Group Two treatment (IAI) was also shown to be highly effective in decreasing subjective pain according to the NRS over the three time points (p < 0.001; repeated measures ANOVA) (Figure 4.6). The data from Group Two revealed the mean NRS was 5.3 for the initial visit, 3.4 for the second visit and 0.9 for the last visit. The improvements shown were statistically significant (p = 0.001) as well as clinically significant according to Salafi *et al*. (2004). The study conducted by Gemmell and Allen (2008) made use of the AAI which is similar to the IAI, however, it is a spring-loaded and single impulse device. In their study, they compared activator TP therapy and IC on MFTPs and they also made use of the NRS as a subjective measurement tool. They found that the activator therapy decreased subjective pain readings 13% more than the IC group. This correlates with the results of this study confirming that the IAI treatment for MFTPs decreases subjective pain.

The inter-group analysis compared the effectiveness of the IAI and dry needling treatments. With respect to the NRS, there was no statistically significant difference between the two groups. However, the effect of time was significant (p < 0.001) as both groups were effective at the same rate (p = 0.362; repeated measures ANOVA) (Table 4.3). This statistic implies that IAI treatment for MFTPs and neck pain is as effective as dry needling with regards to subjective pain rating as measured using the NRS.

5.3.2 Neck Disability Index (NDI)

The NDI addresses subjective topics regarding activities of daily living, pain intensity, concentration and headache symptoms (Vernon and Mior, 1991). This questionnaire was administered at the initial consultation and final consultation to assess the change in subjective disability and pain over the treatment period. The baseline measurements for the NDI readings were relatively low in this study; this may be due to a relatively younger population, no history of cervical trauma and the likelihood of other cervical spine syndromes not being present with the presenting MFTP as the inclusion criteria required for the NRS scores to be between three and eight (Simons, Travell and Simons, 1999).

Intra-group analysis for Group One showed a steady and highly significant decrease in NDI scores over time ($p < 0.001$; repeated measures ANOVA). This implies that dry needling decreased the impact of neck pain on the daily living activities for the participants in this group. This concurs with a study conducted by Itoh *et al*. (2007) where standard acupuncture, sham acupuncture, trigger point acupuncture and non-trigger point acupuncture were compared. The trigger point acupuncture (effectively the same as dry needling) significantly improved NDI scores. The clinical trial conducted by Abdul-Rasheed (2013) also showed improvements in NDI scoring for both treatment Group A (which included dry needling and spinal manipulative therapy (SMT)) and Group B (which included Traumeel® S injection and SMT). Van Der Westhuizen (2012) also concluded that dry needling improved NDI scores as well as Kinesiotape® in a clinical trial.

Intra-group analysis of the IAI group showed a highly significant and steady decrease in NDI readings in this treatment group throughout the time points ($p < 0.001$; repeated measure ANOVA), therefore, implying its effectiveness regarding subjective measures by decreasing the impact of neck pain.

Inter-group analysis in objective three revealed no statistically significant difference between the two treatment groups. The effect of time was statistically significant ($p < 0.001$); as both groups decreased at the same rate ($p = 0.925$; repeated measures ANOVA) (Table 4.4). Figure 4.11 revealed Group One to have a much higher baseline measurement (9.1) than Group Two (4.4), however, the trend in the graph suggests a parallel decrease in the score which means the effectiveness of both treatments were equally significant.

5.3.3 Patient's Global Impression of Change (PGIC)

This questionnaire provided information on activity limitations, symptoms, emotions and the participants overall quality of life (Guy, 2001).

Figure 4.15 shows the highest frequency for Group One was six and the lowest frequency was four, with the most common frequency in Group One being six which when elaborated meant the participants felt “Better, and there was a definite improvement that had made a real and worthwhile difference”. In Group Two, the highest frequency was seven and the lowest frequency was one, the most common frequency in Group Two was seven which when elaborated meant the participants felt “A great deal better, and a considerable improvement had made all the difference”. Therefore, inter-group analysis revealed a slightly greater improvement in Group Two, however, there was no statistically significant difference between Group One and Group Two (p = < 0.172). From these results, we can conclude that both treatment protocols were effective when the participants were reflecting on their quality of life from before to after the treatment interventions were administered. This concurs with the study conducted by Gemmell and Allen (2008) which compared ischaemic compression and AAI treatment on TPs, where both groups improved similarly regarding the PGIC scoring. Gemmell and Allen (2008) assessed their participants using the PGIC as the primary outcome measure; this is because it measures the participant’s improvement not only with regards to the efficacy of treatment but also takes into account the participants expectations. Therefore, for the purposes of the study, this implies that the IAI can be used as an alternative to dry needling in treatment of MFTPs for subjective improvement in a patient’s quality of life.

5.4 OBJECTIVE DATA

5.4.1 CROM II Goniometer

The goniometer measures cervical range of motion (CROM). For this study, the goniometer was used to measure the active CROM in left and right lateral flexion only as the trapezius muscle primarily controls the movement of lateral flexion of the neck (Blikstad and Gamelli, 2008).

Intra-group analysis for Group One, objective one, for both left and right sided CROM in lateral flexion showed a slight but insignificant change in CROM outcome measures over time. For left lateral flexion there was an initial decrease between treatment number 1 and treatment number 2 followed by an increase between treatment number 2 and treatment number 3 (p = 0.081; repeated measures ANOVA) (Figure 4.5). For right lateral flexion there was an initial increase between treatment number 1 and treatment number 2 followed by a

steady continuation in CROM measurements between treatment number 2 and treatment number 3. (Figure 4.6) (p = 0.335; repeated measures ANOVA). This implies that with time, CROM should improve in this group. Studies conducted by Kamanli *et al*. (2005) and Rickards (2006) concur with this study as these studies show an increase in CROM with the use of dry needling treatment. Dry needling increases CROM by decreasing tension within the muscle, thereby, increasing ROM (Kamanli *et al*., 2005).

Intra-group analysis for the Group Two, objective two, CROM for both left and right lateral flexion showed no statistically significant changes in CROM. Left lateral flexion showed a slight initial decrease in CROM measurements between treatment number 1 and treatment number 2 and an increase in CROM measurements between treatment number 2 and treatment number 3 (p = 0.258; repeated measures ANOVA) (Figure 4.9). With right lateral flexion there was a progressive increase in CROM measurements between treatment number 1 and treatment number 2 and a steep increase in CROM measurements between treatment number 2 and treatment number 3 (p = 0.127; repeated measures ANOVA) (Figure 4.10). This implies that with time CROM should increase, this however, was not demonstrated in this study. Therefore, this study differs from the study conducted by Blikstad and Gemmell (2008) which showed 66.7% of the AAI treatment group for MFTPs to increase and improve in left CROM and 40% in right-sided CROM. Therefore, further studies need to be conducted to investigate this.

The inter-group analysis in objective three showed no statistically significant difference between the effectiveness of two treatments for left lateral flexion (p = 0.990; repeated measures ANOVA) (Table 4.6) and right lateral flexion (p = 0.384; repeated measures ANOVA) (Table 4.7). There was a statistical difference on the effect of time between the two groups for left lateral flexion (p = 0.022) and right lateral flexion (p = 0.038). This implies that there is no significant difference between dry needling and IAI TP therapy in terms of CROM as both groups would be equally improved if given more time for improvement.

5.4.2 Algometer

The algometer was used to measure the sensitivity of the MFTPs by measuring the pressure threshold over the MFTP. Algometer readings were taken at the initial, second and at the final consultation. This form of measurement has been proven useful for the assessment of treatment results (Fischer, 1986). Fischer (1986) suggested that the normal readings for PPT in healthy participants were 5.4 kg/cm^2 for males and 3.7 kg/cm^2 for females. This does

not correlate with this study as baseline measures showed Group One to have PPT of 5.5 kg/cm^2 and Group Two 5.4 kg/cm^2 in patients with neck pain.

Intra-group analysis for objective one showed no significant statistical change for Group One in algometer readings over time. This indicates no change in objective pain sensitivity (p = 0.348; repeated measures ANOVA); however, some change is suggested by the trend in the graph (Figure 4.4) indicating a slight but non-significant increase. It may be that the effect of treatment may have been masked by post-needling soreness. Studies by Kamanli *et al*. (2005) and Travell and Simons (1999) suggest dry needling should improve PPT. However, similarly to this study, in the clinical trial conducted by Ferreira (2006), dry needling was shown to increase tenderness in the local area around the needle insertion point which could account for the lack of improvement regarding objective algometry measures.

Objective two showed a statistically significant increase for Group Two in algometer readings over the three time points (p = 0.020; repeated measures ANOVA) (Figure 4.8). This result was also found in the study conducted by Gemmell and Allen (2008), where 30% of the AAI group significantly improved in PPT readings after treatment of the upper trapezius MFTP. Of the AAI group, 46.7% improved significantly for PPT in the study conducted by Blikstad and Gemmell (2008) when treating MFTPs in the upper trapezius. Therefore, this confirms that the IAI can be used on MFTPs to improve PPT.

Inter-group analysis for objective three showed no statistically significant difference in time-group interaction (p = 0.780). However, in Figure 4.13 Group Two had a slightly greater increase in algometry readings, implying an insignificant statistical increase in pain pressure threshold. The effect of time was statistically significant (p = 0.020; repeated measures ANOVA). This indicates that both treatment groups increased and improved over time in terms of algometer outcome measures (Table 4.5). Therefore, this study suggests that the IAI is as effective as DN in the treatment of MFTPs regarding PPT and can be used as an alternative treatment for patients who are contra-indicated for DN. The trends of improvement between Group One and Two in this study were similar to those in the study conducted by Gemmell and Allen (2008) which revealed IC to be as effective as AAI treatment of MFTPs with regards to PPT. The AAI treatment was shown to have improved more than the IC group; however, statistically this was not proven. Similarly, the trends in the graph shown in Figure 4.13 imply that a statistical difference would occur and the IAI would show statistically greater improvement than dry needling, if the period of treatment was extended past the two weeks provided for in this study.

From the literature review in Chapter 2, a reason for this improvement may be because of a decrease in fusimotor and gamma motor neuron activity (Johansson et *al*., 1993), resulting in a decrease in alpha motor neuron activity within the muscle spindle as proposed by the muscle spindle theory (Korr 1975). This would explain the decrease in tension, release of cross-bridges and therefore lengthening of sarcomeres (Potter *et al*., 2005). This normalises the metabolic functioning of the sarcomere (Simons and Simons, 2002) which in turn improves blood supply and restores the supply of ATP. The arrival of ATP restores the functioning of the calcium pump, which allows further release of cross-bridges and a decrease in muscular stiffness (Gissel and Clausen, 2001). The increased blood supply also stops the energy deficiency cycle and removes inflammatory substances thereby removing sensitizing substances from nociceptors (Partanen *et al*. 2010; Simons *et al*., 1999). This relieves Type III and IV sensory afferents from sensitisation by chemical substances and would explain a decrease in PPT (Gladden and Matsuzaki, 2002).

CHAPTER 6 : CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

The aim of this study was to determine the effectiveness of the IAI compared to dry needling in the treatment of MFTPs found in the upper trapezius muscle. This aim arose because dry needling, although an established and efficient technique in reducing MFTP pain and MPS, is not suitable for many patients who cannot and some who will not make use of the technique. This is due to the contraindications that exist, the fear of needles and a lack of patient comfort before and after treatment. Therefore, an alternative such as the IAI was sought. The IAI was shown to be effective on spinal fixations; however, a paucity exists in the literature demonstrating its effectiveness on MPS or MFTPs.

The IREC of DUT granted permission to conduct this study. The participants in this study were divided into two groups. Group One received dry needling and Group Two received IAI treatment. Subjective data was collected with the use of the NRS, NDI and PGIC outcome measures. Objective data was collected making use of algometer and CROM goniometer outcome measures. Each participant received three treatments over a two week period in this single blinded, randomized clinical trial. The data obtained was analysed by IBM SPSS version 23 and ANNOVA testing which showed intra- and inter-group analysis.

All subjective outcome measures revealed clinically significant improvements in both Group One and Group Two with no statistically significant difference between the groups.

Objective CROM goniometer readings revealed both groups to have no statistical improvements in left and right lateral flexion which implies that both treatments had no effect on cervical range of motion.

Objective algometer analysis revealed Group One to have no statistically significant changes while Group Two showed an increase in PPT. However, when the two groups were compared there was no statistically significant difference between them.

There is a paucity in the literature regarding the effectiveness of the IAI on MFTPs, this study shows it to be as effective as dry needling. However, literature reveals dry needling to be effective in cervical range of motion which was not so in this study. This may be due to the

smaller sample size used and a short treatment period of two weeks which makes statistical changes difficult to achieve.

Therefore, in conclusion, the trends in each of the outcomes suggest that the IAI is as effective as dry needling for the treatment of MFTPs.

Regarding the hypotheses in Chapter 1:

The null hypothesis which stated there would be no difference between the two independent samples being compared in terms of subjective and objective outcome measures was accepted.

The alternate hypothesis which stated there would be significant difference between the two groups in terms of subjective and objective findings was rejected.

6.2 LIMITATIONS OF THE STUDY

A smaller sample size was used; this may have been a limitation. Subjective scoring depended on participant honesty, this is however a limitation which is difficult to overcome.

6.3 RECOMMENDATIONS

Recommendations for future studies include:

- A better distribution between age, and possibly a focus on one gender to decrease variables between the groups.
- A larger sample size to represent more clinical and statistical evidence as well as represent the population more effectively.
- A way to decrease perpetuating factors outside of the clinical setting, such as a daily home stretching plan or a posture brace.
- Objective readings to be taken by more than one research assistant, or a digital or electric way to measure objective outcome measures. This will be to remove operator dependencies which may alter true results.
- Measuring chemical and neurophysiological changes with the use of electromyogram biofeedback devices
- A study to investigate range of motion improvements with the IAI.

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APPENDIXES

Appendix A: Permission to use the Chiropractic Day Clinic

MEMORANDUM

To	Prof Puckree Chair : RHDC Prof Adam Chair : IREC
From	Dr Charmaine Korporaal Clinic Director : Chiropractic Day Clinic : Chiropractic and Somatology
Date	25.06.2014
Re	Request for permission to use the Chiropractic Day Clinic for research purposes

Permission is hereby granted to :

Ms Mandy Laing (Student Number: 20902178)

Research title: "**The effectiveness of the Impulse Adjusting Instrument® compared to Dry Needling in the treatment of upper trapezius myofascial trigger points in participants with non-specific neck pain** ".

It is requested that Ms Laing submit a copy of her RHDC / IREC approved proposal to the Clinic Administrators before she starts with her research in order that any special procedures with regards to her research can be implemented prior to the commencement of her seeing patients.

Thank you for your time.

Kind regards

[redacted]

Dr Charmaine Korporaal

Clinic Director : Chiropractic Day Clinic : Chiropractic and Somatology

Cc: Mrs Pat van den Berg : Chiropractic Day Clinic
Dr L O'Connor : Research co-ordinator
Dr D Varatharajullu

Appendix B: Ethical Clearance

DUT DURBAN UNIVERSITY OF TECHNOLOGY

Institutional Research Ethics Committee Faculty of Health Sciences

Rc›om MS 49, Mansfield School Site

Gate 8, Ritson Campus

Durban University of Technology

P O Box 1334, Durban, South Africa, 400 I Tel: 03 1373 2900

Fax: 03 1 373 2407

Email: lavishad@dut.ac.za

http://www.dut.ac.za/research/institutional_research_ethiCs

www.dut.ac.za

28]uly 20 1 5

IREC Reference Number: REC 45/1 5
Ms M Laing
34 Keal Road
Sydenham
Durban
4091
Dear Ms Laing

The effectiveness of the Impulse Adjusting Instrument compared to Dry Needling in the treatment of upper trapezius myofascial trigger points in participants with non- specific neck pain

I am pleased to inform you that Full Approval has been granted to your proposal REC 45/ 1 5.

The Proposal has been allocated the following Ethical Clearance number IREC 070/ 1 5. Please use this number in all communication with this office.

Approval has been granted for a period of two years, 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.

Please note that any deviations from the approved proposal require the approval of the I&EC as outlined in the ITEC SOP's.
Yours Sincerely

[redacted]

DUT DURBAN UNIVERSITY OF TECHNOLOGY

Professor] K Adam, Chairperson: IREC

Appendix C: Permission to advertise

To Whom It May Concern:

My name is Mandy Laing and I am currently doing my Master's Degree in Chiropractic at the Durban University of Technology, South Africa.

The title of my research project is:
The effectiveness of the Impulse Adjusting Instrument® compared to Dry Needling in the treatment of upper trapezius myofascial trigger points in participants with non-specific neck pain

Name of supervisor:	Dr. D. Varatharajullu +27 (31) 204 2533 M.Tech: Chiropractic
Name of Research Student:	Mandy Laing +2772 268 0365 B.Tech: Chiropractic
Name of Institution:	Durban University of Technology, South Africa

The purpose of the study:
This study aims to determine the relative effectiveness of dry needling and the Impulse Adjusting Instrument in patients with myofascial pain syndrome of the trapezius muscle.

Procedures:
The participants will be required to undergo treatment either dry needling or Impulse Adjusting Instrument therapy of the trapezius muscle myofascial trigger points); which will have no adverse side effects.

Benefits:
This study will help to determine if the Impulse Adjusting Instrument is effective in treating myofascial trigger points.

Due to the nature of this study, I am required to seek your permission to utilize these premises to advertise my study in order to obtain research participants

Yours sincerely,

Mandy Laing
(Chiropractic Intern)

Dr D. Varatharajullu
(Supervisor)

I _____ (name) hereby give Mandy Laing consent to conduct the above-mentioned research using these premises for advertising purposes.

Signature: _____Date: _____

Appendix D: Advertisement

Are you between the ages of **18** and **45** and suffer from:

NECK PAIN

Research is currently being carried out at the Durban University of Technology Chiropractic Day Clinic

Free Treatment

is available to those who qualify to take part in this study.

Contact **Mandy Laing** on 072 268 0365 or (031) 373 2205 for more information.

Appendix E: Informed Consent Form

LETTER OF INFORMATION

Welcome to my study, thank you for agreeing to participate

Title of the Research Study: The effectiveness of the Impulse Adjusting Instrument® compared to Dry Needling in the treatment of upper trapezius myofascial trigger points in participants with non-specific neck pain

Researcher: Mandy Laing [B.Tech: Chiropractic]

Supervisor: Dr. D. Varatharajullu [M.Tech: Chiropractic]

Brief Introduction and Purpose of the Study: This research study aims to investigate the relative effectiveness of an adjusting instrument and dry needling in the treatment of myofascial trigger points found in the upper trapezius muscle in patients with neck pain. 40 people will be required to complete this study.

Outline of the Procedures: All your appointments will be made at the Chiropractic Day Clinic (CDC). The first appointment will be a two hour long appointment. On arriving at the appointment you will be given a verbal explanation of the research procedure and will be given a letter of information and informed consent to read and sign. You will be given an opportunity to ask any questions. Each participant will then undergo a full case history, physical examination, cervical examination, pain questionnaires, cervical range of motion test and Algometer testing.

A diagnosis of a myofascial trigger points will be confirmed after manual palpation of the Trapezius muscle and patient feedback. The next appointment will be made within 5 working days. Please do not take any muscle relaxants, NSAIDs, pain medication or steroids for the duration of this study. Please arrive at least 10 minutes before your second appointment. The participants name will then be allocated to their group. The patients are informed that the second and third appointments will be 45minutes long. The first treatment will then commence.

You will then be asked to remove any clothing covering the neck to shoulder area (should you require a clinic gown one will be provided) and will then be asked to lie side lying with the affected side up. Your name will then be checked on the list to see which group you were allocated to. The relevant treatment will then be performed.

In the dry needling group the area to be treated will be sterilized with alcohol prior to treatment. The area to be treated will be marked with a spot of henna to ensure the same spot is treated at each visit. The dry needing will be done with a 25 mm, 0.25g acupuncture needle. The myofascial trigger point is located by palpation and finding a taut muscle band. The needle is inserted between the fingers that locate the myofascial trigger point. The needle is then inserted 1 to 2cm away from the myofascial trigger point so that the needle enters the myofascial trigger point at an angle of about 30º to the surface of the skin. Fanning technique will be used, by reinserting the needle in and out of the myofascial trigger point to penetrate a new part of the trigger point. The area is then palpated again for any tender spots that have remained. If one is found, this process is repeated

The adjusting instrument group will have the same frequency and duration of treatment. The impulse adjuster is placed directly over the trigger point and applied until the instrument reads that the trigger point has been treated by reading the change in frequency in the muscle

You will be thanked for your time and will be allowed to leave.

Risks or Discomforts to the Participant: There are no risks. If you are in the dry needling group there will be slight discomfort in the initial insertion of the needles and during the fanning period if the sensation becomes intolerable, the participant may request to have the needle to be removed and withdrawal from the study. The discomfort of post-needling soreness will not be minimized by the use of cryotherapy (ice applied to the area after dry needling).

Benefits: This study will help to determine if the adjusting instrument is more or less effective than dry needling in the treatment of MFTPs.

Reason/s why the Participant May Be Withdrawn from the Study: You are free to withdraw from this study at any stage without any negative repercussions.

Remuneration: You will not be offered any form of remuneration for taking part in the study.
Costs of the Study: Free of charge for the patient.

Confidentiality: All your medical records will be kept confidential and will be stored in the Chiropractic Day Clinic for 5 years, after which it will be shredded. Your name will not appear on any of the data sheets or thesis.

Research-related Injury: There will be no compensation in the event of an injury.

Please don't hesitate to ask questions on any aspect of this study. Should you have any complaints or queries, please do not hesitate to contact my research supervisor at the above details or the Constitutional Research Ethics Committee Administration: 031 373 2900
Yours sincerely,

Persons to Contact in the Event of Any Problems or Queries:
Head of Department: Dr. A. Docrat, Contact number: 031 373 2589

Supervisor: Dr. D. Varatharajullu, Contact number: 031 373 2923

Institutional Research Ethics administrator, Contact number: 031 373 2900.
Complaints can be reported to the DVC: TIP, Prof F. Otieno on 031 373 2382 or dvctip@dut.ac.za.

CONSENT

Statement of Agreement to Participate in the Research Study:

I hereby confirm that I have been informed by the researcher, _____ (name of researcher), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: _____,
I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.
I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.
I may, at any stage, without prejudice, withdraw my consent and participation in the study.
I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

_____	_____	_____	_____
Full Name of Participant	**Date**	**Time**	**Signature / Right Thumbprint**

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

_____	_____	_____
Full Name of Researcher	**Date**	**Signature**

_____	_____	_____
Full Name of Witness (If applicable)	**Date**	**Signature**

Appendix F: Permission for the use of the Neck Disability Index questionnaire

LETTER OF PERMISSION

To Whom It May Concern:

My name is Mandy Laing and I am currently doing my Master's Degree in Chiropractic at the Durban University of Technology, South Africa.

The title of my research project is:
The effectiveness of the Impulse Adjusting Instrument® compared to Dry Needling in the treatment of upper trapezius myofascial trigger points in participants with non-specific neck pain

Name of supervisor:	Dr. D. Varatharajullu +27 (31) 204 253 M.Tech: Chiropractic
Name of Research Student:	Mandy Laing +72 268 0365 B.Tech: Chiropractic
Name of Institution:	Durban University of Technology, South Africa

The purpose of the study:
This study aims to determine the relative effectiveness of dry needling and the Impulse Adjusting Instrument in patients with myofascial pain syndrome of the trapezius muscle.

Procedures:
The participants will be required to undergo treatment either dry needling or Impulse Adjusting Instrument therapy of the trapezius muscle myofascial trigger points); which will have no adverse side effects.

Benefits:
This study will help to determine if the Impulse Adjusting Instrument is effective in treating myofascial trigger points.

Due to the nature of this study, I am required to seek your permission to utilize the CMCC Neck Disability Index as a means of obtaining data from a participant in terms of neck pain improvement following the treatment intervention.

Yours sincerely,

Mandy Laing (Chiropractic Intern)

Dr D. Varatharajullu (Supervisor)

I _Dr. Howard Vernon_____ (name) hereby give Mandy Laing consent to conduct the above-mentioned research using the CMCC Neck Disability Index.

Signature: _ [redacted] ____ Date: June 25, 2014_____

Appendix G: Case history

CHIROPRACTIC PROGRAMME

CHIROPRACTIC DAY CLINIC

CASE HISTORY

Patient:_____ Date:_____ _____

File# _____ Age: _____

Sex: _____ Occupation: _____

Student:_____ Signature:_____ _____

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: Signature:

Case History:

Examination:

Previous: Current:

X-Ray Studies:

Previous: Current:

Clinical Path. lab:

Previous: Current:

CASE **STATUS:**

PTT:	Signature:	Date:

CONDITIONAL: Reason for Conditional:
Signature: Date:

Conditions met in Visit No:	Signed into PTT:	Date:

Case Summary signed off:	Date:

Student's Case History:

1. **Source of History:**
2. **Chief Complaint: (patient's own words):**

3. Present Illness:

	Complaint 1(principle complaint)	**Complaint 2 (additional or secondary complaint)**
Location Onset : Initial: Recent: Cause: Duration Frequency Pain (Character) Progression Aggravating Factors Relieving Factors Associated S & S Previous Occurrences Past Treatment Outcome:		

4. Other Complaints:

5. Past Medical History:

General Health Status

Childhood Illnesses

Adult Illnesses

Psychiatric Illnesses

Accidents/Injuries

Surgery

Hospitalizations

6. Current health status and life-style:

Allergies

Immunizations

Screening Tests incl. x-rays

Environmental Hazards (Home, School, Work)

Exercise and Leisure

Sleep Patterns

Diet

Current Medication

Analgesics/week:

Other (please list):

Tobacco

Alcohol

Social Drugs

7. Immediate Family Medical History:

Age of all family members

Health of all family members

Cause of Death of any family members

	Noted	Family member		Noted	Family member
Alcoholism			Headaches		
Anaemia			Heart Disease		
Arthritis			Kidney Disease		
CA			Mental Illness		
DM			Stroke		
Drug Addiction			Thyroid Disease		
Epilepsy			TB		
Other (list)					

8. Psychosocial history:

Home Situation and daily life

Important experiences

Religious Beliefs

9. Review of Systems (please highlight with an asterisk those areas that are a problem for the patient and require further investigation)

General

Skin

Head

Eyes

Ears

Nose/Sinuses

Mouth/Throat

Neck

Breasts

Respiratory

Cardiac

Gastro-intestinal

Urinary

Genital

Vascular

Musculoskeletal

Neurologic

Haematological

Endocrine

Psychiatric

Appendix H: Physical examination

CHIROPRACTIC PROGRAMME

PHYSICAL EXAMINATION: SENIOR

Patient Name: _____ **File no:** _____ **Date:** _____ _____				
Student: **Signature:**				
VITALS:				
Pulse rate:			Respiratory rate:	
Blood pressure:	R	L	Medication if hypertensive:	
Temperature:			Height:	
Weight:	Any recent change?	Y / N	If Yes: How much gain/loss	Over what period
GENERAL EXAMINATION:				
General Impression				
Skin				
Jaundice				
Pallor				
Clubbing				
Cyanosis (Central/Peripheral)				
Oedema				

Lymph nodes	Head and neck	
	Axillary	
	Epitrochlear	
	Inguinal	
Pulses		
Urinalysis		
SYSTEM SPECIFIC EXAMINATION:		
CARDIOVASCULAR EXAMINATION		
RESPIRATORY EXAMINATION		
6.4 ABDOMINAL EXAMINATION		
6.5 NEUROLOGICAL EXAMINATION		
6.5.1 COMMENTS		
Clinician: **Signature:**		

Appendix I: Cervical spine orthopedic examination

DURBAN UNIVI
REGIONAL EXAMIN

Patient: _____ File No: _____

Date: _____ Student: _____

Clinician: _____ Sign: _____

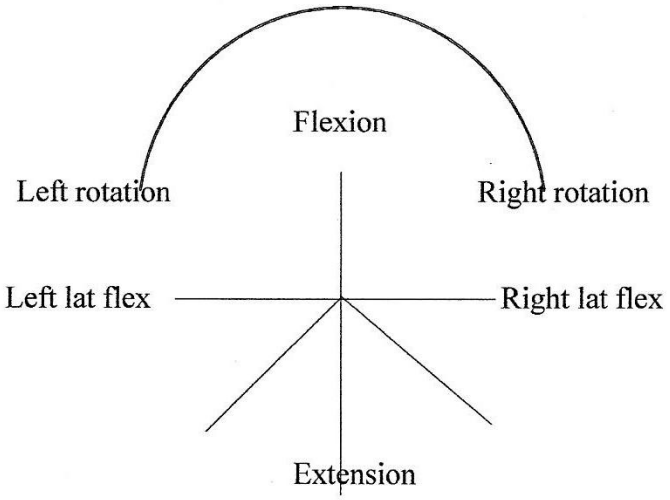
OBSERVATION:

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

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

RANGE OF MOTION:

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



PALPATION:

Lymph nodes
Thyroid Gland
Trachea

ORTHOPAEDIC EXAMINATION:

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

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

NEUROLOGICAL EXAMINATION:

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

Cerebellar tests:	Left	Right
Disdiadochokinesis		

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

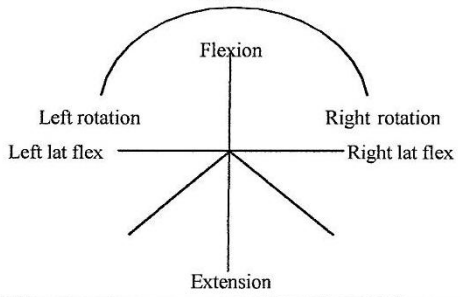
MOTION PALPATION & JOINT PLAY:
Left: Motion Palpation:
Joint Play:
Right: Motion Palpation:
Joint Play:

BASIC EXAM: SHOULDER:
Case History:

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

BASIC EXAM: THORACIC SPINE:
Case History:

ROM:



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

Appendix J: Numerical Pain Rating Scale

Numerical Rating Scale- 101 Questionnaire

Please indicate on the line below, the number between 0 and 10 that best describes the pain you experience **when it is at its least**. A zero (0) would mean “no pain at all” and ten (10) would mean “pain as bad as it could be”. Please write only one number.

……..

Appendix K: Neck Disability Index Questionnaire

DUT DURBAN UNIVERSITY OF TECHNOLOGY

Visit no.____

Neck Disability Index

THIS QUESTIONNAIRE IS DESIGNED TO HELP US BETTER UNDERSTAND HOW YOUR **NECK PAIN** AFFECTS YOUR ABILITY TO MANAGE EVERYDAY -LIFE ACTIVITIES. PLEASE MARK IN EACH SECTION THE **ONE BOX** THAT APPLIES TO YOU.
ALTHOUGH YOU MAY CONSIDER THAT TWO OF THE STATEMENTS IN ANY ONE SECTION RELATE TO YOU, PLEASE MARK THE BOX THAT **MOST CLOSELY** DESCRIBES YOUR PRESENT -DAY SITUATION.

SECTION 1 - PAIN INTENSITY

- ☐ I have no neck pain at the moment.
- ☐ The pain is very mild at the moment.
- ☐ The pain is moderate at the moment.
- ☐ The pain is fairly severe at the moment.
- ☐ The pain is very severe at the moment.
- ☐ The pain is the worst imaginable at the moment.

SECTION 2 - PERSONAL CARE

- ☐ I can look after myself normally without causing extra neck pain.
- ☐ I can look after myself normally, but it causes extra neck pain.
- ☐ It is painful to look after myself, and I am slow and careful
- ☐ I need some help but manage most of my personal care.
- ☐ I need help every day in most aspects of self -care.
- ☐ I do not get dressed. I wash with difficulty and stay in bed.

SECTION 3 – LIFTING

- ☐ I can lift heavy weights without causing extra neck pain.
- ☐ I can lift heavy weights, but it gives me extra neck pain.
- ☐ Neck pain prevents me from lifting heavy weights off the floor but I can manage if items are conveniently positioned, ie. on a table.
- ☐ Neck pain prevents me from lifting heavy weights, but I can manage light weights if they are conveniently positioned
- ☐ I can lift only very light weights.
- ☐ I cannot lift or carry anything at all.

SECTION 4 – READING

- ☐ I can read as much as I want with no neck pain.
- ☐ I can read as much as I want with slight neck pain.
- ☐ I can read as much as I want with moderate neck pain.
- ☐ I can't read as much as I want because of moderate neck pain.
- ☐ I can't read as much as I want because of severe neck pain.
- ☐ I can't read at all.

SECTION 5 – HEADACHES

- ☐ I have no headaches at all.
- ☐ I have slight headaches that come infrequently.
- ☐ I have moderate headaches that come infrequently.
- ☐ I have moderate headaches that come frequently.
- ☐ I have severe headaches that come frequently.
- ☐ I have headaches almost all the time.

SECTION 6 – CONCENTRATION

- ☐ I can concentrate fully without difficulty.
- ☐ I can concentrate fully with slight difficulty.
- ☐ I have a fair degree of difficulty concentrating.
- ☐ I have a lot of difficulty concentrating.
- ☐ I have a great deal of difficulty concentrating.
- ☐ I can't concentrate at all.

SECTION 7 – WORK

- ☐ I can do as much work as I want.
- ☐ I can only do my usual work, but no more.
- ☐ I can do most of my usual work, but no more.
- ☐ I can't do my usual work.
- ☐ I can hardly do any work at all.
- ☐ I can't do any work at all.

SECTION 8 – DRIVING

- ☐ I can drive my car without neck pain.
- ☐ I can drive my car with only slight neck pain.
- ☐ I can drive as long as I want with moderate neck pain.
- ☐ I can't drive as long as I want because of moderate neck pain.
- ☐ I can hardly drive at all because of severe neck pain.
- ☐ I can't drive my care at all because of neck pain.

SECTION 9 – SLEEPING

- ☐ I have no trouble sleeping.
- ☐ My sleep is slightly disturbed for less than 1 hour.
- ☐ My sleep is mildly disturbed for up to 1-2 hours.
- ☐ My sleep is moderately disturbed for up to 2-3 hours.
- ☐ My sleep is greatly disturbed for up to 3-5 hours.
- ☐ My sleep is completely disturbed for up to 5-7 hours.

SECTION 10 – RECREATION

- ☐ I am able to engage in all my recreational activities with no neck pain at all.
- ☐ I am able to engage in all my recreational activities with some neck pain.
- ☐ I am able to engage in most, but not all of my recreational activities because of pain in my neck.
- ☐ I am able to engage in a few of my recreational activities because of neck pain.
- ☐ I can hardly do recreational activities due to neck pain.
- ☐ I can't do any recreational activities due to neck pain.

PATIENT NAME _____ **DATE** _____

SCORE _____ [50]

Appendix L: Patient's Global Impression of Change

Patients' Global Impression of Change (PGIC) Scale

Date: _____

Name: _____ DOB: _____.

Chief Complaint (Presenting Problem): _____.

Since beginning treatment at this clinic how would you describe the change (if any) in ACTIVITY LIMITATIONS, SYMPTOMS, EMOTIONS, and OVERALL QUALITY OF LIFE, related to your painful condition? Please circle the number below that matches your degree of change since beginning care at this clinic for the above stated chief complaint.

No change	Almost the same	A little better	Somewhat better	Moderately better	Better	A great deal better
1	2	3	4	5	6	7

Explanation:

1= No change (or condition has got worse)

2= Almost the same, hardly any change at all

3= A little better, but no noticeable change

4= somewhat better, but the change has not made any real difference

5 = moderately better, and a slight but noticeable change

6 =Better, and a definite improvement that has made a real and worthwhile difference

7 = A great deal better, and a considerable improvement that has made all the difference

Appendix M: Research Assistant Agreement

Statement of Agreement to Participate in the Research Study as a Research Assistant:

I ……....., ID number…… voluntarily agree to participate in this study: **"The effectiveness of the Impulse Adjusting Instrument® compared to Dry Needling in the treatment of upper trapezius myofascial trigger points in participants with non-specific neck pain"** as a research assistant**.**

I will ensure that I maintain a level of confidentiality with regards to the research data that is collected.

Research assistant's name (print) …….

Research assistant's signature: …… Date: ……

Researcher's name (print)…….. Signature: …….

Date: ……

Witness name (print)…….. Signature……

Date: …….

Appendix N: Data collection sheets

ALGOMETER and CROM DEVICE READINGS

Patient Name:

Patient Gender:

Patient code:

File number:

Visit	Date	Trigger point(s) affected	Algometer Reading	CROM Device Reading Left Lateral Flexion (®)	CROM Device Reading Right lateral flexion (®)
1st					
1st					
2nd					
2nd					
4th					
4th					

Appendix O: Memorandum of Understanding

Durban University of Technology

Memorandum of understanding between:

The RESEARCH INSTITUTION'-Durban University of Technology (this includes the respective research student and research supervisor, Department of Chiropractic. The Faculty of Health Sciences Research Committee, The Institutional Research Committee and any other related DUT employees.

AND

The 'MANUFACTURER'- Neuromechanical Innovations (including all members, employees, associates)

This Memorandum of Understanding pertains to the following research project and must be read in conjunction with:

APPENDIX A-Detailed Research Proposal (PG4a)

APPENDIX B-Durban University of Technology Research Committee Research Ethics Policy and Guidelines

Title of the study:

The effectiveness of the Impulse Adjusting Instrument compared to Dry Needling in the treatment of upper trapezius myofascial trigger points

Research Supervisor: Dr D. Varatharajullu (Dept. Chiropractic and Somatology-Durban University of Technology)

This study is a Master's Mini Dissertation conducted in partial compliance with the Master's Degree in Technology in the Department of Chiropractic-Faculty of Health Sciences-Durban University of Technology. This study will obtain ethical approval from the Faculty of Health Sciences Research & Ethics Committee (FRC) of Durban University of Technology.

Please be aware the brand name will not be divulged to the participants and not included in any of the letters of information as well as the dissertation.

Section 1-Funding of the study and financial commitment

1.1 A research allowance of R5000.00 has been awarded by the Dept. Post-graduate Development & Support –The details of the funds approved are described in Section A of the Research Proposal (PG4a) attached.

1.2 The 'MANUFACTURER'- acknowledges that THE RESEARCH INSTITUTION' will have no financial obligations or commitments to the 'MANUFACTURER' what so ever as a result of conducting this study.

1.3 The 'MANUFACTURER'- may not award or incentivize the study or its related parties in any manner what so ever, nor remunerate, award or offer any financial or other donation or gift to any of those involved with the study.

Section 2-Academic processes and outcome

2.1 The FRC has approved the above mentioned Research Supervisor who in conjunction with the Research Student are the sole contributors to the academic content, procedures, results and findings of the study based on the prescribed data analysis in the research proposal, barring amendments required by the approved research examiners appointed by the RESEARCH INSTITUTION.

2.2 The 'MANUFACTURER' acknowledges that the findings upon completion of the study (as determined by the Research Student and Research Supervisors and according to the protocol stated in the attached research proposal) will be final and non-negotiable.

The 'MANUFACTURER'-acknowledges further that it has no authority over the outcome of this study and may not influence the findings or the reporting thereof in any matter.

2.3 Any modification or deviation from the approved research proposal, must be applied for in writing, endorsed by both the Research Student & Supervisors and Head of Department before serving before the FRC/IREC, the final say therein will be determined by the FRC/IREC.

2.4 The 'MANUFACTURER'-acknowledges that it may not influence or make any change to the approved research protocol/proposal.

Section 3-Publication of findings

3.1 The findings and outcome of the above mentioned study remain the intellectual property of the 'RESEARCH INSTITITION' indefinitely. The study will be published in the format of a hard bound dissertation which will be placed in the DUT library.

3.2 Publication of the findings of this study in a journal or other scholarly medium will be at the discretion of the Research student and /or Research Supervisors who will determine the appropriate medium and place of publication as well as content of the publication. Authorship of any scholarly output originating from this study of the Research Student and Research Supervisors and other collaborators appointed by the Research Student and/or the Research Supervisors. Such scholarly publication must include the names of the Researcher and the Research Supervisor as well as the 'RESEARCH INSTITUTION'.

3.3 Any reference what so ever to the findings of this study if quoted or mentioned in any format must make formal reference to the respective dissertation its official title and its author(s) and the owners of the intellectual property thereof i.e. the 'RESEARCH INSTITITION'.

3.4 Any reference what so ever to any secondary publication arising from this original study must make formal reference to the respective dissertation its official title and its author(s) and the owners of the intellectual property thereof i.e. the 'RESEARCH INSTITUTION'

3.5 The 'MANUFACTURER'-may make reference to the outcome of this study in the prescribed manner mentioned in section 3.3 and 3.4 undertaking 3.1 and 3.2.

Section 4-Indemnity

4.1 The Research Student, the Research Supervisor and the research facilities and its staff are duly covered by the 'RESEARCH INSTITUTION' insurance policy pertaining to public liability, injury or harm which may occur as a result of conducting this study.

4.2 The ’MANUFACTURER’-undertakes to indemnify the ‘RESEARCH INSTITUTION’ with regard to any outcome, incidents, injury or harm which occurs as a result of the conduction of this study including the results of the study and publication thereof.

Section 5- Ethical considerations

5.1 Ethical clearance of the proposed study will be granted by the DUT IREC (such ethical clearance become invalid should there be any deviation from the approved research methodology described in the research proposal attached).

5.2 The ‘MANUFACTURER’ undertakes to abide by the DUT Research Committee Research Ethics Policy and Guidelines (APPENDIX B).

5.3 In addition to 5.2 the ‘MANUFACTURER should note and refer to **Section 1.4,2 & 3** of this document.

I __Christopher J Colloca, DC, PhD (Cand)_____ (**name of representative of the ‘MANUFACTURER’)** hereby in my official capacity as representative of the commercial cooling wrap hereby agree to abide by the regulations stated in this memorandum of understanding between the ‘MANUFACTURER’ and the ‘RESEARCH INSTITUTION’

_____ ___March 19 2015___

Signature of official representative of the ‘MANUFACTURER’ Date

I **Ms. Mandy Laing** hereby in my capacity as **the research student** hereby agree to abide by the regulations in this memorandum of understanding between the 'MANUFACTURER' and the 'RESEARCH INSTITUTION'

_____ _____

Signature of research Student Date