DEDICATIONS

I would like to dedicate this work to my parents, for their emotional and financial support throughout the duration of the course. Thanks Mom for teaching me to always look for the light! and providing me with the opportunities to become who I am today.

I love you both...

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ABSTRACT

The purpose of this clinical trial was to evaluate the efficacy of *Magnesium phosphate*, as an adjunct to dry needling, in the treatment of Myofascial Pain Syndrome (MPS), in terms of objective and subjective clinical findings.

MPS is a frequently encountered condition. If not treated adequately, this condition can lead to long term, recurrent pain, as well as patient and physician frustration. Many treatment protocols have been examined with contradictory results and research into epidemiological studies and combinations of various treatment protocols are lacking.

This randomised, clinical trial consisted of a sample size of 60 patients, all suffering from MPS with active trapezius trigger points as the primary symptom. On an initial consultation patients were thoroughly assessed and only patients that conformed to the inclusion criteria were accepted into the study. Patients were divided by random sampling into two groups, group 1 and group 2. Group 1 received treatment of dry needling and a placebo sugar tablet while group 2 received dry needling and *Magnesium phosphate* tissue salts. The allocation of the supplements given to each treatment group was double blinded and neither the researcher nor the patients were aware of what supplement they were receiving: sugar placebo or *Magnesium phosphate*, until after the active part of the research was completed.

Each patient received 4 treatments over a two-week period, with a follow up consultation within five days of the last treatment to avoid data capturing after the fourth consultation from being adversely affected by post needling tenderness. Both groups were assessed for active trigger points on the initial treatment and received dry needling of the original trigger points noted with each consultation. If a trigger point was inactivated during the course of the two-week period, it was no longer needled but pressure algometer readings were still taken with each visit. A patient was considered finished with treatment once all consultations were completed or until the patient was asymptomatic. If a patient was asymptomatic, readings were still taken and the patient was instructed to continue with the supplement unless all the original active trigger points were inactive. If this occurred, a final consultation was then scheduled for data capturing.

Data collection occurred on the initial, second, fourth and follow up visit. Objective data was collected using the algometer and a Myofascial Diagnostic Scale, while subjective data was collected using the Numerical Rating Scale 101 and the McGill Short-form Pain Questionnaire. Subjective data was captured under the supervision of the researcher.

Statistical analysis and data capturing was conducted using the SPSS statistical package. Parametric and non-parametric tests were used for inter and intra-group analysis. The Mann Whitney U-Test was used for inter-group comparison of each ordinal variable and the Two Sample unpaired t-test was used for comparison of continuous variable. Friedmann's test was used for intra-group analysis and if the null hypothesis was rejected for this test, the Dunn's Post test was performed to determine any significant differences.

Results exhibited a substantial improvement in both groups throughout the study, with regards to subjective and objective data. A more consistent, overall improvement was seen in group 2 on inter-group objective examination with regards to the algometer readings on the second and fourth consultations. Group 2 also revealed a statistically significant improvement with regards to objective intra-group comparison between the first and second consultation. Group 2 therefore showed less trigger point tenderness with regards to objective measures on the second and fourth consultation. It can be concluded that patients receiving *Magnesium phosphate* tissue salt supplement responded better to treatment in regards to these measures on the mentioned consultations when compared with the group who received placebo tablets.

This study recommends the use of dry needing in the treatment of MPS. The study suggests that both treatments are effective and that the use of a *Magnesium phosphate* supplement is advocated to reduce trigger point tenderness and post needling tenderness usually experienced after consultations. It is in the opinion of the author that further comparative clinical research needs to be conducted with regards to the long-term effect of the use of *Magnesium phosphate* in the treatment of MPS and a similar study be conducted comparing the effect of a *Calcium phosphate* as a adjunct to dry needling in the treatment of MPS.

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- MPS = Myofascial Pain Syndrome.
- TrP = Trigger point.
- S.D.= Standard Deviation.
- S.E.= Standard Error.
- C.V.= Coefficient of variation, expressed as a percentage.
- P-value = Observed level of significance for the test.
- H_o = Null Hypothesis.
- H_1 = Alternative Hypothesis.
- ∞ = The level of Significance.
- NRS 101 = Numerical Rating Scale.
- MDS = Myofascial Diagnostic Scale.
- SFMPQ = Short Form McGill Pain Questionnaire.
- Group 1 = Dry needling and a placebo supplementation.
- Group 2 = Dry needling and a *Magnesium phosphate* supplementation.

DEFINITIONS

MYOFASCIAL PAIN SYNDROME

A pain syndrome characterized by pain in the regional muscle and it's fascia, accompanied by trigger points that give rise to pain and/or autonomic phenomena in a pattern specific for each muscle. "Pain, tenderness, referred phenomena and dysfunction attributed to myofascial trigger points" (Travell <u>et al</u>.1999:3).

TRIGGER POINTS.

"A hyperirritable spot, usually within a taut band of skeletal muscle, or in its fascia that is painful on compression and that can give rise to characteristic referred pain, tenderness and autonomic phenomena" (Travell <u>et al</u>.1999:3).

ACTIVE TRIGGER POINT

Trigger points that referred a pattern of pain at rest, and or on motion, that is specific for that muscle. An active trigger point is always tender and may prevent full lengthening of the muscle and weakening of the muscle. Pain is referred on direct compression and a twitch response may be mediated when the muscle fibers are adequately stimulated (Travell <u>et al.</u> 1999:1).

LATENT TRIGGER POINTS.

A trigger point that does not produce spontaneous pain, and is only painful when palpated. "Latent trigger points may have all the other clinical characteristics of an active trigger point, from which it is to be distinguished" (Travell <u>et al.</u>1999: 2).

REFERRED PAIN

Pain that arises in a trigger point but is felt at a distance often entirely remote from its source. The pattern of pain is related to its site of origin (Travell <u>et al.</u>1999: 3).

DRY NEEDLING

An invasive needling technique that involves specific insertion of a needle into an active trigger point in the attempt to deactivate it. Different angles of penetration is used but the original point of entry into the skin is maintained. No substances are

injected into the trigger points (Travell et al. 1999: 3).

BIOCHEMISTRY

Derived from the Greek word 'bios', meaning life, and 'chemistry', which is defined as the science of composition, structure, properties and reaction of matter, especially of atomic and molecular systems (Goodwin 1980). "They are vital cell foods and, therefore, are in complete harmony with the human system" (Goodwin 1980 :14).

BIOCHEMICAL TISSUE SALTS

Twelve mineral salts, developed by Dr Schuesslers Biochemical System of Medicine (Goodwin 1980):

- 1) Calcium Fluoride (calc. fluor). 2) Calcium Phosphate (calc.phos.).
- 3) Calcium Sulphate (calc.sulph). 4) Phosphate of Iron (ferr.phos).
- 5) Potassium of chloride (kali. mur.). 6) Potassium Phosphate (kali phos.).
- 7) Potassium sulphate (kali sulph.). 8) Magnesium phosphate (mag. phos.)
- 9) Sodium Chloride (nat.mur.). 10) Sodium Phosphate (nat.phos.).
- 11) Sodium Sulphate (nat.sulph.). 12) Silicic Oxide (silica).

MAGNESIUM PHOSPHATE

Tissue salt no.8. is recognized as an anti-spasmodic tissue salt. "This tissue salt is of importance to muscular tissue ensuring rhythmic and coherent movements" (Goodwin 1980).

NOCICEPTIVE STIMULATION

Stimulation of the nervous system via pain receptors. Nociceptors are one of the 5 types of sensory receptors, and are responsible for detecting physical or chemical damages in the tissue (Guyton 1992).

CHAPTER ONE

1.0 INTRODUCTION

1.1 THE PROBLEM AND IT'S SETTING

Musculoskeletal disorders are recognized as the key occupational injury/illness challenge of the 1990's (Bruce 1995) and are seen as a major cause of activity limitation and long-term disability in the American and Canadian population (Lee 1994). Despite advances in the modern health care, a void still exists in the understanding, evaluating, and managing of common musculoskeletal aches and pains (Bruce 1995). Myofascial pain syndrome (MPS) is a muscular pain disorder involving regional pain referred by trigger points (Fricton 1994, Auleciems 1995). Myofascial trigger points (TrP's) are extremely common and become a painful part of nearly everyone's life at one time or another with MPS a commonly encountered problem in an outpatient setting, and seen as one of the most common pain problems faced by physicians (Auleciems 1995, Travell <u>et al</u>.1999). MPS is however still one of the least understood conditions, often being unrecognised, misdiagnosed, or mistreated, leading to unnecessary pain, suffering and disability (Auleciems 1995).

88.5% of American Pain Society members recognised MPS as a legitimate diagnosis in a standardized survey conducted by the Centre of Pain Studies (Harden <u>et al.</u> 2000). Gerwin (1995), Han and Harrison (1997) and Chaiamnuay <u>et al</u>. (1998) found that the incidence of TrP's ranged between 30-80% of patients presenting with pain.

When treating MPS, the major goal is to relieve pain and tightness of the involved muscles. Treatment protocols vary and include; spray and stretch, transcutaneous electrical nerve stimulation, ultrasound therapy, massage therapy, TrP injection therapy, dry needling and elimination of causative and perpetuating factors (Esenyel <u>et al</u>. 2000). A multidisciplinary approach to treatment has appeared to be more beneficial (Han and Harrison 1997).

Dry needling techniques are well documented as effective forms of therapy (Lewit

1979, Jones 1994, Hong 1994 and Travell <u>et al.</u> 1999) and have shown to decrease or even abolish TrP's (Han and Harrison 1997).

Inorganic mineral therapy is available in the health care field through means of Biochemical tissue salts (Carey 1995:1-33). A range of medicines consisting of twelve common salts found in the body, has been developed (Boericke and Dewey 1992: 34). These salts are viewed by many as critical for health maintenance, and users find them extremely helpful in alleviating a wide range of conditions (Goodwin 1980).

Magnesium phosphate is used as a remedy in the treatment of "nerves and muscle symptoms" (Carey 1995:85). It is prescribed as an antidotal treatment for muscular pains in the neck and shoulder region and associated headaches (Boericke and Dewey 1992:243). These symptoms, used in the prescription of *Magnesium phosphate*, are shared by patients who are suffering from MPS, especially with TrP's in the trapezius muscle, which is the most commonly affected muscle in this condition (Travel <u>et al</u>. 1999).

According to the researcher's knowledge, no study existed combining the treatment of MPS and the use of biochemical tissue salts, namely *Magnesium phosphate*, even though a link between symptoms has been recognized. Research in this field has proven to be lacking.

1.2 STATEMENT OF THE PROBLEMS.

The purpose of this study was to determine the efficacy of a *Magnesium phosphate* tissue salt supplement, as an adjunct to dry needling, in the treatment of MPS, in terms of subjective and objective clinical findings.

1.2.1 First sub-problem

To evaluate the efficacy of a Magnesium phosphate tissue salt supplement, as an

adjunct to dry needling, in the treatment of MPS in terms of subjective clinical findings.

1.2.2 Second sub-problem

To evaluate the efficacy of a *Magnesium phosphate* tissue salt supplement, as an adjunct to dry needling, in the treatment of MPS in terms of objective clinical findings.

1.3 HYPOTHESIS.

1.3.1 The first hypothesis

It is hypothesized that a *Magnesium phosphate* tissue salt supplement, as an adjunct to dry needling, will be more effective than dry needling alone, in the management of MPS in terms of subjective clinical findings.

1.3.2 The second hypothesis

It is hypothesized that a *Magnesium phosphate* tissue salt supplement, as an adjunct to dry needling, will be more effective than dry needling alone, in the management of MPS in terms of objective clinical findings.

1.4 BENEFITS OF THE STUDY.

This research aims to investigate the efficacy of a tissue salt supplement, *Magnesium phosphate*, as an adjunct to dry needling, in the treatment of MPS. Treatment protocols of this commonly occurring condition vary and a combination of treatment is needed to obtain rapid recovery and long term relief from pain. This double-blinded, randomised, clinical trial was designed to determine whether the inclusion of a Biochemical tissue salt, namely *Magnesium phosphate* and dry needling, would result in enhanced recovery and less TrP tenderness in patients suffering from MPS when compared to dry needling alone. This research hopes to assist practitioners in choosing a therapy that had been proven to be effective in the treatment of this condition.

CHAPTER TWO

2.0 REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

This chapter gives an overview on the available information on MPS as well as a brief look at the use of Biochemical tissue salts, specifically *Magnesium phosphate.*

2.2 THE INCIDENCE AND PREVALENCE OF MYOFASCIAL PAIN SYNDROME

Myofascial pain has been identified as one of the most common causes of chronic pain (Fricton 1990) and is frequently encountered in outpatient settings (Auleciems 1995). Reports of the prevalence of MPS in specific patient populations are available and indicate a high prevalence of this condition among individuals with regional pain complaints (Travell <u>et al.</u> 1999). There is however a lack of recent studies investigating the incidence and prevalence of this condition. The incidence of MPS appears to vary between 30 and 85% of people presenting to pain clinics (Han and Harrison 1997, Gerwin 1995, Chaiamnuay <u>et al</u>. 1998), and appears more prevalent in females, although it is found in both sexes (Han and Harrison 1997). Patients aging from 30-49 years old have the highest prevalence of TrP's, with the incidence decreasing with age (Travell <u>et al</u>. 1999).

A study conducted by Chaiamnuay <u>et al.</u> (1998), examined and interviewed 2463 rural Thailand subjects who were suffering from musculoskeletal pain and found that 36.5% had pain of which MPS was the second most common diagnosis. A neurologist examining 96 patients from a community pain medical center found that 93% had at least part of their pain caused by myofascial TrP's and in 73%, myofascial TrP's were considered the primary cause of pain (Gerwin 1995). The prevalence of myofascial TrP's in South Africa has never been determined (Jones 2001), but in a study on the prevalence and types of headaches in

Afrikaans speaking high school children in the greater Durban area (Jansen 1998), TrP's examination revealed a 24.95 - 37.1% prevalence of active trapezius TrP's in a sample population of 1 441 pupils.

2.3 PERPETUATING FACTORS.

Varieties of perpetuating factors are associated with recurrent pain and pain unresponsive to MPS treatment (Auleciems 1995). Perpetuating factors are often over looked and neglected and may well be the key between a successful and failed treatments. Once the perpetuating factors are corrected, pain associated with MPS is more likely to resolve (Auleciems 1995). It is Travell <u>et</u> <u>al.'s(1999)</u> conclusion that perpetuating factors can be viewed as predisposing factors, as their presence can make the muscle more susceptible to the activation of TrP's. This variety of factors make the muscles more likely to develop TrP's initially and increase the irritability of existing TrP's, causing a response to treatment that is neither complete, nor permanent (Travell <u>et al</u>. 1999).

2.3.1. Mechanical/Structural stresses

Mechanical perpetuating factors are often seen in patients suffering from chronic MPS. Skeletal asymmetry and disproportion are recognized by Travell <u>et al</u>. (1999) as the most common source of physical stress leading to the occurrence of TrP's. Auleciems (1995) believes that structural abnormalities can cause increased muscle tension and lead to formation of TrP's.

Travell takes into consideration three types of mechanical stress:

1) Structural inadequacies i.e. compensatory scoliosis, hemiplegia, short upper arms etc. resulting in muscle overload and the formation of TrP's

2) Postural stresses.

3) Constriction of muscles i.e. pressures from a bra strap or bag, or poor positioning on a chair edge.

2.3.2. Nutritional Inadequacies

Water soluble vitamins; B1, B6, B12, folic acid, vitamin C and the elements; Calcium, Iron and Magnesium have been recognized as a concern in MPS (Fricton 1990, Auleciems 1995, Travell <u>et al.</u> 1999) and low levels of these vitamins and minerals have been linked to consistent aggravation of TrP's (Travell <u>et al</u>. 1999). Nearly half of the patients seen by Travell <u>et al</u>. (1999) required resolution of vitamin inadequacies for lasting pain relief. However, conflicting results were concluded by Morgan (1997) in a study of the effectiveness of vitamin supplementation (vitamin C and vitamin B complex), in dry needling and muscle stretching in MPS. Results showed that patients who received supplementation, responded no better than those who did not. Research in this field is lacking and studies are needed to determine the exact relationship between these conditions and the development of MPS.

2.3.3. Metabolic and Endocrine Inadequacies

Metabolic disturbances such as hyperthyroidism, hyperuricemia, increased creatine levels, and estrogen deficiency have been identified to coincide with the presence of TrP's (Fricton 1990). It is Travell <u>et al</u>.'s (1999) opinion that whatever impairs muscle metabolism perpetuates TrP's.

2.3.4 Psychological Factors

It has been hypothesized that patients who experience difficulty in verbalizing anger, hostility, or experience high levels of anxiety, have an increase in muscle contractions due to the stress experienced through these habits (Fricton 1990). Pain attributed to anxiety, fear, anger and other emotional reactions had been seen as a frequent source of muscular tension, and muscle tension is a source of nociceptive stimuli that evolve into the sensation of pain (Cailliet 1988). Sola (1981) believes that a variety of stress inducing stimuli, whether emotional or physical, may be implicated in the onset of myofascial pain and that the power of these stresses to induce pain in an individual depends on the genetics, personality type, conditioning and physiological state of the individual. High anxiety scores have been revealed in patients suffering from MPS (Esenyel <u>et al.</u> 2000) and even though the relationship between stress and MPS is difficult to assess, studies do suggest that a correlation does exist between them (Fricton 1990).

2.3.5 Other Perpetuating Factors_

Chronic infection either due to viral or bacterial disease is also recognized as a perpetuating factor (Aulemiems 1995, Travell <u>et al.</u> 1999).

Impaired sleep and physical and mental fatigue can also be recognized as perpetuating factors (Sola 1981, Travell <u>et al</u>. 1999). Most patients with chronic MPS have difficulty sleeping and reveal a pattern of abnormal sleeping behavior when monitored in a sleep laboratory (Travell <u>et al</u>. 1999). Many patients with chronic fatigue have generalized muscle tenderness and it has been noted that sleep deprivation alone can cause generalized muscle pain that is reversed by restoring normal sleep patterns (Rosen 1993).

2.4 CLINICAL PRESENTATION AND DIAGNOSIS

MPS is defined as a muscular pain disorder involving regional pain referred by TrP's within the myofascial structures that are either locally or at a distance from the site of pain (Fricton 1990). A TrP is an area of hypersensitivity or localized tenderness in a palpable band of painful skeletal muscle, tendon or ligament (Fricton 1994, Hubbard 1998). This point or area of tenderness is usually on an average, between 2-5 mm in diameter (Fricton 1994).

Palpation of these points results either in pain concentrated over the TrP area or pain referred to an area distant from the tender spot, known as the "zone of referral" (Han and Harrison 1997). This nature of pain and referral is used to classify TrP's. TrP's may either be described as active or latent (Travell <u>et al.</u>

1999). Active TrP's are clinically active, by causing pain, and can be identified by the reproduction of the patient's pain, either in the zone of referral, or radiating pain towards the zone of referral, when compressed digitally. The pattern of referral follows a pattern that is reproducible and consistent in patients with similar TrP's and this enables clinicians to use the zone of referral as a guide to locate the TrP's in a muscle for treatment. This pain can be experienced immediately or can be delayed for a few seconds (Fricton 1994). Latent TrP's on the other hand, are silent in respect to pain, are less irritable, and may be seen as asymptomatic, clinically causing pain only when palpated (Bruce 1995). They may however cause restriction of movement and weakness within a muscle and can be responsible for predisposing a patient to an acute attack of pain when minor strain occurs within the affected muscle (Travell <u>et al.</u> 1999). Intense heat or cold, minor overstretching, weather changes, or emotional stimuli may activate latent TrP's to an active level (Bruce 1995).

Characteristically, pain referred by TrP's is the main symptom and is either continuous or intermittent in nature (Auleciems 1995), with an abrupt or gradual onset (Travell <u>et al.</u> 1999) and is a steady, deep and achy pain, with occasional sharp, lancinating, burning or lightening like stabs.

Travell et al. (1999) defines specific criteria for the diagnosis and examination of TrP's:

1.) A taut band and a trigger point.

This is examined for by using palpation. The muscle is palpated using the digits and must be relaxed but in a stretched position. The stretch should not evoke any pain or discomfort. Flat palpation or pincer palpation may be used. Flat palpation is when the fingertips are use to slide the patients skin across the muscle fibres. Pincer palpation is when the belly of the muscle is grasped between the thumb and fingers.

2) Local twitch response.

This occurs when the part of the muscle containing the TrP is rolled under the fingers. This twitch is also observed when a needle is inserted into the trigger area. Most muscles exhibit a vigorous twitch response when they contain TrP's.

3) Jump sign.

When firm pressure is applied to a tender TrP, the behavioral reaction that is a characteristic of MPS, is the patient's response to the pain. The patient reaction may include a withdrawal or a verbal response, and if sufficient pressure is applied to an active TrP, a jump sign is almost always elicited.

4) Referred pain.

Pressure applied to an active TrP will evoke referred pain, as well as local pain over the tender spot.

Clinical features of TrP include (Gerwin et al. 1997):

- 1) Point tenderness on the taut muscle band
- 2) Local twitch response
- 3) Referred pain
- 4) Reproduction of usual pain
- 5) Restricted range of motion
- 6) Weakness without atrophy
- 7) Autonomic symptoms

Identification of a TrP is essential for diagnosis and treatment. As there is no reputable biochemical, electromygraphic, or diagnostic-imaging criteria recognized for the diagnosis of MPS (Lewis and Tehan 1999, Sciotti <u>et al</u>. 2001), manual palpation, recognition of clinical features and patient feed back are the primary methods used for diagnosis and treatment (Fischer 1988, Lewit 1979, Travell <u>et al</u>. 1999, Sciotti <u>et al</u>. 2001). There is criticism on the reliance of these manual methods of diagnosis (Wolfe <u>et al</u>. 1992, Nice <u>et al</u>. 1992) but in a recent study conducted by Gerwin <u>et al</u>. (1997), interrater reliability was

successfully demonstrated when examiners were trained together to establish agreement on palpation skills. This demonstrated that manual diagnosis is reliable when diagnosing MPS, but that clinicians need to be familiar with the criteria for identification and physical findings need to be interpreted similarly (Gerwin <u>et al</u>. 1997).

2.5 PATHOPHYSIOLOGY

Some authors view TrP's as microscopic lesions resulting from overuse, disuse or misuse. A number of causes of TrP formation are speculated, but a widely accepted neurophysical or pathological explanation for the formation of MPS is lacking (Auleciems 1995), and attempts to characterize TrP's have been disappointing and controversial. Three characteristic features of TrP's include; hyperirritability, a region of increased metabolism and/or decreased circulation, and a palpable band (Gatterman 1990).

Biopsy of tender areas have shown no consistent anatomical changes using light microcopy, electron microscopy or histochemisty (Gerwin 1994). Studies involving muscle biopsies of active TrP's have revealed non-specific, dystrophic changes and increases nuclei inside and outside of the muscle fibers (Travell <u>et al</u>. 1999). Fatty infiltration, myofibrillar degeneration, accumulation of acid mucopolysaccharides and local inflammatory responses with lymphatic infiltration have been revealed (Fricton 1990). A progressive degeneration of the muscle with a noted disruption of mitochondria and an associated increased glycogen and actin band lysis has been noted in the long term occurance of TrP's, leading to a disintegration of the contractile fibers and a broken down amorphous ground substance (Fricton 1990, Gerwin 1994).

In their attempt to understand the pathophysiological and electrophysiological mechanism of TrP's, Hong and Simons (1988) discovered that TrP's contained multiple loci that were related to nerve and motor endplates, and that the taut areas were probably related to an excessive release of acetylcholine in abnormal end plates. They concluded that "the pathogenesis appeared to be related to an integrated mechanism in the spinal cord in response to sensitized nerve fibers associated with abnormal endplates"

Hubbard demonstrated spontaneous TrP needle EMG activity that was blocked by sympathetic antagonists. Using dual-channel needle electromyography, abnormal muscle activity was localized in the TrP's and appeared to arise via sympathetic innervation within the muscle spindle. From this research it was determined that TrP's are hyperactive muscle spindles with intrafusal muscle fibers that are in spasm secondary to sympathetic stimulation. TrP's are thus thought to be formed by the combination of traumatic or repetitive overstretching of the spindle and sympathetic mediated tension (Hubbard 1993,1998).

A theory postulated by Travell et al. (1999) is that TrP development may be initiated by acute injury or repetitive microtrauma, causing disruption in the sarcoplasmic reticulum in the muscle fiber. Calcium ions are then released due to the presence of ATP. Ionized calcium from the reticulum then causes an activation of the actin myosin contractile mechanism, leading to the formation of a tense band within the muscle. This contractile activity causes an increase in the metabolic rate, leading to the accumulation of metabolites. Local muscle acidity increases and firing of nociceptives results in local and referred pain. Sensitization of these nerve endings may be responsible for the local twitch response and jump sign. Local reduction in the blood flow in the region of the TrP may result due to a sustained contraction of the muscle and there may be a decreased effectiveness of the calcium pump, which is highly dependent on availability of ATP. As a consequence, a vicious circle is established; sarcomere shortening occurs due to a lack of ATP and an overflow of calcium. Restoration of ATP can not occur as a result of the compromised calcium pump (Travell et al. 1999).

The mechanism of referred pain is unclear; convergence of somatic and visceral afferent inputs with pain projecting neurons in the spinal cord may explain this phenomenon (Travell <u>et al</u>. 1999).

It is Sola's (1981) opinion that TrP's are the result of a self sustaining cycle of local ischaemia, release of bradykinins and prostaglandins, and osmotic

changes in pH, leading to an area of hyperactivity, increased motor and sympathetic activity and pain.

.6 TREATMENT

MPS is often resistant to therapy (Wreje and Brorsson 1995) and a multidisciplinary approach to treatment, which will be discussed in this chapter, has appeared to be most beneficial (Han and Harrison 1997). Management is usually aimed at restoring hyperactive muscle spindles to normal functioning (Hubbard 1998), and there are many suggested methods for providing repetitive stimulation to inactivate TrP's. An accurate diagnosis is imperative when treating MPS and once the TrP and the reference zone has been identified, clinicians can make a choice on what treatment plan to use. When effectively managed, MPS has an excellent prognosis (Auleciems 1995). Treatment includes modalities such as trigger point injection, dry needling, stretch and spray, ice and stretch, heat therapy, electrotherapy, ischaemic compression and spinal adjustments (Auleciems 1995. Han and Harrison 1997, Travell <u>et al</u>. 1999).

2.6.1 Electrotherapies

Transcutaneous Electrical Nerve Stimulation/TENS.

Although not classified as a specific treatment for MPS, TENS has been popular in acute and chronic pain therapy and has been effective in the treatment of TrP's (Bruce 1995, Walsh 1996, Han and Harrison 1997, Hubbard 1998,). TENS works on the principle of the gate control theory, where the low intensity electrical stimulation produced by the machine selectively stimulates input from the large diameter A fibers, which carry non-noxious sensations, such as touch and vibration. This electrically stimulated input closes the pain gate to further ascending spinal cord transmission in the dorsal horn of the spinal cord or at higher levels thus reducing pain experienced (Jenkins 1996, Han and Harrison1997). This form of therapy, is effective in treating the pain produced by TrP's, but alone may not be sufficient enough to produce long term effects in treating MPS (Han and Harrison1997). "TENS has been found not to be as useful when normal neuroarchitecture is lost and is less effective for chronic than for acute pain" (Jenkins 1996).

Ultrasound.

The use of ultrasound has been found by many therapists as an effective form of inactivating TrP's (Travell et al. 1999). A high-frequency acoustic energy is generated to produce thermal and non-thermal effects in the tissues. Pain relief is theorized to be related to the washout effect of pain mediators caused by; an increased blood flow and alterations in the cell membrane permeability that decreases inflammation or changes in the nerve conduction (Travell et al. 1999). A study conducted by Esenvel et al. (2000) to investigate the effectiveness of ultrasound treatment and TrP injection, combined with neck stretching exercises in myofascial TrP's in the trapezius muscle, found ultrasound therapy and TrP injection, used in conjunction with stretching, more effective in reducing pain than ultrasound or injection therapy alone. The authors recommended that ultrasound treatment should be offered as a non-invasive treatment of choice if patients wanted to avoid injections, but a randomised, clinical trial conducted by Gam et al. (1998) to determine the effect of treatment with ultrasound, massage and exercises on myofascial TrP's, concluded that ultrasound therapy was no more effective than sham ultrasound therapy, in the treatment of MPS.

2.6.2 Spray and Stretch

Spray and stretch is viewed as a common, alternative approach, or an adjunct to other therapies (Han and Harrison 1997), as it is quick, simple and one of the least painful techniques available (Travell <u>et al.</u> 1999). The goal when using this

technique is to reduce pain over the TrP, restoring the muscle to its normal length and improving the range of motion. This technique involves the passive stretching of the affected muscle while simultaneously applying (anesthetic) Fluori-Methane or ethyl chloride spray or alternatively ice. The spray/ice is applied in several successive slow, parallel sweeps along the length of the muscle and the muscle is then stretched. The cooling effect produced by the sprays/ice is thought to produce temporary anesthesia by blocking the spinal stretch reflex and the pain sensation at higher centers. This decrease in pain sensation allows passive stretching of the muscle, which helps to inactivate the TrP (Travell <u>et al.</u> 1999). Studies have shown a decrease in TrP sensitivity when using this technique (Andersen 1997, Travell <u>et al.</u> 1999).

2.6.3 Exercise and Stretching Therapy

Stretching and exercise are often used in conjunction with other therapies but alone can be effective in the treatment of TrPs (Mance <u>et al.</u> 1986). The authors recognize the beneficial effects of a exercise programme and "an immediate, aggressive programme of gradual active and passive muscle stretching and strengthening is crucial for long term success in the treatment of MPS" (McClaflin 1994). Individual home exercises can be prescribed to patients, getting them actively involved in the treatment of their condition.

The use of a program of gentle stretching exercises has shown to be effective in chronic patients, helping to alleviate TrP pain (Hubbard 1998). Active rehabilitation programmes should include exercises specific to the painful area (McClaflin 1994). Clinical trials have shown that exercise combined with massage (Gam <u>et al.</u> 1998) and ultrasound treatment, and TrP injection combined with neck stretching exercises (Esenyel <u>et al</u>. 2000), reduce the number and intensity of TrP's and is effective in relieving pain in the neck and shoulders associated with TrP's. This form of therapy is, however, patient dependant, as the patient's compliance is needed to gain beneficial results.

2.6.4 Ischaemic Compression

This method, recommended by Travell and Kraus (Travell <u>et al.</u> 1999) is the application of a sustained pressure to the TrP with sufficient force and duration to inactivate it. The application of a deep pressure produces local ischemia and once released, reactive hyperemia occurs, and an improved circulation results in the area (Auleciems 1995). A home programme consisting of ischaemic compression followed by sustained stretching has shown to be effective in reducing TrP sensitivity and pain intensity in individuals with neck and upper back pain (Hanten <u>et al.</u> 2000).

2.6.5 Injection Therapy and Dry Needling

TrP injection is the injection of TrP's with local anaesthetic or saline (Hubbard 1998). It has been recognized as an effective and therapeutic approach when treating MPS and is postulated that it achieves best results when dealing with chronic cases (Han and Harrison 1997).

Several mechanisms for the effective outcome of injection therapy/dry needling have been postulated (Han and Harrison 1997):

1) The mechanical disruption of the muscle fibers and nerve endings.

2.) The mechanical disruption of the muscle fiber, causing the increased extracellular potassium, which leads to depolarization of the nerve fibers.

3.) Interruption of the positive feedback mechanism that perpetuates pain.

4.) Local dilution of nociceptive substances by the local anesthetic or saline that is infiltrated.

5.) Vasodilatory effect of local anesthetics, which increases removal of metabolites.

Garvey <u>et al</u>. (1989) conducted a randomized double-blinded study on 63 patients with lower back comparing 4 types of therapy; 1) lidocaine 1%injection therapy, 2) lidocaine 1% and triamcinolane injection therapy, 3) acupuncture, and 4) vapococlant spray with acupressure. Results showed that single dry needle acupuncture as well as vapocoolant spray plus acupressure were more effective than the other methods. Frost <u>et al.</u> (1980) demonstrated in a randomized, controlled, clinical trial that the injection therapy of a physiological saline solution gave better relief than the injection of local anaesthetic in the treatment of TrP's. A similar study conducted by Wreje and Brorsson (1995), demonstrated no better clinical outcome between the injection of sterile water and saline in the treatment of patients with chronic MPS.

A study investigating the therapeutic efficacy of invasive needling techniques in the management of MPS (Broome 1996), found that there was no statistically significant difference between saline injection therapy and dry needling when treating TrP's and that both treatments were effective when treating MPS. The author did however recommend dry needling over saline injection therapy due to dry needling being a quicker and easier form of treatment.

Dry needling techniques are well documented as effective forms of therapy (Lewit 1979, Jones 1994 and Travell <u>et al.</u> 1999). Dry needling has been shown to decrease or even abolish MPS, an effect that appears to be mediated by the input into the central nervous system, mechanical disruption or direct stimulation of the TrP's (Han and Harrison 1997).

Hong (1994) conducted a study on the effects of dry needling verses local anaesthetic injection into a TrP and found that both groups had significant improvement after treatment, however post injection tenderness (which was different to TrP pain) developed in all of the patients who had received dry needling, but only in 42% of patients who had received local anaesthetic. This tenderness was of greater intensity and longer duration in the patients who had been treated with dry needling. In a study comparing the effectiveness of dry needling to placebo in the treatment of myofascial TrP's, it was found that at a 5% level of significance, the experimental group improved more than the placebo group in terms of subjective and objective findings (Jones 1994). The experimental group participating in the study also received ergonomic and stretching advice.

Dry needling appears to be as effective as the injection of medication in to TrP's in the clinical outcome of treatment of MPS, however post needling tenderness is reported to be of a higher degree and experienced for a longer duration in patients who receive dry needling (Hong 1994).

2.6.6 Other Forms of Therapy

Heat.

Moist heat relaxes the muscle, decreasing tension on the TrP and decreasing referred pain and local tenderness (Auleciems 1995). Heat is more effective when used during or immediately after passive or active stretching (Mance <u>et</u>

<u>al.</u>1986).

Massage.

Many authors recognize massage as an effective form of therapy in the treatment of MPS. Massage can be used to break down fibrous bands and improve point tenderness and has been shown to be more effective than heat alone (Travell <u>et</u> <u>al.</u> 1999). Various massaging techniques can be used when treating TrP's. A firm, heavy, friction type of massage proves to be more effective than stroking or kneading as it enables the superficial tissue to be moved over the underlying structures, improving mobility. Stripping massage has also shown to be effective and is more superficial than friction massage (Travell <u>et al.</u> 1999). A light pressure is applied in repeated strokes over the tender nodules and gradually increasing the pressure used with each stroke helps to inactivate the TrP (Travell <u>et al.</u>1999).

2.7 BIOCHEMICAL TISSUE SALTS.

Inorganic mineral therapy is available in the health care field through means of biochemical tissue salts (Carey 1995:1-33). This form of therapy is used to maintain or restore the correct balance of natural mineral salts found in the body and was devised by Dr Wilhelm Schuessler in the 19th century (Carey 1995). Using Schuesslers' Biochemical system of Medicine, a range of medicine's consisting of twelve, common salts found in the body, has been developed (Boericke and Dewey 1992 :34). The principle of this system of biochemical salts is related to the principles used in Homeopathy, and even though 'biochemistry and Homeopathy are distinct branches of medicine', they both use the principle of a minute dose and the selection of the remedy according to the symptoms (Goodwin 1980). These salts are however not necessarily regarded as a complete treatment for a disease or symptoms, but a valuable part of treatment in connection with other therapies deemed necessary for the treatment of conditions (Boericke and Dewey 1992).

These biochemical tissue salts are prepared through a process called trituration,

which facilitates assimilation (Carey 1995:29-32). Trituration of the salts enables dilution to such a degree that its molecules may penetrate the epithelium of the mouth, pharynx and esophagus and reach the blood stream through the capillary walls. This method of preparation allows the salts to bypass the stomach (Boericke and Dewey 1992:24).

The twelve tissue salts used are (Carey 1995):

- 1.) Calcium fluoride
- 2.) Calcium phosphate
- 3.) Calcium sulphate
- 4.) Iron phosphate
- 5.) Potassium chloride
- 6.) Potassium phosphate
- 7.) Potassium sulphate
- 8.) Magnesium phosphate
- 9.) Sodium chloride
- 10.) Sodium phosphate
- 11.) Sodium sulphate
- 12.) Silica

2.7.1 Magnesium phosphate

Magnesium phosphate is used as a remedy in the treatment of "nerve and muscle symptoms" (Carey 1995:85). It is prescribed as an antidotal treatment for: "cramping muscles, pain that is sharp, boring, radiating, lightning-like, neuralgic and spasmodic in nature and often accompanied by a constricting feeling. The pain is rarely of a burning nature" (Boericke and Dewey 1992:101). The pain is located mostly over the "nape of the neck and back region" and can "involve the extremities" (Carey 1995:87). Headaches experienced are of a "sharp, neuralgic or shooting nature and are often intermittent". They are usually "located on the occiput, spreading over the entire head" or on the top and back of the head extending into the spine and shoulder blade region (Boericke and Dewey 1992:243). The headaches are "constant while attending school and after mental

labour" (Boericke and Dewey 1992:243).

The use of *Magnesium phosphate* is advocated in muscular symptoms (Hopkins 2001, Van Wyk 2001).

2.8 MUSCLE OVERVIEW

2.8.1 The Trapezius Muscle

The trapezius muscle is considered to be one of the most commonly affected muscles in MPS (Travel et al. 1999, Gerwin 1994).

This muscle is viewed as being tripartite and consists of upper, middle and lower fibers that can function independently. It extends from the occiput to T12 and laterally to the clavicle in front and to the spine of the scapula at the back. The upper trapezius fibers elevate the shoulder and rotate the glenoid fossa so that the socket of the shoulder faces upwards. This rotation is assisted by the lower trapezius fibers. The middle fibers adduct the scapula (Travell <u>et al.</u>1999).

There are six TrP's found within the trapezius muscle, referring pain and a seventh TrP referring autonomic phenomena. The upper fibers contain TrP's 1 and 2, middle fibers TrPs 5, 6 and 7 and the lower fibers TrP's 3 and 4. The referral for each point is as follows (Travell <u>et al.</u>1999):

TrP 1: unilaterally along the posterolateral aspect of the neck to the mastoid process and can be a major source of tension headaches. Pain can, when intense, refer up into the head centering in the temple and orbital region. Jaw pain and molar pain may also be experienced. This TrP is sometimes associated with symptoms of dizziness and vertigo. *TrP 2*: pain is experienced posterior to the cervical referred pain of TrP 1. *TrP 3*: paraspinal pain extends to the higher regions of the cervical region, adjacent mastoid area and acromion. A deep ache may be experienced over the suprascapular region. *TrP 4*: Steady burning pain down and medial to the vertebral border of the scapular. *TrP 5*: Superficial

burning pain medially and between the TrP and the spinous processes of C7 and T 1. *TrP 6*: Aching pain over the shoulder and acromial process. *TrP 7*: Produces sensations and pilomotor erection (goose flesh)known as an autonomic phenomenon on lateral aspect of the arm, this is however infrequently found.

2.9 CONCLUSION

The condition treated with *Magnesium phosphate* shares a combination of symptoms present in MPS, showing that there may be a close link between the two treatments. Research on the effect of a *Magnesium phosphate* tissue salt supplement, as an adjunct to dry needling, in the treatment of MPS is lacking.

The aim of this study is to evaluate the efficacy of *Magnesium phosphate* tissue salt, as an adjunct to dry needling, in the treatment of MPS, in the attempt to find a more effective treatment of this commonly occurring condition. Combining two recognized, accepted modes of treatment for a condition, though approached from different medical directions, enables one to have a more comprehensive approach to patient care in the treatment of MPS. Many treatment protocols have been formed and used and research has shown that a combination of treatment proves to be more effective than one form of treatment alone (Gam <u>et al.</u> 1998, Esenyel <u>et al</u>. 2000, Hanten <u>et al</u>. 2000). The combining of a tissue salt and TrP dry needling, will hopefully aid practitioners in choosing an effective approach when treating patients.

CHAPTER THREE

3.0 MATERIAL AND METHODS OF THE STUDY

3.1 INTRODUCTION AND STUDY DESIGN

This study was designed as a randomised, clinical trial to evaluate the relative effectiveness of a *Magnesium phosphate* tissue salt supplement, as an adjunct to dry needling, in the treatment of MPS. Statistical analysis of subjective and objective data collection allowed for an inter-group as well as a intra-group comparison, to determine whether the combination of a *Magnesium phosphate* tissue salt, to the dry needling process, was more effective than dry needling alone.

3.2 PATIENT SELECTION

Advertisements for patients suffering from neck and shoulder pain, and/or headaches, were posted around the Technikon Natal campus, local sporting institutes and health shops. An advertisement was also placed in the local newspaper and fliers were distributed around local suburbs. Patients responding to the advertisements were interviewed telephonically to determine if they were suitable candidates for the study and an initial consultation was scheduled. Patients underwent further detailed examination on the initial consultation to determine eligibility for the study. (This will be described further, later on in the chapter). A sample size of sixty patients were selected by means of convenience sampling.

3.3 CRITERIA FOR INCLUSION AND EXCLUSION OF SUBJECTS

All subjects included into the study had to meet the inclusion criteria.

3.3.1 Inclusion Criteria

Only patients suffering from active trapezius TrP's were considered for the study and were screened as per the Myofascial Diagnostic Scale (Chettiar 2001) (Appendix C). Patients had to be between the ages of 20 and 60 years old. This age group was used to limit variables associated with advancing age and concomitant age related disease. Patients with concomitant cervical facet syndrome were included into the study but this was not treated. Active trapezius TrP's had to be the primary cause of pain.

3.3.2 Exclusion Criteria

Patients suffering from any known systemic disease e.g. SLE, RA, TB, contraindications to dry needling (namely anticoagulation therapy, skin infections or local malignancies) or cervical spine fractures or dislocations were excluded from the study. Patients with a known history of cervical radiculopathy, myelopathy or advanced degenerative disc disease were also excluded.

Once all these criteria were met, patients were then accepted into the study. Patients were asked not to take any allopathic medication for the condition, nor receive any forms of treatment, including Chiropractic adjustments, electrotherapies or soft tissue therapies for the duration of the study.

On being found eligible for the study, patients had the study criteria described to them and received an information sheet outlining the nature and requirements of the study (Appendix E). Patients were then asked to fill in an informed consent form before treatment commenced (Appendix F).

3.4 SAMPLING

The sample size for the study was sixty patients with thirty per group. Convenience, random, allocation was used to separate the patients into two equal groups. Patients were assigned to either group "1" or "2", with the allocation being double blinded. Neither the researcher nor the patients were aware of the group that they were in until after all the data was collected at the end of the study.

3.5 INTERVENTION

Treatment of both groups,1 and 2 consisted of a maximum of 4 consultations over a two week period. Both groups received a supplement to take over the course of the treatment, however the content of the supplements given to each group was unknown until after all the data had been collected. One group received a *Magnesium phosphate* tissue salt supplement, while the other received a placebo sugar tablet. Patients were instructed to either place the tablets under their tongue or alternatively suck them, allowing the tablets to dissolve in the mouth. Patients in both groups were required to take one tablet, three times a day.

Dry needling was carried out on both groups at each consultation. The treatment site was cleaned with 70% alcohol prior to treatment. A new, sterile, 0.25×30mm needle was used with each treatment and the fanning dry needle insertion method, as used by Rowley in his study of the comparison of two needling methods, was used (Rowley 2001). Patients were treated for the maximum of four allocated treatments, unless they were asymptomatic before the end of the study. If a patient was asymptomatic, dry needling was not carried out, but they were instructed to still continue taking the supplements until the treatment period was over, data was still captured on each consultation. If a patient however became unblinded or aware of what supplement they were receiving, the patient was excluded from the study as this may have led to bias.

3.6 DATA COLLECTION

Patients were assessed subjectively and objectively prior to the first, second and the fourth treatment and on a follow up consultation within a 5-day period of the fourth treatment that was scheduled for data capturing. Patients that were asymptomatic where assessed irrespective of the number of treatments given. The follow up consultation was scheduled five days following the last treatment to prevent data captured after the fourth treatment from being adversely affected due to post needling tenderness. A minimum 24-hour period between each consultation was maintained.

3.6.1 Objective Data

Objective clinical findings were obtained through the use of a pressure algometer (Pain Diagnosis and Thermography Corporation, Pain Threshold Meter, Model PTH – AF2) as demonstrated by Fischer (1987) (Appendix D). With the use of this instrument, localized tenderness could be qualified by measurement of pressure threshold, which was referred to as the minimum pressure (force) that induced pain or discomfort (Fischer 1987). The Algometer Commander, a digital force gauge was used (Livingston, Bernardi, and Carroll 1998). A single score was obtained for each consultation by determining the mean of the recorded values.

A Myofascial Diagnostic Scale was also used (Appendix C). This assesses the extent to which the patients suffer from MPS. Scores were expressed in numbers, the highest score possible being 17. A single score for each consultation was also obtained by determining the sum of the recorded values. The validity of this scale has however never been tested in a clinical trial and its validity is taken at face value.

3.6.2 Subjective Data

Subjective data was obtained by asking the patients to complete two questionnaires. The Numerical Pain Rating Scale (NRS) 101 (Jensen <u>et al.</u> 1986) (Appendix B) was used to monitor patients progress, with a decrease in pain indicating an improvement. The scores for the worst and least pain were recorded and the values were added and then divided by two and expressed as a percentage.

The Short Form McGill pain questionnaire (Melzack 1987) was used to assess the quantity and quality of pain respectively (Appendix A). A single score for each consultation was obtained by adding up the total out of a maximum of 45.

The patients completed both questionnaires under the supervision of the researcher.

3.7 LOCATION OF DATA

The primary data was obtained from the Numerical Pain Rating Scale-101, Short Form McGill Pain Questionnaire, Myofascial Diagnostic Scale and the pressure algometer readings obtained at the first, second, fourth and follow up consultations. All treatment and consultations took place at the Techinkon Natal Chiropractic Day Clinic.

The secondary data was collected from current journals and textbooks from various libraries.

3.8 STATISTICAL ANALYSIS

The SPSS statistical package (as supplied by SPSS Inc, Marketing Department, 444 North Michigan Avenue, Chicago, Illinois, 60611) was used for data entry and analysis.

3.8.1 Method of Data Collection

Since the sample size for each group was large (n >30), both parametric and non-parametric tests were used for inter and intra-group analysis. Non-parametric tests were used to analyze ordinal data. Parametric tests were used to analyze continuous variables (interval and ratio data).

3.8.2 Inter-group comparison using Mann Whitney U-test

The Mann Whitney U-test was used for the inter-group comparison of each of the ordinal variables (Short Form McGill and Myofascial Diagnostic Scale). In each test, the null hypothesis (Ho) stated that there was no difference between the two independent samples being compared, with respect to the variables tested, at $\infty = 0.05$ level of significance. The alternative hypothesis (H₁) states that there is a difference between the two independent samples being compared.

Ho: There was no difference between groups.

H₁: There was a difference between groups.

∞= 0.05

Decision Rule: If $p < \infty$, reject Ho

If $p \ge \infty$, accept Ho

Where p is the observed significance level or p-value.

3.8.3 Inter-group comparison using the two Sample unpaired t-test

The unpaired t-test was used for inter-group comparison of each of the continuous variables (NRS 101 and Algometer). In each test, the null hypothesis (Ho) stated that there was no difference between the two independent samples being compared, with respect to the variables being tested, at $\infty = 0.05$ level of significance. The alternative hypothesis (H₁) states that there was a difference between the two independent samples being compared.

Ho: There was no difference between the two groups.

H₁: There was a difference between the two groups.

 $\infty = 0.05$

Decision Rule: If $p \propto <$, reject Ho

If $p \ge \infty$, accept Ho

Where p is the observed significance level or p-value.

3.8.4 Intra-group comparison using Friedmans Test

The Friedmans test was used for intra-group comparison of all variables (Short Form McGill and Myofascial Diagnostic Scale, NRS 101, Algometer). This test compares three or more matched groups, giving only an overall significance level. In each test, the null hypothesis (Ho) states that there was no improvement between the consultations, with respect to the variables being tested, at $\infty = 0.05$ level of significance. The alternative hypothesis (H₁) states that there was an improvement.

Ho: There was no improvement between consultations.

H₁: There was an improvement between consultations.

 $\infty = 0.05$

Decision Rule: If $p < \infty$, reject Ho

If $p \ge \infty$, accept Ho

Where p is the observed significance level or p-value.

If the null hypothesis is rejected for Friedmans test, then a multiple comparison procedure is applied to determine which of the treatments were significantly different. The Dunn's Post test is performed.

Let Rj and Rj¹ be the Jth and J¹th treatment ranked totals. Let ∞ be the experiment wise error rate. Usually = 0.10. Decision Rule for Dunn's procedure:

If $|Rj-Rj^1| >$, then Rj and Rj¹ are declared significant.

In the above formula:

b = no. of blocks.

k = no. of treatments

Z = value in the inverse nomal distribution corresponding to (1-[$\infty/k(k-1)$]).

To compute the treatment rank totals, the values in each block were ranked and the sum of the ranks for each treatment were computed.

When k = 4 $\infty = 0.10$ z = 2.409

CHAPTER FOUR

4.0 RESULTS

4.1 INTRODUCTION

This chapter represents the results of the data collected from the clinical trial. All the primary data was statically analyzed and tabulated. Measuring criteria included:

- -Numerical Pain Rating Scale
- -Short Form McGill Pain Questionnaire
- -Algometer readings
- -Myofascial Diagnostic Scale

Objective data (Algometer readings, Myofascial Diagnostic Scale) was recorded by the researcher and utilized. Subjective data (Short Form McGill Pain Questionnaire, NRS101) was completed by the patients under the supervision of the researcher and utilized.

4.2 TABLES OF DEMOGRAPHIC DATA.

Table 1: Gender distribution

GENDER	GROUP 1	GROUP 2	TOTAL %
MALES	9 (30%)	11 (36.33%)	33.3
FEMALES	21 (70%)	19 (63.3%)	66.6

Table 2: Age distribution

Age distribution	Group 1	Group 2	Total percentage
20-25	6	6	20%
26-30	5	5	16.6%
31-35	5	5	16.6%

36-40	1	5	10%
41-45	4	2	10%
46-50	4	3	11.6%
51-55	4	3	11.6%
56-60	1	1	3.3%

Table 3: Patient occupation

Occupation	Group1 (placebo)	Group 2 (treatment)	Total %
Student	9	6	25%
Designer	1	2	5%
House wife	1	4	8.3%
Receptionist	6	2	14.3%
Estate agent	1	1	3.3%
Engineer	0	1	1.6%
Admin staff	1	2	5%
Manager	0	1	1.6%
Insurance broker	0	2	3.,3%
Chartered accountant	0	1	1.6%
Teacher	3	3	11%
Attorney	0	1	1.6%
Lecturer	2	1	5%
Car guard	0	1	1.6%
Architecture	0	1	1.6%
Business owner	3	1	6.6%
technician	2	0	3.6%
Tour guide	1	0	1.6%

4.3 TABLES OF STATISTICAL RESULTS

4.3.1 Tables of the statistical results of inter-group comparison for groups 1 and 2 with regards to objective findings.

Table 4: Inter-group comparison between groups 1 and 2, using theUnpaired t-test to analyze results obtained from the Algometer readingsat consultation 1,2,4 and 5.

	Group 1 (placebo)			Group 2 (treatment)			
	Mean	S.D	S.E	P-val ue	Mean	S.D	S.E
Con 1	26.390	8.780	1.600	0.539	24.913	9.720	1.776
Con 2	27.980	10.600	1.940	0.038	22.990	7.100	1.297
Con 4	33.000	12.200	2.230	0.006	25.580	7.640	1.395
Con 5	31.490	12.500	22.800	0.183	27.667	9.250	1.689

For consultation 1, the null hypothesis was accepted for the algometer reading, indicating that there was no difference between groups 1 and 2, at α =0.05 level.

For consultation 2, the null hypothesis was rejected for the algometer readings, indication that there was a statistically significant difference between groups 1 and 2, at α =0.05.

For consultation 4, the null hypothesis was rejected for the algometer readings,

indicating that there was a statistically significant difference between groups 1 and 2, at α =0.05 level.

For consultation 5, the null hypothesis was accepted for the algometer readings, indication that there was no difference between groups 1 and 2, at the α =0.05.

Table 5: Inter-group comparison between groups 1 and 2, using the MannWhitney U-test to analyze results obtained from the MyofascialDiagnostic Scale, at consultations 1,2,4 and 5.

Myofascial Diagnostic Scale							
	Group 1 (placebo)				Group 2 (Group 2 (treatment)	
	Mean	S.D	S.E	P-Val ue	Mean	S.D	S.E
Con 1	10.867	0.482	0.482	0.520	11.200	8.770	1.603
Con 2	9.033	1.991	0.363	0.830	9.230	6.440	1.170
Con 4	5.633	2.834	0.517	0.019	7.100	7.951	1.450
Con 5	3.333	3.241	0.592	0.266	3.800	5.606	1.020

For consultation 1, the null hypothesis was accepted for the Myofascial Diagnostic Scale, indicating that there was no difference between groups 1 and 2 at α =0.05 level.

For consultation 2, the null hypothesis was accepted for the Myofascial Diagnostic Scale, indicating that there was no difference between groups 1 and 2 at α =0.05 level.

For consultation 4, the null hypothesis was rejected for the Myofascial Diagnostic Scale, indicating that there was a statistically significant difference between groups 1 and 2 at α =0.05 level.

For consultation 5, the null hypothesis was accepted for the Myofascial Diagnostic Scale, indicating that there was no difference between groups 1 and 2 at α =0.05 level.

4.3.2 Tables of the statistical results of inter-group comparison for groups 1 and 2, with regards to subjective findings.

Table 6: Inter-group comparison between groups 1 and 2, using the Unpaired t-test to analyze results obtained from the NRS 101, at consultations 1,2,4 and 5.

	Group 1 (placebo)				Group 2 (treatment)		
	Mean	S.D	S.E	P-Val ue	Mean	S.D	S.E
Con 1	51.117	17.997	3.286	0.688	52.950	17.118	3.125
Con 2	38.783	20.870	3.811	0.088	47.433	17.559	3.206
Con 4	30.783	19.032	3.475	0.202	37.633	21.980	4.013
Con 5	22.333	20.735	3.786	0.171	30.083	22.490	4.106

NRS 101

For consultation 1, the null hypothesis was accepted for the NRS 101 questionnaire, indicating that there was no difference between groups 1 and 2, at α =0.05 level

For consultation 2, the null hypothesis was accepted for the NRS 101 questionnaire, indicating that there was no difference between groups 1 and 2, at α =0.05 level.

For consultation 4, the null hypothesis was accepted for the NRS 101 questionnaire, indicating that there was no difference between groups 1 and 2,

at α =0.05 level.

For consultation 5, the null hypothesis was accepted for the NRS 101 questionnaire, indicating that there was no difference between groups 1 and 2, at α =0.05 level.

Table 7: Inter-group comparison between groups 1 and 2, using the MannWhitney U-test to analyze results obtained from the Short Form McGillPain Questionnaire, at consultations 1,2,4 and 5.

	Group 1 (J	olacebo)		P-Val	Group 2 (treatment)		
	Mean	S.D	S.E	ue	Mean	S.D	S.E
Con 1	12.330	6.614	1.208	0.171	15.333	8.778	1.603
Con 2	7.000	4.778	0.872	0.192	9.267	6.448	1.177
Con 4	5.000	5.965	1.089	0.099	8.133	7.951	1.452
Con 5	3.400	4.485	0.898	0.119	5.533	5.606	1.236

Short Form McGill Pain Questionnaire

For consultation 1, the null hypothesis was accepted for the Short form McGill Pain Questionnaire, indicating that there was no difference between groups 1 and 2, at α =0.05 level.

For consultation 2, the null hypothesis was accepted for the Short form McGill Pain Questionnaire, indicating that there was no difference between groups 1 and 2, at α =0.05 level.

For consultation 4, the null hypothesis was accepted for the Short form McGill Pain Questionnaire, indicating that there was no difference between groups 1 and 2, at α =0.05 level.

For consultation 5, the null hypothesis was once again accepted for the Short form McGill Pain Questionnaire, indicating that there was no difference between groups 1 and 2, at α =0.05 level.

4.3.3 Tables of the statistical results of intra-group comparison for groups 1 and 2, with regards to objective findings.

Table 8: Intra-group comparison using Friedman's test to analyze resultsobtained from the Algometer readings, between consultation 1 and 2, 4and 5.

Algometer readings

		Group 1	Group 1 (placebo)			Group 2 (treatment)			
	Cons 1	Cons 2	Cons 4	Cons 5	Cons 1	Cons 2	Cons 4	Cons 5	
Mean	26.391	27.980	33.080	31.495	24.913	22.990	25.590	27.667	
S.D.	8.789	10.665	12.221	12.514	9.726	7.103	7.641	9.254	
P-value		0.003	(<.001)			0.003	(<.001)		

For group 1, the null hypothesis was rejected for the algometer readings, indicating that there was a statistically significant improvement between consultations, at α =0.05 level.

For group 2, the null hypothesis was rejected for the algometer readings, indicating that there was a statistically significant improvement between consultations, at α =0.05 level.

Since the null hypothesis was rejected for the Algometer readings, the Dunn's procedure was preformed to determine which of the treatments were significantly different. This procedure was done for both groups so that a comparison could be made.

Table 9: Treatment ranks and rank totals for the algometer readings

Consultation	Mean rank	Rank total
ALGOM 1	2.27	2.27×30 =68.1
ALGOM 2	1.95	1.95×30 =58.5
ALGOM 4	2.65	2.65×30 =79.5
ALGOM 5	3.13	3.13×30 =93.9

R ₁ =68.1	R ₂ =58.5	R ₃ =79.5	R ₄ =93.9	
b=30 (no of	f blocks)	k=4 (no of	treatments)	z=2.409

if $|Rj-Rj^1| \ge$

≥ ≥ ≥24.09 ≥ 24.09, then Rj and Rj¹ are declared significant.

$$|R_1 - R_2| = |68.1 - 58.5|$$

= 9.6

Since 9.6 < 24.09, R_1 and R_2 were declared not different.

Since 11.4 < 24.09, R₁ and R₃ were declared not different.

$$|R_1 - R_4| = |68.1 - 93.9|$$

= 25.8

Since 25.8 > 24.09, R_1 and R_4 were declared different.

Since 14.4 < 24.09, R₃ and R₄ were declared not different.

Table: 10 Treatment ranks and rank totals for the algometer readings (placebo)

Consultation	Mean rank	Rank total
ALGOM 1	1.85	1.85×30 =55.5
ALGOM 2	2.37	2.37×30= 71.1
ALGOM 4	2.98	2.98×30= 89.4
ALGOM 5	2.80	2.80×30= 84

R ₁ =55.5	R ₂ =71.1	R	₃ =89.4	R ₄ =	84	ŀ
R ₁ -R2 =	55.5-71.1					
	= 15.6					
o						

Since 15.6 < 24.09. R₁ and R₂ were declared not different.

$$|R_1 - R_3| = |55.5 - 89.4|$$

= 33.9

Since 33.9 > 24.09, R₁ and R₃ were declared different.

$$|R_1 - R_4| = |55.5 - 84|$$

= 28.5

Since 28.5 > 24.09, R_1 and R_4 were declared different.

 $| R_3 - R_4 | = | 89.4 - 84 |$ = 5.4

Since 5.4 < 24.09, R_3 and R_4 were declared not different.

Table 11 : Intra-group comparison for groups 1 and 2, using Friedman's test to analyze results obtained from the Myofascial Diagnostic Scale, at consultations 1, 2, 4 and 5.

Myofascial Diagnostic Scale

		Group 1 (placebo)				Group 2 (treatment)		
	Cons 1	Cons 2	Cons 4	Cons 5	Cons 1	Cons 2	Cons 4	Cons 5
Mean	10.867	9.033	5.633	3.333	11.233	9.233	7.100	3.800
S.D.	1.907	1.991	2.834	3.241	1.455	2.208	2.998	2.953
P-value	0.003 (<.001)				0.003	(<.001)		

For group 1, the null hypothesis was rejected for the Myofascial Diagnostic Scale, indicating that there was a statistically significant improvement between consultations, at α =0.05 level of significance.

For group 2, the null hypothesis was also rejected for the Myofascial Diagnostic Scale, indicating that there was a statistically significant improvement between consultations, at α =0.05 level of significance.

Since the null hypothesis was rejected for the Myofascial Diagnostic Scale, the Dunn's procedure (multiple comparison test) was performed to determine which of the treatments were significantly different for the two groups.

Table 12:Treatment ranks and rank totals for the Myofascial Diagnostic Scale

Consultation	Mean rank	Rank total
Mds 1	3.83	3.83×30= 114.9
Mds 2	2.83	2.83×30= 84.9
Mds 4	2.15	2.15×30= 64.5
Mds 5	1.18	1.18×30= 35.4

 R_1 =114.9 R_2 =84.9 R_3 =64.9 R_4 =35.4

 $|R_1 - R_2| = |114 - 84.9|$ = 30 Since 30 >24.09, R_1 and R_2 were declared different.

 $| R_1 - R_3 | = | 114.9 - 64.9 |$ = 50

Since 50 > 24.09, R₁ and R₃ were declared different.

$$|R_1 - R_4| = |114.9 - 35.4|$$

Since 78.6 > 24.09, R_1 and R_4 were declared different.

$$| R_3 - R_4 | = | 64.9 - 35.5 |$$

=29.5

Since 29.5 >24.09, R_3 and R_4 were declared different.

Table 13: Treatment ranks and rank totals for the Myofascial DiagnosticScale (placebo)

Consultation	Mean rank	Rank total
Mds1	3.78	3.78×30= 113.4
Mds 2	3.03	3.03×30 =90.9
Mds 4	1.97	1.97×30 =59.1
Mds 5	1.22	1.22×30 =36.6

 R_1 =113.4 R_2 =09.9 R_3 =59.1 R_4 =36.6

$$| R_1 - R2 | = 113.4 - 90.9 |$$

= 22.5

Since 22.5 < 24.09, R_1 and R_2 were declared not different.

 $| R_1 - R_3 | = | 113.4 - 59.1 |$ = 54.3

Since 54.3 > 24.09, R₁ and R₃ were declared different.

Since 78.6 > 24.09, R₁ and R₄ were declared different.

$$| R_3 - R_4 | = | 59.1 - 36.6 |$$

=22.5

Since 22.5 < 24.09, R₃ and R₄ were declared not different.

4.3.4 Tables of the statistical results of intra-group comparison for groups 1 and 2, with regards to subjective findings.

Tables 14: Intra-group comparison for groups 1 and 2, using Friedman'stest to analyze results obtained from the Short form McGill PainQuestionnaire at consultations 1, 2,4 and 5.

		Group 1 (placebo)			Group 2 (treatment))
	Cons 1	Cons 2	Cons 4	Cons 5	Cons 1	Cons 2	Cons 4	Cons 5
Mean	12.333	7.000	5.000	3.400	15.333	9.267	8.133	5.533
S.D.	6.614	4.778	5.965	4.485	8.778	6.448	7.951	5.606
P-value	0.000 (<.001)				0.000	(<.001)		

Short-form McGill Pain Questionnaire

For group 1, the null hypothesis was rejected for the, McGill Short-form Pain Questionnaire, indicating that there was a statistically significant improvement between consultations, at α =0.05 level of significance.

For group 2, the null hypothesis was also rejected for the McGill Short-form Pain Questionnaire, indicating that there was a statistically significant improvement between consultations, at α =0.05 level of significance.

Since the null hypothesis was rejected for the McGill Short-form Pain Questionnaire, the Dunn's procedure (multiple comparison test) was performed to determine which of the treatments were significantly different, for both groups.

Table: 15 Treatment ranks and rank totals for the McGill Short from PainQuestionnaire.

Consultation	Mean rank	Rank total
Mcgill1	3.83	3.83×30= 114.9
Mcgill2	2.33	2.33×30= 69.9
Mcgill4	2.35	2.35×30= 70.5
Mcgill5	1.48	1.48×30= 44.4

R ₁ =114.9	R ₂ =69.9	R ₃ =70.5	R ₄ =44.4	
b=30 (no of	blocks)	k=4 (no of	treatments)	z =2.409

$$|R_1 - R_2| = |114.9 - 69.9|$$

= 45

Since 45 > 24.09 R₁ and R₂ were declared different.

$$| R_1 - R_3 | = | 114.9 - 70.5 |$$

= 44.4

Since $44.4 > 24.09 R_1$ and R_3 were declared different.

$$| R_1 - R_4 | = | 114.9 - 44.4 |$$

= 70.5

Since 70.5 > 24.09, R_1 and R_4 were declared different.

$$| R_3 - R_4 | = | 70.5 - 44.4 |$$

= 26.1

Since 26.1 > 24.09, R_3 and R_4 were declared different.

Table 16: Treatment ranks and rank totals for the McGill Short from PainQuestionnaire(placebo)

Consultation	Mean rank	Rank total
Mcgill1	3.73	3.73×30= 111.9
Mcgill2	2.80	2.80×30= 84
Mcgill4	2.02	2.02×30= 60.6
Mcgill5	1.45	1.45×30= 43.5

 R_1 =111.9 R_2 =84 R_3 =60.0 R_4 =43.5

$$|R_1 - R_2| = |111.9 - 84|$$

= 27.9

Since 27.9 > 24.09, R₁ and R₂ were declared different.

$$|R_1 - R_3| = |111.9 - 60.6|$$

= 51.3

Since 51.3 > 24.09, R₁ and R₃ were declared different.

$$| R_1 - R_4 | = | 111.9 - 43.5 |$$

= 68.4

Since 68.4 > 24.09, R₁ and R₄ were declared different.

$$|R_3 - R_4| = |60.6 - 43.5|$$

= 17.1

Since 17.1 < 24.09, R_3 and R_4 were declared not different.

Table 17: Intra-group comparison for groups 1 and 2, using Friedman'stest to analyze results obtained from the NRS 101 at consultations 1, 2,4and 5.

NRS 101

		Group 1 (placebo)			Group 2 (treatment)			
	Cons 1	Cons 2	Cons 4	Cons 5	Cons 1	Cons 2	Cons 4	Cons 5
Mean	51.117	38.783	30.783	22.333	52.950	47.433	37.633	30.083
S.D.	17.999	20.871	19.032	20.735	17.118	17.560	21.980	22.490
P-value	0.000 (<.001)				0.000	(<.001)		

NRS 101

For group 1, the null hypothesis was rejected for the, NRS 101, indicating that there was a statistically significant improvement between consultations, at α =0.05 level of significance.

For group 2, the null hypothesis was also rejected for the NRS 101, indicating that there was a statistically significant improvement between consultations, at α =0.05 level of significance.

Since the null hypothesis was rejected for the NRS 101, the Dunn's procedure (multiple comparison test) was preformed to determine which of the treatments were significantly different, for both groups.

Table18:Treatment ranks and rank totals for the NRS 101

Consultat	ion Mea	in rank	Rank total
NRS 1	3.37	,	3.37×30= 101.1
NRS 2	2.90)	2.90×30= 87
NRS 4	2.27	7	2.27×30= 68.1
NRS 5	1.47	7	1.47×30= 44.1
R ₁ =101.1	R ₂ =87 R ₃ =68.1	R ₄ =44.1	

b=30 (no of blocks) k=4	(no of treatments) z =2.409

$$| R_1 - R_2 | = | 101.1 - 87 |$$

= 14.1

Since 14.1 < 24.09, R₁ and R₂ were declared not different.

$$| R_1 - R_3 | = | 101.1 - 68.1 = 33$$

Since 33 > 24.09, R_1 and R_3 were declared different.

$$|R_1 - R_4| = |101.1 - 44.1|$$

= 57

Since 57 > 24.09, R₁ and R₄ were declared different.

$$| R_3 - R_4 | = | 68.1 - 44.1 |$$

= 24

Since 24 < 24.09, R_3 and R_4 were declared not different.

Table 19:Treatment ranks and rank totals for the NRS 101(placebo)

Consultation	Mean rank	Rank total
NRS 1	3.58	3.58×30= 107.4
NRS 2	2.90	2.90×30 =87
NRS 4	2.18	2.18×30 =65.4
NRS 5	1.33	1.33×30 =39.9

R₁=107.4 R₂=87 R₃=65.4 R₄=39.9

 $| R_1 - R_2 | = | 107.4 - 87 |$ = 20.4

Since 20.4 < 24.09, R₁ and R₂ were declared not different.

 $| R_1 - R_3 | = | 107.4 - 65.4 |$ = 42 Since 42 > 24.09, R_1 and R_3 were declared different.

 $| R_1 - R_4 | = | 107.4 - 39.9 |$ = 67.5

Since 67.5 > 24.09, R_1 and R_4 were declared different.

| R₃-R₄ | = |65.4-39.9 |

= 25.5

Since 25.5 > 24.09, R_3 and R_4 were declared different.

CHAPTER FIVE

5.0 DISCUSSION

5.1 INTRODUCTION

This chapter consists of a discussion regarding the results reported on in chapter4. Objective measures referred to include the Algometer and MyofascialDiagnostic Scale, while subjective measures include the NRS 101 and Short formMcGill Pain Questionnaire.

Data Obtained from inter-group evaluation is in respect to the first, second, fourth and fifth (follow up) consultation, giving an indication of any statistically significant differences in the subjective and objective findings in terms of the initial presenting signs and symptoms, and the progression between each group throughout the two-week treatment period.

The data obtained from intra-group evaluation also refers to the first, second, fourth and fifth (follow up) consultation, giving an indication of any statistically significant difference between treatments within each group.

5.2 DEMOGRAPHIC DATA

The gender distribution in groups 1 and 2 were similar, however there were twice as many females than there were males (Table 1) who participated in the study. This corresponds with the gender distributions of other similar studies regarding MPS (Wheeler <u>et al</u>. 1998), and other authors conclude that the condition is more prevalent in females than in males (Han and Harrison 1997, Travell <u>et al</u> .1999).

The mean ages for each group were also similar. The age distribution 20-25 held the largest number of patients (20%), with ages 26 - 30 and 31 - 35 having the second largest number of patients (16.6%) (Table 2). Literature has shown that patients aging from 30 - 49 years old have the highest prevalence of TrP's, with

the incidence decreasing with age (Travell <u>et al.</u> 1999). This shows a close correlation with the study as even though the age category 20 - 25 has the highest number of patients, patients aging from 20 - 35 show the highest prevalence, with a decreasing prevalence of the condition with age. This high percentage of patients aging from 20 - 25, is due to the fact that there were 11 students that participated in the study. The research was conducted in a tertiary educational institution and therefore there were a large number of younger patients who responded to the research, causing an increased numbers of patients in this age category. A decreasing prevalence in elderly patients may also be due to the fact that there is an increased dependence on others with age and a majority of elderly patients may not have the ability to respond to the research due to a lack of independence and transport.

Trapezius TrP's 1 and 2 were found to be the most prevalent in both groups of patients who participating in the study, TrP's 3 and 4 were also commonly seen in both groups and TrP's 5, 6 and 7 were infrequently seen. Patients were randomly allocated into groups before active TrP's were identified but no particular difference in TrP prevalence was seen between the two treatment groups. TrP 1 is the most observed of all the myofascial TrP's in the body and TrP 7 is seldom found (Travell <u>et al.</u> 1999) confirming the prevalence of the respective TrP's in this study with other similar studies.

Analysis of patient's occupation for this study, shows that there is the highest prevalence of MPS in students and receptionist /secretaries, and that the majority of patients suffering from MPS are people whose occupation entailed some form of computer or desk work (table 3). Jones(1994) also noted that 65% of patients who participated in his study of "The Effectiveness of Myofascial Trigger Point Therapy on Myofascial Pain Syndrome Trigger Points", were office bound. Fricton <u>et al</u>. (1985) states that although TrP's occur in any skeletal muscle, they are most frequently found in the head, neck, shoulders and lower back. This illustrates the important role posture and ergonomics play in the prevalence of TrP's, and the occurrence of TrP's may be regarded as an occupational hazard.

This role was however not assessed in this research and should be evaluated in further studies.

5.3 SUBJECTIVE DATA

5.3.1 NRS 101

This questionnaire is used to monitor levels of pain perception and quality experienced by patients. Its validity and reliability was established by Jensen <u>et</u> <u>al.</u> (1986). A reduction in the mean score indicates an improvement (decrease) in the pain experienced. The easy manner of using the NRS 101 makes it an ideal tool to use in research of this nature and this scale and other similar such scales are used in various other comparable studies (Garvey 1989, Wreje and Brorsson 1995).

Inter-group comparison

For all the data, the null hypothesis was accepted, indicating that throughout the treatment, there was no difference between the two groups with regards to this questionnaire (worst and least pain experienced). When comparing the two mean values for each group, one can see that a constant improvement was maintained for both groups throughout the treatment period.

Intra-group comparison

Group 2 showed no significant difference between the first and second and the fourth and final consultation (follow up). This indicates no statistically significant difference within the group on these consultations with regards to the NRS 101. A significant difference was seen between the first and fourth and first and final (follow up) consultations, indicating a significant improvement occurring as treatment progressed. Group 1 showed no statistically significant difference was also seen between the first and second consultation, but a significant difference was also seen between the first and fourth, first and final, and the fourth and final consultations indicating a consistent improvement with each consultation after the second treatment.

5.3.2 Short Form McGill Pain Questionnaire.

This pain questionnaire is described by Melzack (1987) "as a means of subjectively providing information regarding the sensory, affective and evaluative dimensions of the patients pain". An improvement is noted by a decrease in the overall values scored.

Inter-group comparison

For all the data, the null hypothesis was once again accepted, indicating that throughout the treatment period there was no difference, with regards to this pain questionnaire, between the two groups.

Intra-group comparison

Group 2 showed a significant difference between the first and second, fourth, and final (follow up), and between the fourth and final (follow up) consultations. This indicates an overall improvement with each consultation with regards to the SFMPQ. Group 1 showed a significant difference between the first and second, fourth, and final (follow up). A significant difference was not seen between the fourth and final consultation.

Patient's mental state and attitude to treatment, as well as their mood at the time of data collection can largely influence the outcome of the subjective data collected. This may be taken into consideration but due to the large (30) sample size; it is unlikely that this may have directly affected the outcome of the study.

For both groups, inter-group statistical analysis of subjective data showed no statistically significant difference between the two groups when using the mentioned questionnaires, although for both sets of data, a constant improvement was seen within each group (one can compare the mean value at each consultation) as the study progressed, and a considerable improvement was seen in both groups between the first and last treatments (Table 6 and 7). All intra-group subjective measures for both groups showed an improvement between the first and final consultations, indicating an overall improvement with both treatments given. These results obtained are similar to findings seen by Mac Dougall (1999), in her study of "The Relative Effectiveness of Proprioceptive Neuromuscular Facilitative Stretching as Compared to the Static Stretching in the Treatment of Active Myofascial Trigger Points". Subjective measures (NRS and SFMPQ were also used) revealed an improvement between the first and last consultations. The study differs in that a one-month follow up was included into the study programme to determine the long term effectiveness of the treatment protocol and the re-occurrence of the condition. A significant improvement was not seen in both groups between the first and follow-up consultation, indicating that the effectiveness was not maintained. The follow up consultation included in this study design was not scheduled one month following the final treatment as the long term effectiveness was not being examined. The follow up consultation was incorporated into the study to avoid data capturing on the final consultation from being adversely affected by post treatment tenderness.

A clinical improvement was evident in both groups, characterizing a decrease in patients' perception of the intensity and the quality of their pain as the treatment progressed. For both groups, inter-group analysis revealed a constant, overall

improvement and intra-group analysis showed an improvement between the first and final consultations. This indicates the effectiveness of dry needling in the treatment of MPS in the above study. The effectiveness of dry needling can be demonstrated in various other similar such studies (Hong 1994). One can conclude that clinically, patients in both groups felt an improvement during the treatment and this improvement was maintained throughout until the final treatment.

Magnesium phosphate, as an adjunct to dry needling, therefore did not prove to be more effective than dry needling alone in reducing the patients intensity and quality of pain in terms of subjective measures.

5.4 OBJECTIVE DATA

5.4.1 Algometer readings

The algometer was used to measure the amount of force that the patient could tolerate on the TrP. An improvement is signified by a decrease in the sensitivity of the TrP and thus an increased pressure allowed over the spot.

Inter-group comparison

For data collected on the first and fifth consultation, the null hypothesis was accepted, indicating that there was no difference between the two groups. Data collection on the second and forth consultation showed that the null hypothesis was rejected, an indication that there was a statistically significant objective difference between the two groups on these consultations. To compare results between the two groups, the Coefficient of variation (C.V) for each group was computed. The group for which the C.V is less is considered to be more consistent, and therefore the group is considered to have performed better. At consultation two, even though group 1 showed a higher mean value, the C.V for group 2 is lower.

(Group 1= 38.11%; group 2= 30.89%).

At consultation four, the C.V for group 2 is once again lower.

(Group1 = 37.02%, group 2= 29.86%)

According to Fischer (1986), immediate effect of a treatment is expressed by a difference in pressure threshold measured before and after a therapeutic session, while long term effects may be assessed by repeated measures. The results of this study confirm this, as there was an increase in the pressure tolerated, signifying the improvement felt by the patients. No algometer readings were taken directly after treatment but readings were taken on the next consecutive consultation. This was done to avoid a decreased pressure tolerance due to any post needling tenderness that may have resulted from the treatment. Algometer readings showed that group 2 had a lower C.V on the second and fourth consultations. Group 2 is therefore assumed to have responded better on the whole on the second and fourth consultation when compared with group 1 and is seen as more consistent with regards to improvement on these particular consultations. Group 2 was the group that received the Magnesium phosphate supplement as an adjunct to the dry needling. It is in the author's opinion and experience that post needling tenderness is usually experienced to a greater degree after the first treatment of dry needling than any other successive treatment. This is also demonstrated in a study by Hong (1994) when comparing pain intensity immediately after the first and second treatment of dry needling in patients where a twitch response was not elicited. Post injection tenderness usually develops 2-8 hours after dry needling and is described as a pain different from the patient's original myofascial pain (Hong 1994). Patients in the group who were receiving the Magnesium phosphate supplements responded better clinically to treatment on the second and fourth consultation in regards to decreased sensitivity and increased pain tolerance over the TrP's. Magnesium phosphate is prescribed in muscular symptoms and is "quick to relieve pain, especially cramping, shooting, darting or spasmodic pains," and this tissue salt is important to the muscular tissue "ensuring rhythmic and coherent movement" (Goodwin 1980:22 - 23). TrP's induce abnormal muscular and autonomic nervous functions resulting in pain, spasm, tremor, stiffness etc. and may maintain a state of reflex muscle guarding by spontaneously firing into the nervous system (Travell et al. 1999). It is the author's opinion that the use of these salts helped decrease the pain experienced due to the presence of active TrP's and helps in

restoring the muscle to it's normal functioning and thus assisting in improving the pain threshold on the mentioned consultations. For both groups an overall improvement is seem between the first and final consultations. A decrease in the mean algometer values is seen in each group when comparing the mean values between the first and final consultations, but these values fluctuated over the treatment period. This may be due to the fact that no stretching exercises were done with the patients after receiving dry needling and a home exercise programme was not given. Stretching following TrP injection/needling is seen as an integral part of the treatment and failure to stretch following injection and / or dry needling can lead to failure of treatment (Travell et al. 1999: 85). Ice and stretching is often used after dry needling to relax remaining tense fibers, followed by the application of a heat pack to reduce post injection/needling tenderness (Travell et al .1999). Post injection/needling tenderness after a few days is often caused by a remaining residual tight band in the muscle and it is in Travells et al. 's (1999) opinion that this can be quickly released by passive stretching with the use of a vapocoolant spray. Patients may have suffered from an increased post needling tenderness as a result of not stretching after receiving dry needling and may have confused this tenderness with pain that they were familiar with due to the presence of TrP's.

Intra-group analysis

Group 2 showed a significant difference between the first and final consultation, indicating an overall progression in treatment throughout the treatment period. Group 1 showed a significant difference between the first and fourth and first and final consultations. Improvement differences seen on the various consultations between the two groups may be explained once again by the failure to ice and stretch after treatment and the failure to eliminate perpetuating factors. A proportion of patients who participated in the research were regular patients at the Chiropractic Clinic and they may have been aware of the importance of perpetuating factors and may have been given various stretches for the condition at prior consultations. They therefore might have had an increased improved when compared to other patients who were not aware of any stretches, as no stretching or postural advice was given to patients until after the research was complete.

5.4.2 Myofascial Diagnostic Scale

This scale was used to determine the extent to which patients were suffering from MPS. A decreased score with treatment indicates an improvement.

Inter-group comparison

Data collection on the first, second and fifth consultation showed that the null hypothesis was accepted, indicating that there was no difference between the two groups on these consultations. Data collection on the fourth consultation showed that the null hypothesis was rejected, indicating that there was a statistically significant difference between the two groups. When comparing the C.V for each group at the given consultation, the C.V. for group 1 (placebo) was lower. (Group 1 = 50.31%; group 2 = 111.9%).

Intra-group comparison

Group 2 showed a significant difference between the first and second; fourth, and final (follow up), and between the fourth and final (follow up) consultations. This indicates an overall improvement with each consultation with regards to the Myofascial Diagnostic Scale. Group 1 showed no significant difference between the first and second, and fourth and final consultations, but a significant difference was seen between the first and fourth and the first and final consultations.

Inter-group analysis showed a statistically significant difference between the two groups on the fourth consultation with regards to this scale. Group 1 has a lower C.V on this consultation, which shows that group 1 responded better to treatment on the fourth consultation, with respect to the MDS, indicating a better response to treatment on a whole at this particular consultation. Objectively, a significance was seen on the second consultation in favour of treatment received by group 2. Consultation four showed conflicting results as algometer readings showed a significant improvement in group 2 and MDS showed a significant improvement in group 1. The MDS is a newly formed method of objective measurement and its

reliability and validity on a whole has not yet been demonstrated in a controlled study. Conflicting results may have arisen from inaccurate utilization of this scale.

Scoring relies on patients' response to various diagnostic criteria and this may have been adversely affected by patient's inaccurate responses. Snapping palpation to evoke a local twitch response is not always easily elicited and this criteria in the scale may have obscured results. The Soft Tissue Tenderness grading used was dependent on the patients' response to pressure applied by the examiner. Patients' individual pain tolerance levels, which are either higher or lower for each individual patient, may have affected this, and the force used by the examiner on the tender areas may have altered with each consultation. The criteria used in this scale that appeared to be the most reliable was the presence of a palpable band within the muscle and the pain experienced in the reference zone. This scale may have caused inaccuracy with data capturing and consequently altered results.

5.5 CONCLUSION

When analyzing the inter-group subjective measures, the first hypothesis is rejected, indicating no significant difference between the two groups, however the effectiveness of dry needling is demonstrated by the constant, overall improvement seen in both groups. With regards to the algometer readings, the second hypothesis was accepted. Patients who received the Magnesium phosphate supplement (group 2) showed an increased pain tolerance over the tender TrP's. Magnesium phosphate has been documented to relieve muscular pains of TrP nature and results of this study demonstrated that dry needling combined with a Magnesium phosphate supplement, increased the pain tolerance over the TrP, indicating that the tissue salt and the effect of the dry needling process worked together to alleviate the TrP pain. This indicates that a tissue salt supplement, Magnesium phosphate, as an adjunct to dry needling, was more effective than dry needling alone in terms of objective measures. In both intra-group analyses, a significant improvement was seen in both treatment groups. A significant difference was only noted between the first and second consultation in both groups with regards to subjective measures (SFMPQ) and only in group 2 with regards to objective measures (MDS).

5.6 LIMITATIONS OF THE STUDY.

Subjective measurements may have been limited in terms of the condition being treated and the treatment protocol being administrated due to patients filling in questionnaires in order to please the researcher therefore influencing the outcome of the results. Objective measures may have been influenced by human error when recording data and faulty use of the apparatus. Taking into account the use of the digital algometer in regards to objective measures should also be considered. This apparatus should only be used in a double blinded study, such as in this particular one, so that researchers bias doesn't affect the out come. This apparatus is operator dependent as the sensitivity is strongly influenced by the force the examiner uses when applying pressure to the tender TrP's. The digital algometer is perhaps over sensitive and readings may be influenced by patient's delay in quick interpretation of pain experienced. It is therefore important to make sure that patients and the clinicians are well educated on the use of this apparatus when using it. A trial should initially be performed on an unaffected part of the patients body e.g. the thenar eminance, so that the patient can feel how the apparatus works. The procedure of taking an average of three reading on each TrP's may also have influenced the final data obtained on each measurement as it was noted that the area being tested either showed an increased sensitivity due to the repeated stimulation of the TrP area with the algometer, causing a decrease in the pain threshold with each measurement, or a desensitizing effect with an increased threshold, due to the ischemic affect of the algometer over the TrP area with each reading. This is one of the disadvantages of using this apparatus and this could possibly be corrected by taking only a single reading on each TrP, instead of an average of three.

Accuracy when re-finding the initial active TrP's may have also influenced data outcome. It is suggested that active TrP's be marked with indelible ink or Henna, so that the involved, original TrP's can be easily located throughout the treatments.

Although the study did include a 5 day follow up, this may have been shortsighted as the research was only spread out over a two week period and a one month follow up would have aided in determining the long-term effects of the two treatments.

A study conducted by Hopwood and Abram (1994) to investigate the factors associated with failure of TrP therapy concluded that several factors should be considered when treating TrP's in that the problem is multidimensional, including a variety of factors influencing the treatment outcome. Perpetuating factors are important and a large part of managing MPS is recognizing any underlying problems that might influence the patient's pain by increasing tension and irritability in the muscle or muscle group (Fomby 1997). It is difficult to accurately assess results as each patient's lifestyle, occupation, social activities etc. were not taken into consideration and possible contributing factors, such as exercise habits, posture, body mechanics, work ergonomics and stress were not reviewed. It is recognized that once perpetuating factors are corrected, pain associated with MPS is more likely to resolve. The study did not incorporate any stretches or ergonomic and posture advise to patients until after the study was completed and therefore perpetuating factors may have persisted through out the study influencing the presence of the TrP's.

From this study, and other similar studies mentioned in chapter 2, we can deduce that dry needling is an effective form of therapy when treating MPS. Many patients however have adverse feelings towards the needling process. Thirty five percent of interested persons responding to the advertisements decided not to partake in the study when the treatment protocol of dry needling was mentioned and the use of a needle in the treatment proved to create limitations when finding a sample for the study. Patients who were skeptical and nervous about the procedure before the start of the research were, however, more relaxed and willing to use dry needling as a form of treatment in the future once they realized that the treatment was not as painful or invasive as they imagined, and the effectiveness of the treatment helped alleviate their concerns.

5.7 COMPARISON OF THE RESULTS WITH SIMILAR/OTHER MPS STUDIES

Wreje and Brorsson (1995) conducted a randomised, controlled trial to test the

hypothesis that cutaneous injections of sterile water had no benefit over saline, as a method of pain reduction among patients suffering from MPS. A sample size of 117 patients was used (91 females, 26 males) and patients only received one treatment. Only subjective measures (visual analogue scale) were recorded before treatment, 10 minutes after the intervention and once again 14 days later. No significant difference in pain level reduction was seen between the two groups at the end of the study. A large sample size is favorable as it creates a greater potential of the sample being a true representation of the population. The use of only subjective measuring tools may not provide an accurate interpretation of results obtained and the use of subjective and objective measuring tools are usually used in such studies (Hong 1994, Jones 1994).

Broome (1996) compared the therapeutic efficacy of invasive needling techniques in the management of a MPS. The study contained a sample size of 30 patients,15 per group, one of which received saline injection and the other dry needling. Both groups were educated on perpetuating factors and were instructed to follow a specific stretching program. Treatment extended over a three week period with a one month follow up and included treatment of the trapezius, levator scapulae, rhomboid major and minor, infraspinatus, supraspinatus, teres major and minor, and the pectoralis major TrP's. The study showed that there was no statistically significant difference between the two treatment groups and both groups showed an improvement to treatment.

Morgan (1997) compared the effectiveness of vitamin supplementation in dry needling and muscle stretching therapy in MPS. This double blinded study contained a sample size of 30 patients (15 patients per group) and was extended over a treatment period of three weeks with a one month follow up. Morgan treated the trapezius, rhomboid and infraspinatus muscles. Patients were also instructed to stretch after treatments, as well as regularly during the days between treatments (three times a day). Both groups in Morgan's study showed a significant improvement over the treatment period, but this was not maintained over the follow up period and no significant difference was seen between the two treatment groups. Both of the above studies contained a small sample size (30), resulting in a sample population that may not be representative of the population of people suffering from MPS. There is also a greater chance of a type two error occurring (accepting a false null hypothesis) on statistical analysis of a smaller sample size. Treatment in Morgan and Broome's studies involved the inactivation of TrP's in the neck and shoulder regions (trapezius, rhomboid, supraspinatus, infraspinatus and teres major and minor) where as in this study, TrP's treatment was limited to the trapezius muscle. Only the trapezius muscle was selected for this study to try and increase homogeneity but TrP's in the trapezius muscle may have been adversely affected due to the presence of satellite TrP's in the neck and shoulder region. Failure to recognize and treat other TrP's in the myotatic unit may be the cause of failure of treatment by continued aggravation of TrP's being treated in the trapezius muscle (Travell et al. 1999:86).

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS.

6.1 CONCLUSION

Inter-group comparison between groups 1 (dry needling) and 2 (*Magnesium phosphate* as an adjunct to dry needling), revealed no significant differences with regards to the response to treatment in terms of subjective measures. (NRS 101 and Short form McGill Pain Questionnaire)

A constant, similar, improvement for both groups was revealed throughout the treatment period.

However, objectively, the Algometer readings revealed a better, more consistent, response to treatment within group 2 on the second and fourth consultation. Group 2 received the *Magnesium phosphate* supplementation and the outcome of results obtained on these consultations may have been due to the effect of the *Magnesium phosphate* given.

The Myofascial Diagnostic Scale indicated a significant difference between the two groups on the fourth consultation, with a more consistent improvement noted in group 1. Both groups showed a constant, positive, overall improvement to treatment with regards to objective measures.

Intra-group analysis revealed that both groups showed a significant improvement within the two-week period, with both groups showing a considerable improvement between the first and final consultation with regards to both subjective and objective measures. Group 2 did however show a statistically significant improvement with regards to objective measures (MDS) between the first and second consultation that was not noted with in group 1.

Analysis of data therefore reveals that the first hypothesis is rejected, as there was no significant difference between the two groups (group 1-dry needling and a placebo supplement, group 2-dry needling and a *Magnesium phosphate* supplement) with regards to subjective data. The second hypothesis was however accepted with regards to objective measures (Algometer readings) on the second and fourth consultations, indicating that a *Magnesium phosphate* tissue salt supplement, as an adjunct to dry needling, was more effective than dry needling alone, in the management of MPS.

From the results it appears that both treatment groups, dry needling (group 1) and dry needling and an adjunct of *Magnesium phosphate* (group 2) have been shown to be effective in the treatment of MPS with regards to subjective and objective measures. Statistical analysis revealed that group 2 did show a significant difference in improvement on the second and fourth consultation with regards to the inter-group comparison of algometer readings. This can be interpreted as a less generalized TrP tenderness experienced on the second and fourth consultation within group 2, indicating less post needling tenderness experienced by this group on these consultations, thus indicating the positive effect of a *Magnesium phosphate* tissue salt supplement, as an adjunct to dry needling in terms of objective measures when comparing Algometer readings between the two groups.

It is in the author's opinion that the use of a *Magnesium phosphate* tissue salt, should be used in combination with dry needling when treating MPS for a more consistent improvement and less post needling tenderness. *Magnesium phosphate* helps restore the muscle to its normal functioning (Goodwin 1980), and thus helps reduce tenderness and pain in the TrP area. Tissue salts are relatively inexpensive and can be used by persons of all ages and can be taken at all times, even during pregnancy (Goodwin 1980). This is beneficial to all practitioners as *Magnesium phosphate* can therefore be administered to all patients who suffer from MPS, assisting the treatment process and helping alleviate commonly occurring pain. From this study we can see that the use of this supplement helped to reducing the effect of post needling tenderness, which appears to be a drawback when using a treatment protocol involving dry needling. This is beneficial to all practitioners who use dry needling to treat MPS as dry needling is recognized as a easy, quick form of treatment (Broome 1996) that is

effective (Lewit 1979, Jones 1994, Travell <u>et al.</u> 1999). *Magnesium phosphate* may consequently aid in achieving a more promising outcome when dealing with MPS.

6.2 **RECOMMENDATIONS**

It is recommended that monitoring of patients with regards to regular consumption of tablets be incorporated into the study. Patients should have been provided with a chart or form of monitoring device to help ensure patients compliance with respects to taking of the *Magnesium Phosphate* supplements. The study relied on patient's compliance and this cannot be guaranteed and this may have influenced the outcome of the study.

It is recommended that the treatment is discussed with each patient, explaining the dry needling process to them and allowing them to voice any adverse feelings, as, if the patient is not comfortable with the process, the patients mind set may adversely effect the outcome of the treatment. Dry needling has been shown to be an effective form of therapy and the patient should always be encouraged to view this form of treatment with an open mind, as it may be the treatment they respond best to. Dry needling is a relatively new form of treatment in the scope of the Chiropractic profession and it is up to practitioners to educate patients on its uses and benefits.

A higher degree of comparability between groups allows for a more valid trial conclusion (Haldeman, 1992:418). A limited variation in patient occupation, hobbies and sporting activities with respects to patient selection may help increase the strength of the study. This would help limit any influence a patient's occupation or sporting activities may have on the outcome of the study and limit aggravating or perpetuating factors. Perpetuating factors were not taken into consideration and stretching and ergonomic advice was not given until after the study was complete, this does not accurately reflect true clinical practice and practitioner should consider this when interpreting results from this clinical trial.

It is recommended that patient's personalities and mental states are taken into consideration. A stress and or personality type questionnaire should be incorporated into the study with regards to stresses experienced in the patient's daily life style. A person's psychological state may have a great influence on their interpretation of pain and may influence their response when referring to the pain experienced during the study. It was noted that a patients' pressure pain threshold was greatly diminished in patients who were stressed or depressed on the day of assessment and this influenced results obtained. Patients' sleep patterns and the average hours of sleep a night should also be incorporated into the questionnaires.

It is recommended that Stress management techniques be incorporated into the treatment programs when dealing with MPS. This will incorporate a multidisciplinary approach when dealing with MPS. A multidisciplinary approach will help improve the outcome and overall wellness of the patient when dealing with MPS and encourages a holistic approach to treatment from a Chiropractic point of view. In this study the only form of treatment received with each consultation was dry needling. It is the author's recommendation that cryotherapy (over the tender TrP) and stretching exercises are always given after each treatment of dry needling and that perpetuating factors are always eliminated when treatment a patient to help reduce re-occurrence of the condition and alleviate pain.

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The efficacy of *Magnesium phosphate,* as an Adjunct to Dry Needling in the Treatment of Myofascial Pain Syndrome.

Shaana van Aardenne¹

ABSTRACT. Objectives: The use of a tissue salt supplement as an adjunct to dry needling has not been described in literature. The goal of this study was to evaluate the efficacy of a *Magnesium phosphate* tissue salt supplement, as an adjunct to dry needling, in the treatment of Myofascial Pain Syndrome (MPS). **Method**: This randomised, clinical trial consisted of a sample size of 60 patients, all suffering from MPS with active trapezius trigger points as the primary symptom. Patients were divided by random sampling into two groups, either receiving treatment of dry needling and a placebo sugar tablet or dry needling and *Magnesium phosphate* tissue salts. Each patient received 4 treatments over a two-week period, with a follow up consultation within five days of the last treatment. Allocation of the supplements given was double-blinded and both groups of patients were instructed to take one tablet three times a day. Statistical analysis included Parametric and non-parametric tests for inter and intra-group analysis.

Results:Results exhibited a substantial improvement in both groups throughout the study, with regards to subjective and objective data. A more consistent, overall improvement was seen in the group that received *Magnesium phosphate* on inter-group objective examination with regards to the algometer readings on the second and fourth consultations, revealing a less trigger point tenderness. A statistically significant improvement with regards to objective intra-group comparison between the first and second consultation was also seen. Results revealed that patients receiving *Magnesium phosphate* responded better to treatment in regards to these measures on the mentioned consultations when compared with those who received placebo tablets.

Conclusion The study demonstrates the effectiveness of dry needing in the treatment of MPS and the use of a *Magnesium phosphate* supplement exhibited reduced trigger point pain and tenderness usually experienced after consultations, avocating the use of *Magnesium phosphate* in the treatment of MPS. Further clinical research needs to be conducted with regards to the long-term effect

of the use of *Magnesium phosphate* in the treatment of MPS and a similar study comparing the effect of a *Calcium phosphate* as a adjunct to dry needling in the treatment of MPS may prove to be beneficial.

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KEYWORDS. Myofascial Pain Syndrome, Trigger points, post needling tenderness *Magnesium phosphate.*

INTRODUCTION

MPS is defined as a muscular pain disorder involving regional pain referred by trigger points (TrP's) within the myofascial structures (7). A TrP is an area of increased hypersensitivity or localized tenderness in a palpable band of painful skeletal muscle, tendon or ligament (8,18). Myofascial pain has been identified as one of the most common causes of chronic pain (9) and is frequently encountered in outpatient settings (1). Reports of the prevalence of MPS in specific patient populations are available and indicate a high prevalence of this condition among individuals with regional pain complaints (26). The incidence of MPS appears to vary between 30% and 85% of people presenting to pain clinics (16,12, 5) and arises more commonly in females, although it is clearly found in both sexes (16). Patients aging from 30-49 years old have the highest prevalence of TrP's, with the incidence decreasing with age (26). There is however a lack of recent updated studies investigating the incidence and prevalence of this condition. Varieties of perpetuating factors are associated with recurrent pain and pain unresponsive to MPS treatment (1). Perpetuating factors are numerous, underestimated, and require special knowledge to recognize their importance when dealing with TrP's (26). Characteristically, pain referred by TrP's is the main symptom and is either continuous or intermittent in nature (1), with an abrupt or gradual onset (26) and is recognized as a steady, deep and achy pain, with occasional sharp, lancinating, burning or lightening like stabs. A number of causes of TrP formation are speculated, but a widely accepted neurophysical or pathological explanation for the formation of MPS is lacking (1), and attempts to characterize TrP's have been disappointing and controversial. MPS is often resistant to therapy (28) and a multidisciplinary approach to treatment, has appeared to be most beneficial (16). Management is usually aimed at restoring hyperactive muscle spindles to normal functioning (18), and there are many suggested methods for providing repetitive stimulation to inactivate TrP's. Treatment includes modalities such as trigger point injection, dry needling, stretch and spray, ice and stretch, heat therapy, electrotherapy, ischaemic compression and spinal adjustments (1.16,26). Trigger point injection/needling has been recognized as an effective and therapeutic approach when treating MPS. A study conducted on the effects of dry needling verses local anaesthetic injection into a TrP and found that both groups had significant improvement after treatment, however post injection tenderness (which was different to TrP pain) developed in all of the patients who had received dry needling, but only in 42% of patients who had received local anaesthetic (17).

Inorganic mineral therapy is available in the health care field through means of biochemical tissue salts (4) and is used to maintain or restore the correct balance of natural mineral salts found in the body. The principle of this system of biochemical salts is related to the principles used in Homeopathy, and even though

'biochemistry and Homeopathy are distinct branches of medicine, they both use the principle of a minute dose and the selection of the remedy according to the symptoms (15). These salts are however not necessarily regarded as a complete treatment for a disease or symptoms, but a valuable part of treatment in connection with other therapies deemed necessary for the treatment of conditions (15). *Magnesium phosphate* is used as a remedy in the treatment of "nerve and muscle symptoms" (4), and is prescribed as an antidotal treatment for: "cramping muscles, pain that is sharp, boring, radiating, lightning-like, neuralgic and spasmodic in nature and often accompanied by a constricting feeling (2). The pain is recognized to be located mostly over the "nape of the neck and back region" and can "involve the extremities" (4). The condition treated with *Magnesium phosphate* shares a combination of symptoms present in MPS, showing that there may be a close link between the two treatments.

PATIENTS AND METHOD.

Advertisements for patients suffering from neck and shoulder pain, and/or headaches, were posted around the local campus, sporting institutes and health shops. Patients responding to the advertisements were interviewed telephonically to determine if they were suitable candidates for the study and underwent further detailed examination on the initial consultation to determine eligibility into the study. A sample size of sixty patients were selected by means of convenience sampling. All subjects included into the study had to meet inclusion criteria and only patients suffering from active trapezius TrP's as the primary cause of pain were considered for the study and were screened as per the Myofascial Diagnostic Scale (6) to determine the extent to which they suffered from MPS. On acceptance in to the study, patients were asked not to take any allopathic medication for the condition, nor receive any forms of treatment, including Chiropractic adjustments, electrotherapies or soft tissue therapies for the duration of their participation in the study. Convenience, random, allocation was used to separate the patients into two equal groups. Both groups received a supplement to take over the course of the treatment. Group 1 received a placebo supplement and group 2 received Magnesium phosphate; neither the researcher nor the patients were aware of the group that they were in until after all the data was collected at the end of the study. Patients in both groups were required to take one tablet, three times a day and were instructed to either place the tablets under the tongue or alternatively suck them, allowing the tablets to dissolve in the mouth. Treatment of both groups,1 and 2, consisted of a maximum of 4 consultations over a two week period and active treatment of dry needling was carried out on both groups at each consultation. The treatment site was cleaned with 70% alcohol prior to treatment and a new, sterile, 0.25×30mm needle was used with each treatment. The fanning dry needle insertion method was used (25). Patients were treated for the maximum of four allocated treatments, unless they were asymptomatic before the end of the study. Patients were assessed subjectively and objectively prior to the first, second and the fourth treatment and on a follow up consultation within a 5-day period of the fourth treatment that was scheduled for data capturing. Objective clinical findings were

obtained through the use of a pressure algometer (Pain Diagnosis and Thermography Corporation, Pain Threshold Meter, Model PTH – AF2) (10,23), and a Myofascial Diagnostic Scale (6). Subjective data was obtained by asking the patients to complete two questionnaires. The Numerical Pain Rating Scale (NRS) 101 (20)and the Short Form McGill pain questionnaire (24) were used. Due to the sample size for each group, both parametric and non-parametric tests were used for inter and intra-group analysis. Non-parametric tests were used to analyze ordinal data. Parametric tests were used to analyze continuous variables (interval and ratio data).

The Mann Whitney U-test was used for the inter-group comparison of each of the ordinal variables (Short Form McGill and Myofascial Diagnostic Scale). In each test, the null hypothesis (Ho) stated that there was no difference between the two independent samples being compared, with respect to the variables tested, at ∞ =0.05 level of significance. The alternative hypothesis (H₁) stated that there was a difference between the two independent samples being compared.

The unpaired t-test was used for inter-group comparison of each of the continuous variables (NRS 101 and Algometer). In each test, the null hypothesis (Ho) stated that there was no difference between the two independent samples being compared, with respect to the variables being tested, at $\infty = 0.05$ level of significance. The alternative hypothesis (H₁) states that there was a difference between the two independent samples being compared.

The Friedmans test was used for intra-group comparison of all variables (Short Form McGill and Myofascial Diagnostic Scale, NRS 101, Algometer). In each test, the null hypothesis (Ho) states that there was no improvement between the consultations, with respect to the variables being tested, at $\infty = 0.05$ level of significance. The alternative hypothesis (H₁) states that there was an improvement.

If the null hypothesis was rejected for Friedmans test, then a multiple comparison procedure was applied to determine which of the treatments were significantly different and the Dunn's Post test was then performed.

RESULTS

The gender distribution in groups 1 and 2 were similar, however there were twice as many females than there were males, (Table 1) who participated in the study. This corresponds with the gender distributions of other similar studies regarding MPS (27).

Table 1: Gender distribution

GENDER GROUP 1 GROUP 2 TOTAL %

MALES	9 (30%)	11 (36.33%)	33.3
FEMALES	21 (70%)	19 (63.3%)	66.6

The mean ages for each group were also similar. The age distribution 20-25 held the largest number of patients (20%), with ages 26 - 30 and 31 - 35 having the second largest number of patients (16.6%) (Table 2). Literature has shown that patients aging from 30 - 49 years old have the highest prevalence of TrP's, with the incidence decreasing with age (26).

Age distribution	Group1 (placebo)	Group 2 (treatment)	Total percentage of patients
20-25	6	6	20%
26-30	5	5	16.6%
31-35	5	5	16.6%
36-40	1	5	10%
41-45	4	2	10%
46-50	4	3	11.6%
51-55	4	3	11.6%
56-60	1	1	3.3%

Table 2: Age distribution

Analysis of patient's occupation showed that there was the highest prevalence of MPS in students and receptionist /secretaries, and that the majority of patients suffering from MPS where people whose occupation entailed some form of computer or desk work. Although TrP's occur in any skeletal muscle, they are most frequently found in the head, neck, shoulders and lower back (7). This illustrates the important role posture and ergonomics play in the prevalence of TrP's, and the occurrence of TrP's may be regarded as an occupational hazard.

Trapezius TrP's 1 and 2 were found to be the most prevalent in both groups of patients who participating in the study, TrP's 3 and 4 were also commonly seen in both groups and TrP's 5, 6 and 7 were infrequently seen. TrP 1 is the most observed of all the myofascial TrP's in the body and TrP 7 is seldom found (26).

For both groups, inter-group statistical analysis of subjective data showed no statistically significant difference between the two groups although for both sets of data, a constant improvement was seen within each group when comparing the mean value at each consultation as the study progressed, and a considerable improvement was seen in both groups between the first and last treatments. All intra-group subjective measures for both groups showed an improvement between the first and final consultations, indicating an overall improvement with both

treatments given. *Magnesium phosphate*, as an adjunct to dry needling, therefore did not prove to be more effective than dry needling alone in reducing the patients intensity and quality of pain in terms of subjective measures.

The second hypothesis was however accepted with regards to objective measures (Algometer readings) on the second and fourth consultations, indicating that a *Magnesium phosphate* tissue salt supplement, as an adjunct to dry needling, was more effective than dry needling alone, in the management of MPS.

ALGOMETER READINGS

Inter-group comparison between groups 1 and 2, using the Unpaired t-test to analyze results obtained from the Algometer readings at consultation 1,2,4 and 5.

ALGOMETER READINGS.										
	<u>Group 1 (</u>	placebo)			Group 2 (treatment)					
	<u>Mean</u>	<u>S.D</u>	<u>S.E</u>	<u>P-val</u> ue	<u>Mean</u>	<u>S.D</u>	<u>S.E</u>			
<u>Con 1</u>	<u>26.390</u>	<u>8.780</u>	<u>1.600</u>	<u>0.539</u>	<u>24.913</u>	<u>9.720</u>	<u>1.776</u>			
<u>Con 2</u>	<u>27.980</u>	<u>10.600</u>	<u>1.940</u>	<u>0.038</u>	<u>22.990</u>	<u>7.100</u>	<u>1.297</u>			
<u>Con 4</u>	<u>33.000</u>	<u>12.200</u>	<u>2.230</u>	<u>0.006</u>	<u>25.580</u>	<u>7.640</u>	<u>1.395</u>			
<u>Con 5</u>	<u>31.490</u>	<u>12.500</u>	22.800	<u>0.183</u>	<u>27.667</u>	<u>9.250</u>	<u>1.689</u>			

Data collected on the first and fifth consultations showed that the null hypothesis was accepted, indicating that there was no difference between the two groups. Data collection on the second and forth consultation showed that the null hypothesis was rejected, an indication that there was a statistically significant objective difference between the two groups on these consultations. To compare results between the two groups, the Coefficient of variation (C.V) for each group was computed. The group for which the C.V is less is considered to be more consistent, and therefore the group is considered to have performed better. At consultation two, the C.V for group 2 was lower.

(Group 1= 38.11%; group 2= 30.89%).

At consultation four, the C.V for group 2 was lower. (Group1 = 37.02%, group 2= 29.86%).

Intra-group comparison using Friedman's test to analyze results obtained from

the Algometer readings, between consultation 1 and 2, 4 and 5.

Algometer readings								
		Group 1	(placebo)		Group 2 (treatment)			
	Cons 1	Cons 2	Cons 4	Cons 5	Cons 1	Cons 2	Cons 4	Cons 5
Mean	26.391	27.98	33.08	31.495	24.913	22.99	25.59	27.667
S.D.	8.789	10.665	12.221	12.514	9.726	7.103	7.641	9.254
P-value		0.003	(<.001)			0.003	(<.001)	

For both groups the null hypothesis was rejected, indicating that there was a statistically significant difference between consultations. The Dunn's procedure was preformed to determine which treatments were significantly different. A significant difference was seen in Group 2 between the first and final consultation, indicating an overall progression in treatment throughout the treatment period. Group 1 showed a significant difference between the first and fourth and first and final consultations.

MYOFASCIAL DIAGNOSTIC SCALE

Inter-group comparison between groups 1 and 2, using the Mann Whitney U-test to analyze results obtained from the Myofascial Diagnostic Scale, at consultations 1,2,4 and 5.

Myofascial Diagnostic Scale										
	<u>Group 1 (</u>	(placebo)	<u>Group 2 (</u>	treatment)						
	<u>Mean</u>	<u>S.D</u>	<u>S.E</u>	<u>P-Val</u> ue	<u>Mean</u>	<u>S.D</u>	<u>S.E</u>			
<u>Con 1</u>	<u>10.867</u>	<u>0.482</u>	<u>0.482</u>	<u>0.520</u>	<u>11.200</u>	<u>8.770</u>	<u>1.603</u>			
<u>Con 2</u>	<u>9.033</u>	<u>1.991</u>	<u>0.363</u>	<u>0.830</u>	<u>9.230</u>	<u>6.440</u>	<u>1.170</u>			
<u>Con 4</u>	<u>5.633</u>	<u>2.834</u>	<u>0.517</u>	<u>0.019</u>	<u>7.100</u>	<u>7.951</u>	<u>1.450</u>			
<u>Con 5</u>	<u>3.333</u>	<u>3.241</u>	<u>0.592</u>	<u>0.266</u>	<u>3.800</u>	<u>5.606</u>	<u>1.020</u>			

Data collection on the first, second and fifth consultation showed that the null hypothesis was accepted, indicating that there was no difference between the two groups on these consultations. Data collection on the fourth consultation showed that the null hypothesis was rejected, indicating that there was a statistically significant difference between the two groups. When comparing the C.V for each group at the given consultation, the C.V. for group 1 (placebo) was lower. (Group 1 = 50.31%; group 2 = 111.9%).

Intra-group comparison for groups 1 and 2, using Friedman's test to analyze results obtained from the Myofascial Diagnostic Scale, at consultations 1, 2, 4 and 5.

Myofascial Diagnostic Scale

	Group 1 (placebo)					Group 2 (treatment)			
	Cons 1	Cons 2	Cons 4	Cons 5	Cons 1	Cons 2	Cons 4	Cons 5	
Mean	10.867	9.033	5.633	3.333	11.233	9.233	7.1	3.8	
S.D.	1.907	1.991	2.834	3.241	1.455	2.208	2.998	2.953	
P-value	0.003 (<.001)					0.003	(<.001)		

For both groups the null hypothesis was rejected indicating that there was a statistically significant improvement between consultations, at α =0.05 level of significance. The Dunn's procedure revealed a significant difference between the first and second; fourth, and final (follow up), and between the fourth and final (follow up) consultations for Group 2, indicating an overall improvement with each

consultation. Group 1 showed no significant difference between the first and second, and fourth and final consultations, but a significant difference was seen between the first and fourth and the first and final consultations.

NUMERICAL RATING SCALE 101

Inter-group comparison between groups 1 and 2, using the Unpaired t-test to analyze results obtained from the NRS 101, at consultations 1,2,4 and 5.

<u>NRS 101</u>

		roup 1				roup 2	
		nlaceho)				eatment)nla	
	<u>Mean</u>	<u>S.D</u>	<u>S.E</u>	P-Value	<u>Mean</u>	<u>S.D</u>	<u>S.E</u>
<u>Con 1</u>	<u>51.117</u>	<u>17.997</u>	<u>3.286</u>	<u>0.688</u>	<u>52.950</u>	<u>17.118</u>	<u>3.125</u>
<u>Con 2</u>	<u>38.783</u>	<u>20.870</u>	<u>3.811</u>	<u>0.088</u>	<u>47.433</u>	<u>17.559</u>	<u>3.206</u>
<u>Con 4</u>	<u>30.783</u>	<u>19.032</u>	<u>3.475</u>	<u>0.202</u>	<u>37.633</u>	<u>21.980</u>	<u>4.013</u>
<u>Con 5</u>	<u>22.333</u>	<u>20.735</u>	<u>3.786</u>	<u>0.171</u>	<u>30.083</u>	<u>22.490</u>	<u>4.106</u>

For all the data the null hypothesis was accepted, indicating that throughout the treatment, there was no difference between the two groups with regards to this questionnaire (worst and least pain experienced). When comparing the two mean values for each group, one could see that a constant improvement was maintained for both groups throughout the treatment period.

Intra-group comparison for groups 1 and 2, using Friedman's test to analyze results obtained from the NRS 101 at consultations 1, 2,4 and 5.

NRS 101

Group 1 (placebo)

Group 2 (treatment)

				NRS 101	RS 101				
	Cons 1	Cons 2	Cons 4	Cons 5	Cons 1	Cons 2	Cons 4	Cons 5	
Mean	51.117	38.783	30.783	22.333	52.95	47.433	37.633	30.083	
S.D.	17.999	20.871	19.032	20.735	17.118	17.56	21.98	22.49	
P-value		0.000	(<.001)			0.000	(<.001)		

For both groups the null hypothesis was rejected indicating that there was a statistically significant improvement between consultations, at α =0.05 level of significance. Since the null hypothesis was rejected the Dunn's procedure was preformed to determine which of the treatments were significantly different. No significant difference was seen in group 2 between the first and second and the fourth and final consultations (follow up), indicated no statistically significant difference within the group. A significant difference was seen between the first and fourth and first and final (follow up) consultations, indicating a significant improvement occurring as treatment progressed. Group 1 showed no statistically significant difference was seen between the first and second consultation, but a significant difference was seen between the first and final consultations indicating a consistent improvement with each consultation after the second treatment.

SHORT FORM McGILL PAIN QUESTIONNAIRE

Inter-group comparison between groups 1 and 2, using the Mann Whitney U-test to analyze results obtained from the Short Form McGill Pain Questionnaire, at consultations 1,2,4 and 5.

Short Form McGill Pain Questionnaire

	Group 1	(placebo)		Group 2 (treatment)			
	<u>Mean</u>	<u>S.D</u>	<u>S.E</u>	<u>P-Val</u> ue	<u>Mean</u>	<u>S.D</u>	<u>S.E</u>
<u>Con 1</u>	<u>12.330</u>	<u>6.614</u>	<u>1.208</u>	<u>0.171</u>	<u>15.33</u> <u>3</u>	<u>8.778</u>	<u>1.603</u>
<u>Con 2</u>	<u>7.000</u>	<u>4.778</u>	<u>0.872</u>	<u>0.192</u>	<u>9.267</u>	<u>6.448</u>	<u>1.177</u>
<u>Con 4</u>	<u>5.000</u>	<u>5.965</u>	<u>1.089</u>	<u>0.099</u>	<u>8.133</u>	<u>7.951</u>	<u>1.452</u>
<u>Con 5</u>	<u>3.400</u>	<u>4.485</u>	<u>0.898</u>	<u>0.119</u>	<u>5.533</u>	<u>5.606</u>	<u>1.236</u>

For all the data the null hypothesis was accepted, indicating that throughout the treatment period there was no difference between the two groups.

Intra-group comparison for groups 1 and 2, using Friedman's test to analyze results obtained from the Short form McGill Pain Questionnaire at consultations 1, 2,4 and 5.

Short-form McGill Pain Questionnaire

	Group 1 (placebo)				Group 2 (treatment)			
	Cons 1	Cons 2	Cons 4	Cons 5	Cons 1	Cons 2	Cons 4	Cons 5
Mean	12.333	7	5	3.4	15.333	9.267	8.133	5.533
S.D.	6.614	4.778	5.965	4.485	8.778	6.448	7.951	5.606
P-value	0.000 (<.001)					0.000	(<.001)	

For both groups the null hypothesis was rejected indicating that there was a statistically significant improvement between consultations.

Since the null hypothesis was rejected, the Dunn's procedure was performed to determine which of the treatments were significantly different. Group 2 showed a significant difference between the first and second, fourth, and final (follow up), and between the fourth and final (follow up) consultations, indicates an overall improvement with each consultation. Group 1 showed a significant difference between the first and second, fourth, and final (follow up) consultations. A significant difference was not seen between the fourth and final consultations.

DISCUSSION

From the results it appears that both treatment groups, dry needling (Group 1) and dry needling and an adjunct of *Magnesium phosphate* (Group 2) have been shown to be effective in the treatment of MPS with regards to subjective and objective measures.

Statistical analysis revealed that group 2 did show a significant difference in improvement on the second and fourth consultation with regards to the inter-group comparison of algometer readings. Group 2 had a lower C.V on the second and fourth consultations and is therefore assumed to have responded better on the whole when compared with group 1 and is seen as more consistent with regards to improvement on these particular consultations. Group 2 received the Magnesium phosphate supplementation and the outcome of results obtained on these consultation may have been due to the effect of the Magnesium phosphate given. Magnesium phosphate is prescribed in muscular symptoms and is "quick to relieve pain, especially cramping, shooting, darting or spasmodic pains," and this tissue salt is important to the muscular tissue "ensuring rhythmic and coherent movement" (15). TrP's induce abnormal muscular and autonomic nervous functions resulting in pain, spasm, tremor, stiffness etc. and may maintain a state of reflex muscle guarding by spontaneously firing into the nervous system (26). It is the researchers opinion that the use of these salts helped decrease the pain experienced due to the presence of active TrP's and helped in restoring the muscle to it's normal functioning and thus assisting in improving the pain threshold on the mentioned consultations.

A decrease in the mean algometer values is seen in each group when comparing the mean values between the first and final consultations, but these values fluctuated over the treatment period. This may have been due to the fact that no stretching exercises were done with the patients after receiving dry needling and a home exercise programme was not given. Stretching exercises following TrP injection/needling is seen as an integral part of the treatment and failure to stretch following injection can lead to failure of treatment (26). Ice and stretching is often used after dry needling to relax remaining tense fibers, followed by the application of a heat pack to reduce post injection tenderness (26). Post injection/needling tenderness after a few days is often caused by a remaining residual tight band in the muscle and this can be quickly released by passive stretching with the use of a vapocoolant spray (26). Patients may have suffered from an increased post needling tenderness as a result of not stretching after receiving dry needling and may have confused post needling tenderness with pain that they were familiar with due to the presence of TrP's. Perpetuating factors are important and a large part of managing MPS is recognizing any underlying problems that might influence the patient's pain by increasing tension and irritability in the muscle or muscle group (11). It is difficult to accurately assess results as each patient's lifestyle, occupation, social activities etc. were not taken into consideration and possible contributing

factors, such as exercise habits, posture, body mechanics, work ergonomics and stress were not reviewed. It is recognized that once perpetuating factors are corrected, pain associated with MPS is more likely to resolve. The study did not incorporate any stretching exercises or ergonomic and posture advice to patients until after the study was completed and therefore perpetuating factors may have persisted through out the study influencing the presence of the TrP's. It is the researchers recommendation that cryotherapy (over the tender TrP) and stretching exercises are always given after each treatment to avoid an increased post needling tenderness experienced and that perpetuating factors are always eliminated with treatment.

Consultation four showed conflicting results as algometer readings showed a significant improvement in group 2 and MDS showed a significant improvement in group 1. The MDS is a newly formed method of objective measurement and its reliability and validity on a whole has not yet been demonstrated in a controlled study, and it's validity is taken at face value. Conflicting results may have risen from inaccurate utilization of this scale. Scoring relies on patients' response to various diagnostic criteria and this may have been adversely affected by patient's inaccurate responses. Snapping palpation to evoke a local twitch response is not always easily elicited and this criteria in the scale may have obscured results. The Soft Tissue Tenderness grading used was dependent on the patients' response to pressure applied by the examiner. Patients' individual pain tolerance levels, which are either higher or lower for each individual patient, may have affected this, and the force used by the examiner on the tender areas may have altered with each consultation. The criteria used in this scale that appeared to be the most reliable was the presence of a palpable band within the muscle and the pain experienced in the reference zone. This scale may have caused inaccuracy with data capturing and consequently obscured results.

It is in the author's opinion that the use of a *Magnesium phosphate* tissue salt, should be used in combination with dry needling when treating MPS for a more consistent improvement and less post needling tenderness. *Magnesium phosphate* helps restore the muscle to its normal functioning (15), and thus helps reduce tenderness and pain in the TrP area. Tissue salts are relatively inexpensive and can be used by persons of all ages and can be taken at all times, even during pregnancy (15). This is beneficial to all practitioners as *Magnesium phosphate* can therefore be administered to all patients who suffer from MPS, assisting the treatment process and helping alleviate commonly occurring pain. From this study we can see that the use of this supplement helped to reducing the effect of post needling tenderness, which appears to be a drawback when using a treatment protocol involving dry needling. This is beneficial to all practitioners who use dry needling to treat MPS as dry needling is recognized as a easy, quick form of treatment (3) that is effective (22,21). *Magnesium phosphate* may aid in achieving a more promising outcome when dealing with this commonly occurring condition.

RECOMMENDATIONS

Although the study did include a 5 day follow up, this may have been shortsighted as the research was only spread out over a two week period and a one month follow up would have aided in determining the long-term effects of the two treatments. A patient's personalities and mental states should also be taken into consideration. A stress and or personality type questionnaire should be incorporated into the study with regards to stresses experienced in the patient's daily life style. A person's psychological state may have a great influence on their interpretation of pain and may influence their response when referring to the pain experienced during the study. It was noted that patients pressure pain threshold was greatly diminished in patients who were stressed or depressed on the day of assessment and this influenced results obtained. It is recommended that Stress management techniques be incorporated into the treatment programs when dealing with MPS. This will incorporate a multidisciplinary approach when dealing with MPS. A multidisciplinary approach will help improve the outcome and overall wellness of the patient when dealing with MPS and encouraging a more comprehensive approach to treatment.

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