A SYSTEMATIC REVIEW OF THE NON-INVASIVE THERAPEUTIC MODALITIES IN THE TREATMENT OF MYOFASCIAL PAIN AND DYSFUNCTION

By

Adelle Kemlall Roopchand

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I, Adelle Kemlall Roopchand, do declare that this dissertation is representative of my own work in both concept and execution and that any use of work by others has been acknowledged in the text.

Adelle Kemlall Roopchand	Date

Approved for submission

Dr. C. Korporaal M.Tech: Chiropractic, CCFC, CCSP, ICSSD Supervisor	Date
Dr. G. Harpham M.Tech: Chiropractic Co-Supervisor	Date

Dedication

To my parents,

Dad, every dream I have dreamed has been for you. I hope you are looking down upon me and are proud of who I am

and

Mum, your everlasting support, sacrifice, strength and guidance have helped me turn so many dreams into reality. If I can grow to be half the woman you are my life will be complete.

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To my colleagues, the roads we have travelled upon have not always been easy, after many long sleepless nights and anxious days we have reached the end of this journey, but we have learned together and learned from each other. I wish you all success and happiness. Together lets fly the

flag of Chiropractic high. Thank you all for the memories we have made and the good times we have shared.

To my lecturers, clinicians and other members of staff, thank you for the knowledge and skills that you have taught me, you have all contributed greatly to the person I have grown to be.

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Abstract

Background: Myofascial Pain and Dysfunction (MPD) is a diagnosis commonly encountered by practitioners, hence, there are several treatment approaches employed by various practicing physicians. Practitioners are required to perform evidence-based protocols on patients; however, such intervention becomes increasingly difficult with the increasing volume of evidence available with regards to treatment of MPD. A systematic review provides a well-structured, critical analysis of the available protocols, and as such, provides practitioners with an evidence-based summary of the available modalities and the effectiveness of these modalities. Thus, the aim of the study was to systematically review and evaluate the literature to determine the effects of various non-invasive modalities on MPD.

Objectives: Studies investigating various non-invasive modalities were identified, evaluated against the inclusion criteria and then reviewed against PEDro criteria to present current available evidence regarding their effectiveness as a source of treatment for MPD.

Methods: A literature search was conducted, based on key terms including: active and latent myofascial trigger points, manual therapy, manipulation, acupressure, massage, muscle stretching, ultrasound, transcutaneous electric nerve stimulation, electric stimulation therapy, magnetic field therapy, and exercise therapy. Databases searched were: PubMed, EBSCOhost, Medline, CINAL, Proquest, Health Source, Sport Discus, Science Direct, Springer Link, Google Scholar and Summons. The articles were screened according to inclusion and exclusion criteria, after which a secondary hand and reference searches were performed. Thereafter, the articles were reviewed by four independent reviewers and the researcher. The PEDro Scale was used to determine methodological rigor of the included studies. The results were then analysed and ranked.

Results: Following the screening process during data collection for this study, a total of 25 studies were identified and included. The review and ranking of these studies revealed a moderate level of evidence present for the effectiveness of Topical Agents. A limited level of

evidence was noted for TENS, Ischemic Compression, Ultrasound, Laser and Other Modalities. Approximately 25% of the reviewed studies involved combination therapies; hence their outcomes cannot be applied to the effectiveness of individual modalities.

Conclusion: Upon comparison of the quality of evidence available for the various types of modalities present for the treatment of MPD, it was noted that Topical Agents were supported by a stronger level of evidence than TENS, Ischeamic Compression, Ultrasound, Laser and Other Modalities. However, due to a lack of strong overall evidence for any of these modalities it has been concluded that more research is required to establish which modality is in fact the most effective.

Keywords: active and latent myofascial trigger points, manual therapy, manipulation, acupressure, massage, muscles stretching exercises, ultrasound, transcutaneous electric nerve stimulation, electric stimulation therapy, magnetic field therapy, exercise therapy, ischeamic compression.

Table of Contents

List of Figures

List of Tables

Chapter Five

List of Appendices

Definitions

Case Studies and Observational Studies: studies in which patients are observed before and after receiving specific interventions, without random allocation or control groups (Cassell and Symons, 2005; Creswall, 2009; Wells *et al.,* 2011; Shaughnessy *et al.,* 2005).

Data: A collection of information and statistics combined for use in analyses and referencing (Mouton, 1996).

Intervention: An act performed with the aim of assisting in the treatment or cure of a condition (Haldeman, 2005).

Invasive Therapy: refers to any therapy that penetrates below the soma (anything derived from the ectoderm of the embryo) and / or is taken orally, rectally or has its means of action applied through a mechanism that is not directly related to the soma (Huber *et al.,* 2001).

Myofascial Pain and Dysfunction (MPD): MPD is defined as the presence of muscular pain that may be generalized or localized. This pain is caused by the presence of hypersensitive spots within the muscle, known as MFTPs (Travell and Simons, 1992; Perez-Palomares *et al.,* 2009; Srbely, 2010 and Rodriguez-Fernandez *et al.,* 2011).

Myofascial Trigger Points (MFTP): A MFTP is defined as a hyperirritable and hypersensitive nodule within a muscle that occurs due to acute or chronic overload of that muscle (Travell and Simons, 1992; Sorrell and Flanagan, 2003; Fernandez-de-las-Penas *et al.,* 2006; Ge *et al.,* 2011).

Narrative reports: studies similar to systematic reviews that analyse articles, but in a narrative manner (Creswall, 2009).

Non-invasive Therapy: refers to any therapy that is applied to the soma (anything derived from the ectoderm of the embryo) from an external source (Huber *et al., 2001*).

Non-randomized Controlled Trials (non-RCT): studies in which participants that were not allocated into groups through the use of random allocation (Creswall, 2009; Wells *et al.,* 2011).

Peer-reviewed articles: Articles that have been reviewed by individuals in the same field, who possess knowledge on the subject (as in the context of this study, the individuals have knowledge of MPD (Scollen and Scollen, 1995).

Randomized Controlled Trials (RCT): studies in which the participants are allocated randomly. This type of study is known as the gold standard for a clinical trial. RCTs are often used to test the effectiveness of various types of interventions (Cochrane 2011).

Sample: A small part which is considered to be representative of a larger community (Mouton, 1996). I have removed amount - an amount of what?

Systematic Review: a "systematic review is a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyze data from the studies that are included in the review" in order to determine the level of evidence with regards to a specific treatment or condition (Buchbinder *et al.,* 2006).

Abbreviations

ADP:	Adenosine Diphosphate
AECC:	Anglo-European Chiropractic College
AMFTPs:	Active Myofascial Trigger Points
ATP:	Adenosine Triphospate
ATrPT:	Activator Trigger Point Therapy
CONSORT:	Consolidated Standards of Reporting Trials
COT:	Control TENS
CROM:	Cervical Range of Motion
EPS:	Electric Point Stimulation
ESWT:	Extracorporeal Shock Wave Therapy
HFT:	High Frequency low-intensity TENS
HIT:	High Frequency high intensity TENS
HPPTUS:	High-Power Pain Threshold Ultrasound
IC:	Ischeamic Compression
IMT:	Intra-oral Myofascial Therapy
INS:	Interactive Neurostimulation Therapy
LLLT:	Low Level Laser Therapy
LMFTPs:	Latent Myofascial Trigger Points
MBT:	Myofascial Band Therapy
MFTP:	Myofascial Trigger Point
mins	Minutes
MPD:	Myofascial Pain and Dysfunction
Non-RCT:	Non-randomized Controlled Trial
NRS:	Numeric Rating Scale
PA:	Pressure Algometer
PhH:	Phonophoresis of Hydrocortisone
PPA:	Pain Pressure Algometer
PPT:	Pain Pressure Threshold
PR:	Pressure Release
PRISMA:	Preferred Reported Items for Systematic reviews and Meta Analyses
RCT:	Randomized Controlled Trial

rMS:	Repetitive Magnetic Stimulation
ROM:	Range of Motion
SEA:	Spontaneous Electrical Activity
sec	Seconds
TENS:	Transcutaneous Electric Nerve Stimulation
TMJ:	Temporomandibular Joint
TPI:	Trigger Point Injection
TrPPR:	Trigger Point Pressure Release
US:	Ultrasound
VAS:	Visual Analogue Scale

CHAPTER ONE
INTRODUCTION

1.1 Introduction

Myofascial Pain and Dysfunction (MPD) is a diagnosis often encountered by practicing chiropractors (Rickards, 2006). The concept of MPD has been a topic of discussion for decades among health care professionals worldwide (Dommerholt *et al.,* 2006; Rodriguez-Fernandez *et al.,* 2011; Muscolino, 2012). MPD is defined as the presence of muscular pain that may be generalized or localized. This pain is caused by the presence of hypersensitive spots within the muscle, known as myofascial trigger points (MFTPs) (Travell and Simons, 1992; Perez-Palomares *et al.,* 2009; Srbely, 2010; Rodriguez-Fernandez *et al.,* 2011).

In order to address MFTPs and thus MPD, patients may be treated by the use of simple lifestyle changes (e.g. exercise, diet) medication (e.g. analgesics, muscle relaxants, antidepressants, non-steroidal anti-inflammatory drugs) and manual therapies (e.g. manipulation, dry needling, massage, ischaemic compression, ultrasound, laser therapy, transcutaneous electric nerve stimulation (TENS), the spray and stretch method, hot and cold therapy as well as myofascial trigger point injection) (Alvarez and Rockwell, 2002).

Research has indicated that dry needling (an invasive technique) is generally the most effective modality for MPD; however, in cases where invasive modalities are inappropriate such as, patients who are extremely young or old as well as patients who have clotting disorders and other contraindications to needling, effective non-invasive techniques are required (Bruce, 1995; Han and Harrison, 1997; Alvarez and Rockwell, 2002). These non-invasive techniques, which are most commonly used for the treatment of these patients include, but are not limited to: ischaemic compression, laser, topical agents, hot and cold therapy, stretching techniques, TENS and ultrasound (Alvarez and Rockwell, 2002; Rickards, 2006; Vernon and Schneider, 2008). This research aimed to; highlight the most clinically efficient non-invasive treatment protocols by means of a systematic review. In doing so, such a review may provide practitioners with the evidence they require to choose the most effective non-invasive modality for patients. This would enable the practitioner to gain quick and effective access to information on the most clinically effective non-invasive interventions in order to facilitate the best possible outcome for their

patient. In addition, such a review ensures that practitioner treatment protocols are a combination of clinical knowledge, research evidence and patient preference (Murray *et al.,* 2007).

Consequently, a systematic review is utilised as a research platform to record, analyse and report current research evidence. Moreover, a "systematic review is a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review" in order to determine the level of evidence with regards to a specific treatment or condition (Buchbinder *et al.,* 2006). Furthermore, with the development and progression of manual health care professions, chiropractic in particular, there have been a considerable number of clinical trials performed to investigate the effectiveness of various non-invasive modalities (Vernon and Schneider, 2008). Therefore, this systematic review creates a critical evidence based evaluation of the available modalities, thus establishing the most effective non-invasive modality for the alleviation of MPD.

1.2 Aims and Objectives

1.2.1 Aims

This study aimed to determine the level of evidence available for the treatment of MPD in which non-invasive techniques were used, by creating an evidence based, non-bias critical analysis of previously conducted RCTs in order to investigate the efficacy of these non-invasive techniques.

1.2.2 Objectives

Objective one determined the level of methodological rigour (via an accepted systematic review scale - the PEDro Scale) of studies investigating non-invasive myofascial techniques. This was achieved through the following methodological steps:

- All articles investigating the effectiveness of non-invasive myofascial techniques by means of randomised clinical controlled trials (RCTs) for the treatment of MPD were identified by means of electronic data base searches (primary search).

- A secondary hand search and a reference search for articles that may have been omitted during the electronic searches were performed (Moher *et al.,* 2003 and Liberati *et al.,* 2009).
- Articles included in the systematic review from both the primary and secondary searches were screened for use by the inclusion and exclusion criteria.
- All the included articles were critically assessed by means of a blinded review using the PEDro Scale.

Objective two contextualised and summarized the available level of evidence for the use of non-invasive myofascial techniques in clinical practice. This was presented via a summary of the available evidence for each intervention, which was correlated with the clinical outcomes achieved in the respective articles.

1.3 Rationale

MPD forms a large component of the many conditions which are encountered by chiropractors / manual therapists on a regular basis (Travell and Simons, 1992; Bruce, 1995; Han and Harrison, 1997 and Chaiamnuay *et al.*, 1998; Haldeman, 2005; Fernandez-de-las-Penas, *et al.*, 2010). There are various modalities used for the treatment of MPD which is caused by MFTPs (Gerwin, 2010). These modalities include protocols such as: dry needling, ultrasound, TENS, heat therapy, stretching techniques, and exercise protocols. The effectiveness of these modalities vary greatly (Alvarez and Rockwell, 2002; Chaitow and DeLany, 2002; Rachlin and Rachlin, 2002; Gerwin, 2010).

It has been indicated that dry needling despite its invasive nature is more effective than the non-invasive treatment protocols used (Bruce, 1995; Han and Harrison, 1997; Alvarez and Rockwell, 2002). Thus, it is more commonly used as a treatment modality for MPD (Huguenin, 2004). Despite the effectiveness of dry needling, it cannot be used for certain patients, for example; the geriatrics, paediatrics, patients with clotting insufficiencies, and / or patients with phobias for needles (Alvarez and Rockwell, 2002). It is in these cases that the various non-invasive therapies become a focus of attention (Chaitow and DeLany, 2000; Gerwin, 2001; Hains *et al.*, 2010).

A dilemma arises when practitioners are required to make evidence based decisions on which non-invasive modality is most effective (Gerwin, 2010). This is where systematic reviews serve as a source of critically analysed and summarized information. Two previous systematic reviews regarding this topic have been completed: Rickards (2006) compiled a systematic review which only rated studies performed on active MFTPs. This study concluded that only a small percentage of the articles included in the study were actually effective in the treatment of active MFTPs, however, it was also noted that for reliable conclusion of the effectiveness of these interventions further research was required. Later, Vernon and Schneider (2008) compiled a review which included active and latent MFTPs. This study concluded that there was acceptable support for certain manual therapies and physiological therapies in the treatment of MFTPs. However, this review included acupuncture studies, which are invasive in nature and it did not include modalities such as: proprioceptive neuromuscular facilitative stretching and the use of heat and ice (as other optional non-invasive modalities). Therefore, there was a lack of a cohesive systematic review that included all non-invasive therapies for MFTPs (Dommerholt and Hijbrechts, 2010).

Thus this systematic review aimed to identify and critically assess non-invasive studies, including those which were not included in previous reviews as well as those which have been conducted during the period that extends from the end of data collection of previous systematic reviews, to the beginning of data collection of this systematic review.

1.4 Benefits

MPD, as a result of MFTPs, is a diagnosis that affects many patients and the treatment for this specific diagnosis varies greatly (Travell and Simons, 1992; Alvarez and Rockwell, 2002; Rickards, 2006; Gerwin, 2010).Consequently, there are a large number of studies that attempt to address the effectiveness and efficacy of the various interventions for the various nuances of the clinical presentation of the MPD / MFTPs syndromes. This creates a vast amount of information that may have limited applicability in clinical practice. This predisposes the interventions utilized to treat MPD / MFTPs to be applied in clinical practice without the required underpinning literature to support evidence based, patient informed and ethical practice (Sackett *et al.*, 1997; Chapman-Smith, 2000), because of its extensive use (Travell and Simons, 1992; Hong and Simons, 1998 Testa *et al.,* 2003 and Yap, 2007).

In order to address these problems, there are several different research mechanisms, such as a meta-analysis, a systematic review, a commentary and / or narrative report / literature review (Centre for Reviews and Dissemination, 2008; Cochrane, 2011).

In this context, the narrative report / literature review and commentary are representations of literature which has not undergone critical analysis of the data collection, measurement and reporting processes. By contrast, the meta-analysis is a critical, strictly statistical analysis of the literature. This latter report requires specific research skills and experience to both interpret and understand the information (Dagenais and Haldeman, 2012). Additionally, a meta-analysis requires the multiple rigorously structured published studies in order to allow for maximum efficacy with regards to the analysis of the clinical outcomes, thus, allowing for the achievement of a conclusion in favour / not in favour of a particular technique (Mulrow, 1994; Bero *et al.,* 1997; Bero *et al.,* 1998).

Systematic reviews, on the other hand, aim to gather, analyse and summarize the evidence available on the efficacy of these treatment methods (Moher *et al.,* 2000; Moher *et al.,* 2003; Liberati *et al.,* 2009; Buchbinder *et al.,* 2006). As a result, the systematic review employs both research techniques as well as critical analysis of the publication in order to draw conclusions that are accessible to field practitioners (Eddy, 1982; Bero *et al.,* 1998). This is because systematic reviews allow for evidence to be evaluated without needing evidence that may not yet be available (Fisher *et al.,* 1990; www.pedro.org.au, 1999; Wells *et al.,* 2011). However, whatever data is available still constitutes sufficient data to rigorously interrogate and critique in order to arrive at a clinically relevant conclusion (Eddy, 1982; Bero *et al.,* 1998). Thus, this form of investigation enables the researchers, clinicians and academics to have access to readily available information about a particular review (Dagenais and Haldeman, 2012).

Therefore in essence, systematic reviews provide relatively current, summarization of research resources for practitioners in clinical practice (Williamson *et al.,* 1989; Davidoff *et al.,* 1995; Cook *et al.,* 1997; Shea *et al.,* 2007). This has been attributed to the systematic reviews, as they produce information that enables concise answering of clinical questions which cannot be answered by the evidence produced by single primary studies (Eddy, 1982; Davidoff, 1995; Fox, 2005). In addition, the systematic review also provides a nexus from which further research questions can be developed and investigated (Chalmers and Haynes, 1994; Cook *et al.,* 1997;

Lavis *et al.,* 2005; Shea *et al.*, 2007). A systematic review is able to achieve these outcomes as it provides a level field of comparison whilst still taking into consideration the discrepancies amongst the outcomes of clinical publications with regards to their scientific rigour (Eddy, 1982; Pedrini *et al.,* 1996; Cook *et al.,* 1997; Moher *et al.,* 2003).

Furthermore, systematic reviews also provide a source of information for health care administrators / medical aid schemes and other third party payers, which they are able to utilize to determine and drive policy (Mulrow, 1994; Chalmers and Haynes, 1994; Cook *et al.,* 1997) and for use in their decision making processes (Moher *et al.,* 2003; Fox, 2005).

In the context of the discussion above (clinical, academic and / or research), systematic reviews provide for collaboration platforms and frameworks (Chalmers and Haynes, 1994) and are able to drive the allocation of resources (Chalmers and Haynes, 1994).

Therefore, it is essential that systematic reviews are regularly completed in fields that generate many clinical studies with regards to clinical interventions. Thus, according to the Cochrane recommendations, it is noted that systematic reviews should ideally be updated at least every two years (Higgins and Green, 2011). Considering that the previous reviews on MPD / MFTPs were completed in 2006 and 2008, this systematic review will present an update of the evidence (with particular reference to non-invasive therapies) which will allow practitioners to make treatment protocol decisions based on the most recent studies, and the critical analysis of their outcomes. By enabling practitioners to make more educated decisions (Liberati *et al.,* 2009), this study enables better and more effective patient care and pain relief from MPD due to MFTPs based on evidence based principles (Sackett *et al.,* 1996).

1.5 Limitations

The included articles were limited to those which had been originally published in English or had been translated into English (Egger *et al.,* 1997; Moher *et al.,* 2000; Sterne *et al.,* 2001; Shea *et al.,* 2007; Cochrane, 2011). Therefore, a number of publications may have been excluded from this systematic review. This limitation was as a result of a limited budget (financial and time) within the structure of this Master's degree. Due to the mentioned budget limitation, translation of non-English studies was not possible. Thus, it is recommended that future systematic reviews investigating non-invasive interventions for MFTPs and MPD include non-English publications to assess for and reduce the language bias (Moher *et al.,* 1999) that their exclusion may have introduced. This recommendation, although contrary to the literature (Moher *et al.,* 1996; Egger *et al.,* 1997), is made to improve the clarity of future systematic reviews (Moher *et al.,* 1998). This is, however, in agreement with the suggestion that studies which have yielded positive outcomes seem to have been published in the English language or in particular countries (Moher *et al.,* 2000; Moher *et al.,* 2003; Shea *et al.,* 2007; Cochrane 2011).

The articles included were limited to published and peer reviewed articles. Although peer reviewed articles increases the credibility of a study, other studies, such as non-published articles (for example: Master's dissertations) cannot be ignored because outcomes from such investigations may reflect significant evidence which may have contributed to this review. Exclusion of such data is referred to as publication bias (Moher *et al.,* 2000; Moher *et al.,* 2003; Shea *et al.,* 2007; Cochrane 2011). The inclusion of what is referred to as "grey literature" (unpublished / non-peer reviewed / difficult to locate / difficult to retrieve literature) in the literature search and the systematic review is one approach that can be used to overcome this bias (Cook *et al.,* 1993; Man-Son-Hing *et al.,* 1998; Moher *et al.,* 1999). However, according to Cook *et al.,* (1993); Last, (1995); and McAuley *et al.,* (2000), the use of grey literature is still a source of debate, as it requires multiple analysis tools that may not be comparable and may also skew results when the predominance of studies are not well structured.

Although the reviewers involved in this study were provided with the PEDro Scale and an explanatory guide (Baynham, 1995; Scollen and Scollen, 1995) (Appendix 1.1) for the use of this scale, this scale was open to the reviewers' personal interpretation. This could have allowed differences between the reviewers' PEDro Scale rankings that were not directly as a result of the

methodological rigor of the study under review (Bero *et al.*, 1998). However, it must also be considered that the converse may be true, in that individual interpretation of presentation of a study could also have resulted in variations in the reporting of the scale. Therefore, when needed, the researcher was available to explain, but not assist the reviewers with interpretation of any individual study (Bero *et al.*, 1998).

Lastly, further perplexing factors which need to be regarded as external limitations include indexing inconsistencies (Hersh and Hickman, 1992; Vilke *et al.*, 1995; Moher *et al.*, 1999) and the reporting style adopted by authors of trials (Moher *et al.*, 1994; Begg *et al.*, 1996; Moher *et al.*, 1996), according to their respective guidelines e.g. the **CONSORT (viz. Consolidated Standards of Reporting Trials)** (Cochrane, 2011).

1.6 Conclusion

This chapter has outlined the basic foundation for this study. However, a proper understanding of MPD, MFTPs and systematic reviews is required to fully interpret and appreciate such a study. Therefore, Chapter Two focuses on presenting the literature that provides in depth explanations of these topics; Chapter Three describes the detailed methodology that was used to perform the review and ascertain viable results whereas Chapter Four presents the findings from the reviews performed. Chapter Five interprets these findings in relation to the literature and Chapter Six concludes the study and provides suggestions for future studies.

CHAPTER TWO
LITERATURE REVIEW

2.1 Introduction

This chapter consists of a detailed discussion of the relevant literature regarding the aetiology, epidemiology, physiology as well as the anatomy of MFTPs. This will be followed by a discussion on MPD and how myofascial trigger point result in diagnosis as well as a discussion on the non-invasive treatment of MPD. This will follow with an explanation of the concept of, reasons for and the correct procedure with regards to systematic reviews.

2.2 Anatomy of Skeletal Muscle

Skeletal muscle is voluntary muscle that is involved in the movement and stabilization of the joints (Standring, 2008). Under normal circumstances, the main functions of these muscles are to produce movement of the body and to resist the force created by gravity (Levangie and Norkin, 2004). They are also involved in providing heat for the body (Tortora and Derrickson, 2006). These skeletal muscles consist of varied combinations of long cylindrical muscle fibres (Wheater *et al.*, 1993). These muscles vary in size and shape with general characteristics being a fleshy bundle. The contractile belly of the muscle fibres which are attached to bones and joints via non-contractile bands of tissue are known as tendons (Standring, 2008). Normal joint function is most often reliant on appropriately functioning muscles (both singularly and in conjunction with other skeletal muscles) to achieve the normal functional ability and therefore the required movement (Myers, 2006; Veeger and van der Helm, 2007; Moraes *et al.*, 2008; McKinley and O'Loughlin, 2012).

In order to achieve this optimum function, muscles are required to function well at a cellular level. Thus, it is necessary to look at the micro / cellular level of a muscle (Figure 2.1).

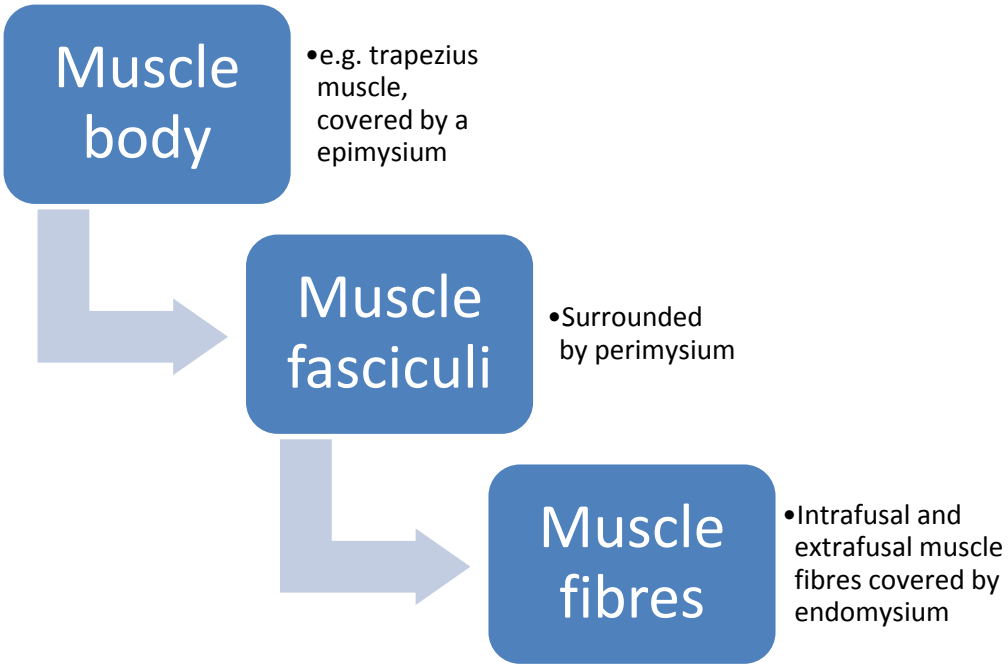

Figure 2.1: Muscle structure (schematic) (Adapted from Wheater *et* al., 1993; Young *et al.*, 2006; Tortora and Derrickson, 2011)

Each of the muscle fibres are encapsulated by sacromeres, which contain contractile proteins known as myofilaments (e.g. actin and myosin), which are responsible for the contractile process within a muscle fibre (Clancy and McVicar, 2002). Upon muscle contraction, these muscle fibers shorten, thus creating a shortening in the muscle itself (Dalley and Moore, 2006; Tortora and Derrickson, 2006; Robergs and Roberts, 1997; Standring, 2008). This contractile process starts with calcium being released (as a result of Acetylcholine release) (Dommerholt *et al.*, 2006) and depolarization of the muscle fibre) by the sacroplasmic reticulum into the sarcoplasm (Beck, 2009). This calcium binds with troponin resulting in the movement of tropomyosin away from the myosin binding sites on the actin filaments, releasing the actin and myosin to start the contractile cycle (Tortora and Derrickson, 2011). This process also releases and enables ADP and several other enzymes, which strengthen the actin-myosin complex and assist in shortening the sarcomere (Robergs and Roberts, 1997). However, the cycle ends when ATP binds to the actin-myosin bond, which breaks the bond. This bond would then remain open if troponin were free in the sarcoplasm. However, if calcium is still available, there is little chance that the troponin will bind to the myosin, leaving the site open for the actin to re-engage. This implies that the contraction will again occur, a sequence referred to as "contraction cycling" (Robergs and Roberts, 1997). This cycle may continue as long as there is sufficient ATP and calcium in the

region of the binding sites, as these two elements facilitate the contractile process within the muscle fibre (Clancy and McVicar, 2002).

The above can be summarised effectively in the four basic phases of skeletal muscle contraction as depicted in Figure 2.2.

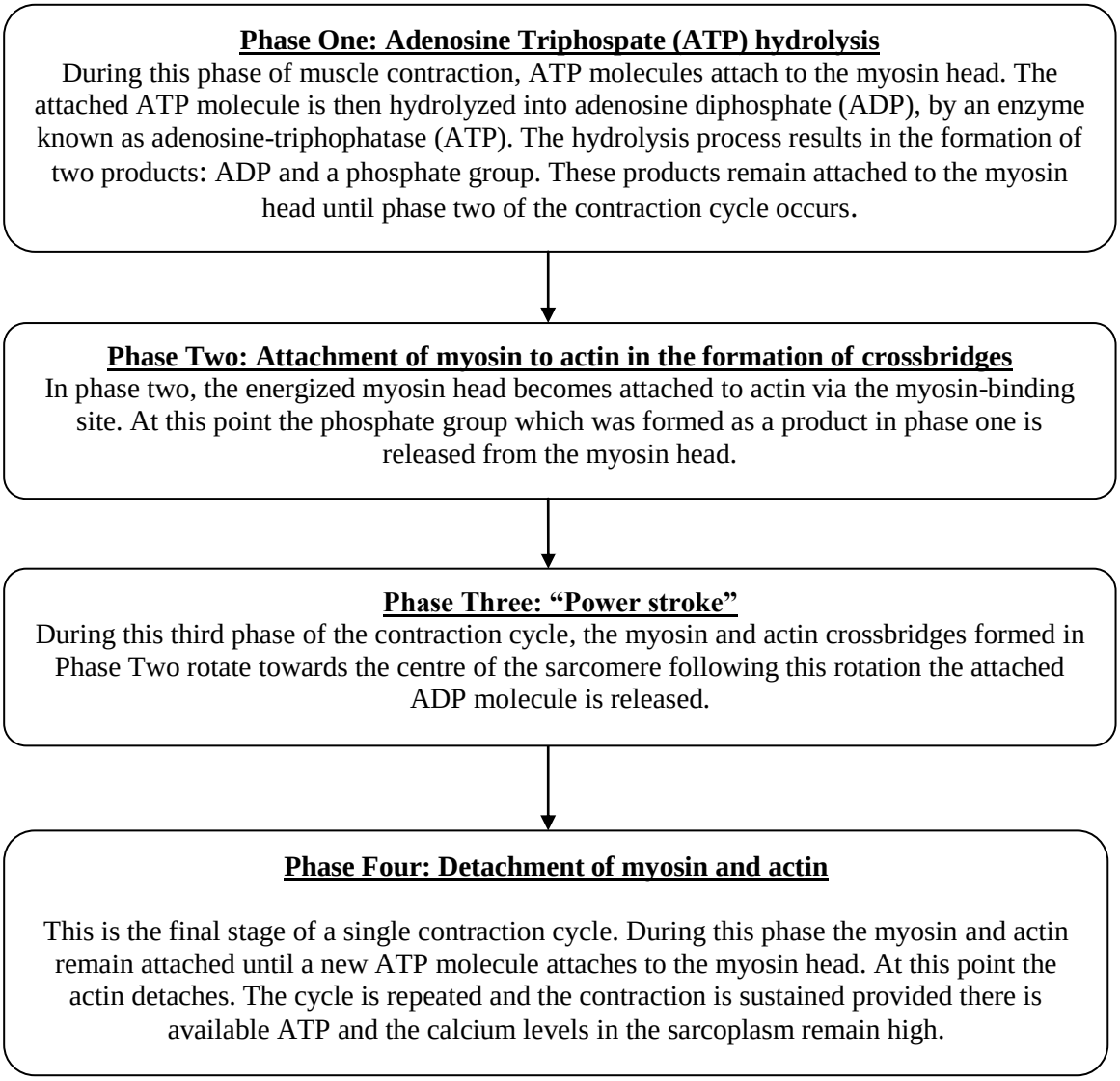

Figure 2.2: The physiology of the contraction cycle in skeletal muscle (Tortora and Derrickson, 2006).

To maintain this level of activity, ATP production and the release of calcium along with nutrients and oxygen need to be continually supplied and conversely waste products need to be removed (Clancy and McVicar, 2002; Beck, 2009). These processes therefore underpin the ability of a muscle to sustain a contraction. They are, however, negatively impacted by muscular contractions obstructing blood flow (also known as a "relative ischemia") (Travell, Simons and

Simons, 1999) which limits the muscle's ability to obtain nutrients and oxygen, generate ATP, and allow for calcium transport as well as to remove accumulating waste products. Gissel, (2006) and Ge *et al.*, (2011) see these processes as a self-limiting factor, implying that when the muscle is depleted of the required nutrients, it will relax and allow for replenishment (a mechanism that attempts to prevent the muscle reaching fatigue). However, this self-righting mechanism is only possible when the nutrients / minerals needed to pump the calcium back into the sacroplasmic reticulum are sufficient in order to achieve the task (Robergs and Roberts, 1997). When this does not happen, it is thought that the muscle stays within a state of continued contraction or hypertonia and the process becomes a strong negative feedback loop which reinforces the contraction (Gissel, 2006). This is evidenced when there is abnormal depolarization of the motor end plates (McPartland and Simons, 2006). This was more recently supported by Ge *et al.*, (2011), who indicated that a disturbance of muscle tissue can be noted immediately after the termination of any muscle contraction (evidenced by cytoskeletal disturbances, loss of myofibrillar registry and / or the loss of cell integrity neuroaxonal degeneration). These changes are often observed in conjunction with hypercontracted muscle regions, along with the invasion of inflammatory cells and neuromuscular transmission disorders (Chang *et al.*, 2008). The muscle fibre hypercontraction seems to occur alongside fibre plasma membrane lesions and results in short sarcomere lengths (Duncan and Jackson, 1987; Friden and Lieber, 1998). These changes are further complicated by the influx of calcium from the interstitium, mitochondrial overload and the development of reactive oxygen species (Gissel, 2006; Ge *et al.*, 2011); which increase the damage in a "self-reinforcing manner" and maintain the contractile state of the muscle (Gissel, 2006). This hypothesis supports Shah *et al.*, (2005), who indicated that elevations of inflammatory mediators (e.g. substance P, CGRP, bradykinin) are present in active MFTPs, as compared to latent MFTPs and/ or normal muscle (Shah *et al.*, 2005). This is thought to arise out of the inflammatory reaction and hypercontractile phases that are continually maintained – an inherent component of the integrated hypothesis (Simons, 2008). Shah *et al.*, (2005) suggests there is the negative feedback loop which connects the "energy crisis" within the MTFP to the changes surrounding it and is responsible for the noxious stimulation of local nociceptors (which in turn are responsible for local and / or referred pain associated MFTPs / MPD) (Travell, Simons and Simons, 1999; Chaitow and DeLany, 2000).

2.3 Myofascial Trigger Points

2.3.1 Definition

A MFTP is defined as a hyperirritable and hypersensitive nodule within a muscle that occurs due to acute or chronic overload of that muscle (Travell and Simons, 1992; Sorrell and Flanagan, 2003; Fernandez-de-las-Penas *et al.,* 2006; Ge *et al.*, 2011). These nodules can be divided into two major groups; active and passive MFTPs (Travell and Simons, 1992; Gerwin, 2001 and Ge *et al.,* 2011). An active MFTP is a trigger point that is painful at rest and without any external stimulus, it produces pain patterns specific to the muscle within which it is present and it produces clinically significant effects (Chaitow and DeLany, 2000 and Bron *et al.,* 2011). Conversely, a latent MFTP is asymptomatic at rest and only produces pain upon the introduction of an external stimulus such as palpation (Travell and Simons, 1992; Dommerholt *et al.,* 2006 and Rodriguez-Fernandez *et al.,* 2011).

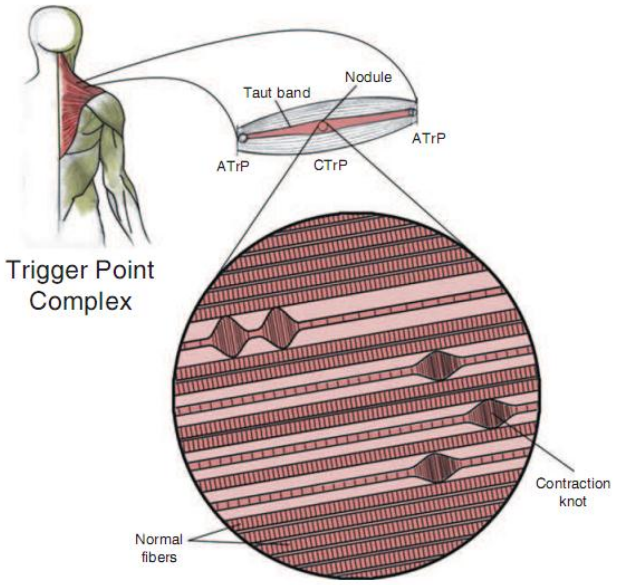

Figure 2.3: The trigger point complex (Gerwin 2010) (Permission for use of this image was received via personal communication with the author (Gerwin, 2014) (Appendix 2.1).

In both forms, MFTPs form an extremely important component of musculoskeletal dysfunction (Fricton *et al.,* 1985; Skootsky *et al.,* 1989; Gerwin, 1995 and Fernandez-de-las-Penas *et al.,* 2003). Pain caused by MFTPs, (if not treated correctly and effectively) will have the potential to become a hindrance to normal functioning and daily functioning of the body may become

hampered (Travell and Simons, 1992; Harden *et al.,* 2000; WHO, 2006; Huguenin, 2004 and Yap, 2007).

2.3.2 Aetiological and Perpetuating Factors of MPD and MFTPs

Although the precise aetiology of MFTPs remains unknown, there are many factors which have been noted to contribute to their development and progression (Baldry, 1993; Gerwin, 2001). The major contributor to the formation of MFTPs is a change in the demand placed on a specific muscle. Therefore, it can be assumed that either acute direct trauma or chronic micro-trauma processes can play significant roles in MFTP development (Alvarez and Rockwell, 2002; Sharma *et al.*, 2010). Incidents of acute direct trauma may include: sports injuries, direct blows to the involved area, car accidents and other falls or injuries. Chronic micro-trauma occurs when there is prolonged and repeated shortening of the muscle fibers. This can be as a result of elements such as poor posture, poor motor habits as well as aspects such as, ill-fitting clothing, shoes and ill-proportioned work appliances (Travell and Simons, 1992; Baldry, 1993; Gerwin, 2001 and Huguenin, 2004).

Dommerholt *et al.,* (2006) indicated that the aetiological factors that result in the development of MFTPs can be divided into four major categories based on muscle function / dysfunction;

- **Low level contractions**: Overloading of a muscle results in potential damage and degeneration of small (Type I) fibers within the muscle, as they are usually recruited first and de-recruited last during muscle contraction. The damage to these fibers increases the calcium levels and perpetuates the cycle as explained in Figure 2.2.
- **Changes in intramuscular pressure**: A continuous contraction cycle due to chemical imbalances results in excessive pressure on the capillaries supplying the muscle. This causes decreased circulation within the muscle.
- **Direct trauma**: Direct injury to the muscle causes the sarcoplasmic reticulum to be damaged, thus causing an increase in calcium and a decrease in ATP. This causes MFTPs by the Pathophysiology (explained in Figure 2.6).
- **Eccentric and sub-maximal concentric contractions**: Firstly, these exercises have been linked to a decrease in blood flow which causes ischemia within the muscle. Secondly, the lengthening of muscle fibers that occurs as a result of eccentric and sub-maximal concentric contractions has been noted to be uneven and irregular. This causes a change

in the organization of the A-band as well as streaming of the Z-band, thus resulting in disruptions of the cytoskeleton proteins.

In contrast, Gerwin (2010) utilises the following description of aetiological and perpetuating factors, which is based predominantly on the type of predisposing factor:

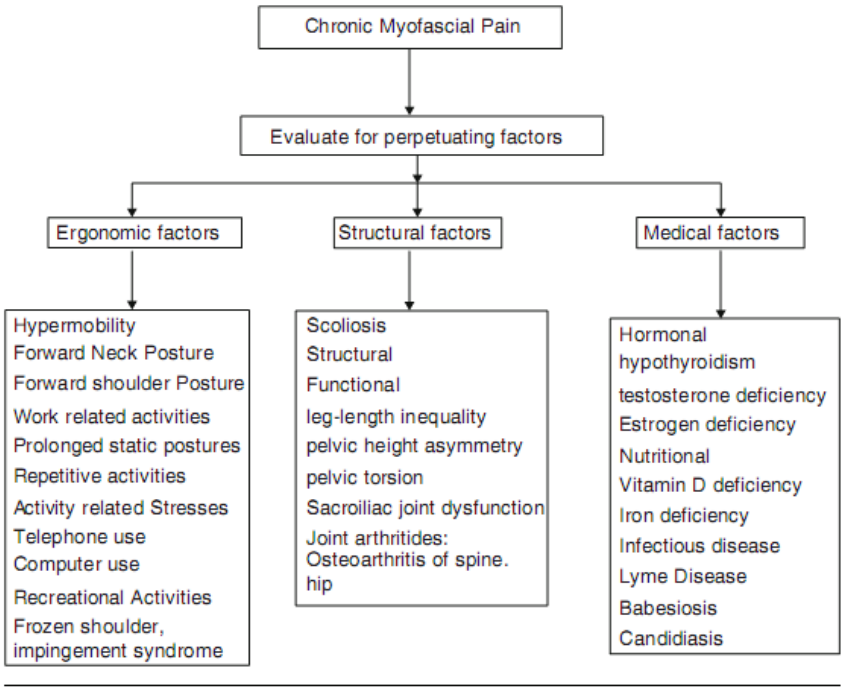

Figure 2.4: The evaluation of perpetuating factors (Gerwin 2010) (Permission for use of this image was received via personal communication the author (Gerwin, 2014) (Appendix 2.1).

Whereas Baldry (1993), Travell and Simons (1999), Chaitow and Delany (2002), Gerwin (2004) and Yap (2007) have classified MFTPs according to Table 2.1, in which precipitating factors are divided into Mechanical and Disease related, which in turn, are further classified into primary and secondary causes. This categorization seems to be inclusive of the suggested categories shown in Figure 2.4 and the list by Dommerholt (2006).

Table 2.1 Precipitating Factors

Mechanical causes	**Disease related causes**		
Primary Causes	Secondary Causes	Primary Causes	Secondary Causes
Ergonomic stresses Forward head posture Hypermobility syndromes Mechanical abuse- this may be through acute, sustained or repetitive muscle overload i.e. prolonged muscle contraction Sacroiliac joint dysfunction Muscle imbalances (mechanical asymmetries) Somatic (muscle-joint) dysfunction Trauma Nerve root compression	Compensating synergist and antagonist muscles Satellite referral MFTPs	Febrile illness Drug induced myalgia Systemic biochemical imbalances	Infections Allergies Nutritional deficiencies Low oxygenation of tissues

Adapted from Baldry (1993), Travell and Simons (1999), Chaitow and DeLany (2002), Gerwin (2004) and Yap (2007)

By contrast, Hubbard (1998), Travell and Simons (1999), Chaitow and DeLany (2002), and Yap (2007) have separately highlighted a number of perpetuating factors, which they have listed distinctly from those that are associated predisposing or aetiological factors:

Table 2.2 Perpetuating Factors

1	Mechanical stresses, such as: furniture not ergonomically arranged, poor posture, prolonged immobility, skeletal anomalies such as a shorter leg, small hemipelvis or a long second metatarsal bone (Morton's foot).
2	Nutritional inadequacies, such as: decreased levels of vitamins B1, B6, B12, folic acid and iron. Inadequate levels of calcium, potassium, and several trace minerals will result in abnormal muscle functioning.
3	Metabolic and endocrine inadequacies: hypometabolism (hypothyroidism), hyperuricemia and hypoglycaemia perpetuate MFTPs.
4	Psychological factors, such as: anxiety and depression may delay recovery of MFTPs.
5	Chronic infection, such as: viral, bacterial or parasitic.
6	Other factors: physical and emotional stress; strenuous activity and prolonged immobilization can perpetuate MFTPs, impaired sleep, fatigue, cold damp weather, allergy, chronic visceral disease, and radiculopathies.
7	LMFTPs: reactivation may lead to perpetuation of symptomatology of MPD It may also predispose to development of AMFTPs.

Adapted from Hubbard (1998), Travell and Simons (1999), Chaitow and DeLany (2002), and Yap (2007)

2.3.3 Pathophysiology of the Formation of MFTPs

MFTPs have been described as a constant shortening of the involved muscle (Travell and Simons, 1992). This is a result of an abnormal contraction cycle with the muscle fibers (Hye Min Ji *et al.*, 2012). The formation of a MFTP is diagnosed as a constant contraction of the involved muscle, which indicates that in the case of muscles containing MFTPs, the cycle explained in Figure 2.2 is not interrupted.

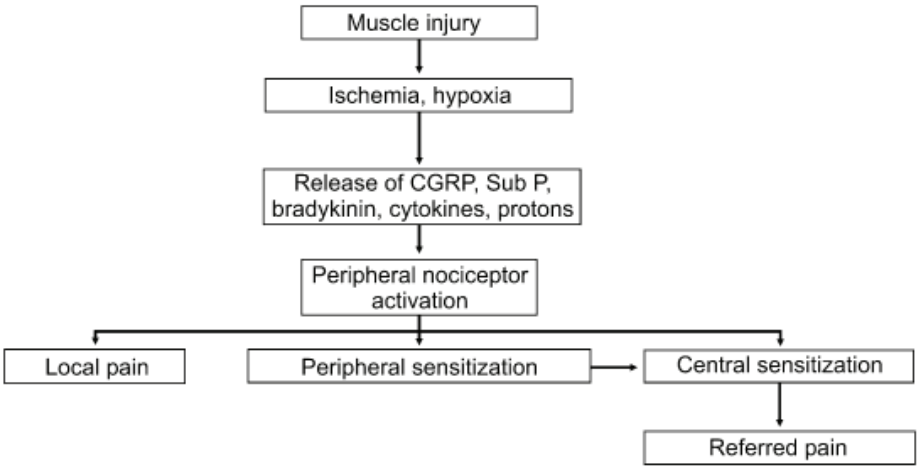

Figure 2.5: Sensitization as a result of muscle injury (Gerwin, 2010) (Permission for use of this image was received via personal communication with the author) (Gerwin, 2014) (Appendix 2.1).

The possible pathophysiology of a MFTP described in Figures 2.2 – 2.5, is outlined in Figure 2.6 on page 18.

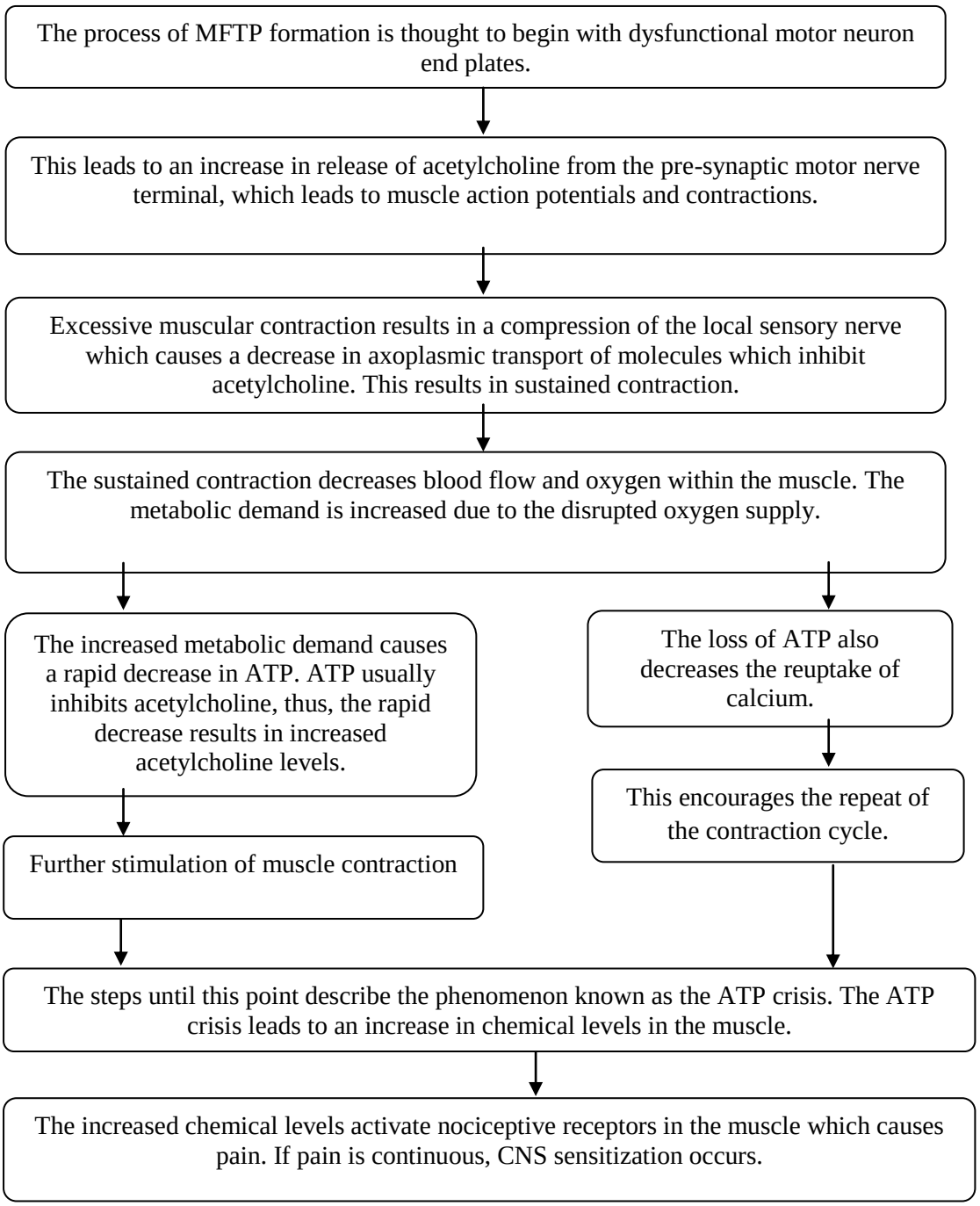

Figure 2.6: The pathophysiology of the development of a MFTP (Travell and Simons, 1992; Gerwin, 2001; Sharma *et al.*, 2010; Rodriguez-Fernandez *et al.*, 2011 and Hye Min JI *et al.*, 2012).

The pathophysiology of MPD / MFTPs is characterized by a number of essential clinical features (Travell and Simons, 1999; Fernandez de Las Penas *et al.*, 2005; Dommerholt *et al.*, 2006; Cummings and Baldry, 2007), which include, but may not be limited to:

- A sensitive point or nodule within a taut band of skeletal muscle.
- A local twitch response which can be noted on palpation of the muscle.
- A characteristic pattern of spontaneous referred pain (if it is an active MFTP).
- The presence of pain on sustained compression over the sensitive point (both for an active and latent MFTP).

With the MFTPs usually located in the taut band of contracted muscle fibres (Figure 2.7), resulting in a local twitch response when palpated (Lavelle *et al.*, 2007), it has been hypothesised that MFTPs occur at motor neuron-end-plates and therefore contain a neurovascular bundle (viz. motor nerve endings and nociceptive sensory afferent nerve endings) (Figure 2.6) (Travell and Simons, 1999; Mense *et al.*, 2001; Baldry, 2001; Cummings and Baldry, 2007).

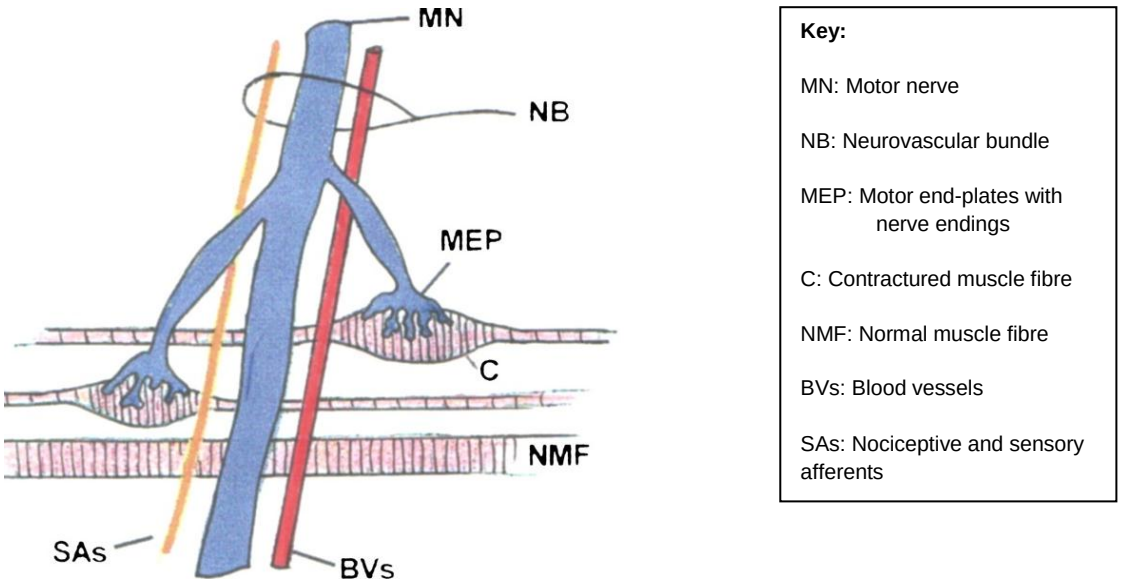

Figure 2.7: Representation of a MFTP within a muscle spindle
Adapted from Cummings and Baldry (2007) and Veerasamy (2014)

Cummings and Baldry, (2007) state that the key pathophysiological anomalies associated with MFTPs may be found within its motor end-plate zone. This zone is where the motor nerve (Figure 2.7) divides into various branches as it enters the muscle (Figure 2.6). Each branch has a terminal claw-like motor end-plate, which is attached and embedded into the surface of a muscle

fibre (Figure2.7) (Cummings and Baldry, 2007). Thus, the precipitating factors to MFTP development are thought to cause cell membrane damage. This is starting point of muscle damage and development of the MFTP. It is facilitated by the release of acetylcholine at the motor end-plates (Yap, 2007; Ge *et al.*, 2011). Perpetuating the cycle of muscular pain and spasm, further release of acetylcholine at the motor end-plates produces the spontaneous electrical activity (SEA) (Shah, 2005; Ge *et al.*, 2011), within a MFTP (Simons *et al.*, 2002). In this context, SEA is registered by performing intramuscular needle electromyography (EMG) on a muscle which is at rest (Ge *et al.*, 2011). It is one of the characteristics of MFTPs (Hubbard and Berkoff, 1993; Simons *et al.*, 2002).

Hubbard and Berkoff's (1993) study showed that SEA was demonstrated at sites in a MFTP, whereas similar activity was not found at adjacent non-tender/non-MFTP sites (Lavelle *et al.*, 2007) and according to Cummings and Baldry (2007), the work of Couppe´ *et al.*, (2001) was the first blinded study to confirm the presence of SEA at MFTPs.

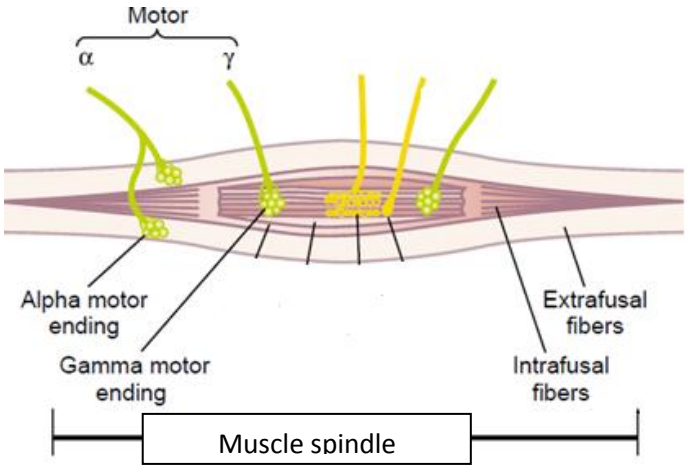

Figure 2.8: Muscle spindle
Adapted from Guyton and Hall (2006)

Large extrafusal (alpha motor unit) skeletal muscle fibres (Figure 2.8) are located outside the muscle spindle and the small intrafusal skeletal muscle fibers (gamma motor unit) (Figure 2.8) within the muscle spindle. According to Ge *et al.*, (2011), the origination of spontaneous electrical activity is from the extrafusal motor end plate and not the intrafusal motor endplate. Therefore, in this context, SEA is characterised by dysfunctional extrafusal motor end-plate potentials (Simons *et al.*, 2002) within the muscle fibres which exhibit muscle tissue disruption in

the form of a muscle cramp potential (Xu *et al.*, 2010; Ge *et al.*, 2011). It may also be involved in the formation of the taut muscular band as found with MFTPs, as the SEA is clinically represented by this focal muscle fibre contraction (Ge *et al.*, 2011).

Associated with these localised muscle cramps, are induced intramuscular hypoxia, increased accumulation of algesic substances, direct mechanical stimulation of pain receptors and tenderness as a result of an inflammatory response (due to tissue degeneration) (Simons and Mense, 1998; Laferriere *et al.*, 2008; Ge *et al.*, 2011). Barbara *et al.*, (2012), Cagnie *et al.*, (2010) and Flogren *et al.*, (2006) indicated changes in the microcirculation during these static low-level muscle contractions in MPD. These studies have showed decreased oxygen saturation in the trapezius muscle as well as a decrease in blood flow (Barbara *et al.*, 2012). All of these contribute significantly to the formation of muscle tension and MFTPs (Simons and Mense 1998; Laferriere *et al.*, 2008; Ge *et al.*, 2011).

2.3.4 Diagnosis and examination for MFTPs

MFTPs are diagnosed purely on examination and history taking. An important aspect of examination for the presence of MFTPs is the method used during palpation (Travell and Simons, 1992; Gerwin, 2001 and Sharma *et al.*, 2010). The two generally used methods of palpation are;

- Flat palpation: here the practitioner applies pressure in a systematic fashion along the involved muscle using the fingertips of two or more digits (Travell and Simons, 1992; Dommerholt *et al.*, 2006; Yap, 2007 and Montanez-Aguilera *et al.*, 2010). As indicated in Figure 2.9

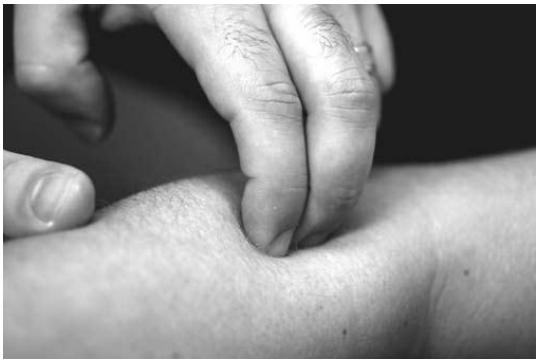

Figure 2.9: Flat palpation used during the examination for MFTPs (Dommerholt *et al.,* 2006) (Permission for use of this image was received via personal communication with the author (Dommerholt, 2014) (Appendix 2.2).

- Pincer palpation: here the practitioner applies pressure by gripping the involved muscle between the thumb and the fingers (Travell and Simons, 1992; Dommerholt *et al.,* 2006; Yap, 2007 and Montanez-Aguilera *et al.,* 2010). As indicated in Figure 2.10.

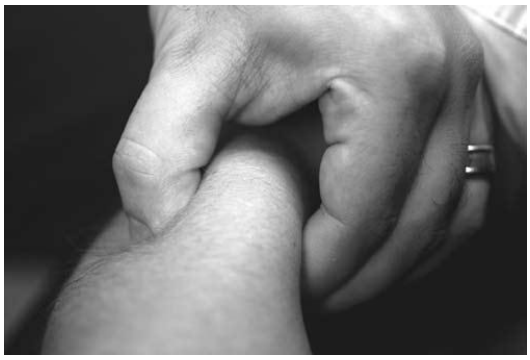

Figure 2.10: Pincer palpation used during the examination for MFTPs (Dommerholt *et al.,* 2006) (Permission for use of this image was received via personal communication Dommerholt, 2014) (Appendix 2.2).

Upon examination, a MFTP is diagnosed or identified by the following criteria (Travell and Simons, 1992; Gerwin, 2001; Sorrell and Flanagan, 2003 and Montanez-Aguilera *et al.,* 2010):

1. The ability to palpate a taut band within a muscle.
2. Upon palpation of this taut band, a specific area of hypersensitivity will be present (Figure 2.11).

3. Presence of a local twitch response: this is when the part of the muscle containing a MFTP rapidly and involuntarily contracts upon stimulation by palpation.
4. Palpation of the MFTP will result in a typical referred pain (a specific pain pattern that radiates around and away from the affected area, which is associated with MFTP stimulation in specific muscles).
5. Pain that occurs at rest, according to the specific referral pattern for a muscle, will be noted only in the presence of an active MFTP.

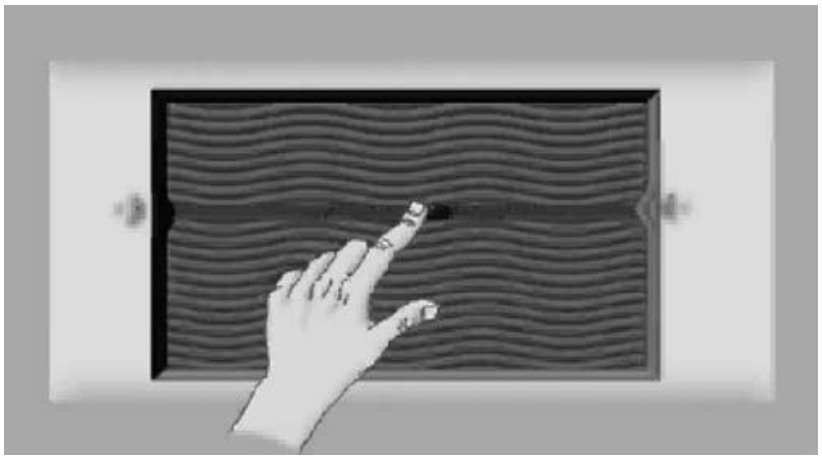

Figure 2.11: Palpation of a hypersensitive area with a taut band (Dommerholt *et al.*, 2006) (Permission for use of this image was received via personal communication Weisskircher, 2014) (Appendix 2.3).

A summary of the literature indicates that the following signs and symptoms may be utilised in the diagnosis of MFTPs

Table 2.3 MFTPs dysfunction

Motor	**Sensory**	**Autonomic**
Taut band Muscle pain Spontaneous pain referral-only AMFTPs Local twitch response Jump sign Restricted ROM of the affected tissues and loss of coordination Muscular fatigue	Local tenderness Pain referral Peripheral and central sensitization-allodynia, hyperalgesia Pain on compression	Vasoconstriction Vasodilatation Lacrimation Piloerection

Adapted from Travell and Simons, (1999); Fernandez de Las Penas *et al.*, (2005); Dommerholt *et al.*, (2006)

The Myofascial Diagnostic Scale (MDS) was developed as a means by which to clinically quantify the severity of MPD by using the diagnostic criteria outlined by Travell and Simons (Vaghmaria, 2005). In the MDS, emphasis is placed on four major criteria; pain referral, local twitch response, soft tissue tenderness and the presence of a palpable taut band within the muscle, with points allocated to each criterion (Table 2.4).

Table 2.4 Myofascial Diagnostic Scale (Chettiar, 2001)

Trigger Point Signs:		4
1. Soft tissue tenderness • No Tenderness • Tenderness to palpation WITHOUT grimace or flinch • Tenderness to palpation WITH grimace or flinch • Tenderness with withdrawal (+ jump sign) • Withdrawal to non-noxious stimuli (i.e. Superficial palpation, gentle percussion)	0 1 2 3 4	
2. Snapping palpation of the trigger point evokes a local twitch response		4
3. The trigger point is found in a palpable taut band		4
4. Moderate, sustained pressure on the trigger point causes or intensifies pain in the reference zone		5
TOTAL		**17**

Vaghmaria (2005) conducted a study that concluded that MDS is an effective method of MPD diagnosis. However, Myburgh *et al.*, (2008) stated that the use of this method is of poor efficacy. Hence, practitioners tend to use the criteria at varying degrees instead of the scale itself.

There are no lab tests or imaging studies which can be used to confirm the presence of MFTPs, however, it is interesting to note that microscopically the palpable hypersensitive nodule within a muscle known as a MFTP appears more darkly stained than ordinary skeletal muscle fibers. Also, EMG over a muscle containing a MFTP has revealed increased spontaneous electrical activity over the area containing the MFTP in comparison to adjacent muscles (Sharma *et al.*, 2010). Studies conducted by Simons *et al.*, (1995a), Simons *et al.*, (1995b) and Simons *et al.*, (1995c) and Hong and Simons (1998) discuss the use of SEA as a means by which to identify the

presence of MFTPs. SEA is a minute and very sensitive area of continued low amplitude activity which is found more commonly in muscles with MFTPs than in muscles without MFTPs.

2.3.5 Types of MFTPs

All MFTPs can be discussed according to the definition, pathophysiology, aetiology and perpetuating factors as well as the diagnosis and examination explained in Sections 2.3.1-2.3.4. However, there are various types of MFTPs. These types and their definitions have been tabulated in Table 2.5.

Table 2.5: Types of MFTPs (Travell and Simons, 1992)

Type of MFTP	Definition
Primary MFTP	A MFTP that is present in a muscle due to active or chronic trauma or overload to that specific muscle, which is not influenced by the presence of MFTPs in surrounding musculature.
Associated MFTP	A MFTP that develops due the increased mechanical demand placed on a muscle due as it compensates for the presence of MFTPs in another muscle.
Satellite MFTP	A MFTP in a muscle that becomes active because that specific muscle is found within the referral zone of MFTPs in another muscle. This MFTP is a type of associated MFTP.
Secondary MFTP	A MFTP that becomes active due to compensatory action of a muscle in response to MFTPs present in another muscle. This action can be as a synergist or an antagonist. This MFTP is a type of associated MFTP.

MFTPs are said to be the main cause and contributor to MPD (Sharma *et al.,* 2010), which will be the next topic of discussion.

2.4 Myofascial Pain and Dysfunction

2.4.1 Definition

The concept of MPD has been a topic of discussion for decades among medical professions worldwide (Dommerholt *et al.,* 2006; Rodriguez-Fernandez *et al.,* 2011 and Muscolino, 2012). MPD is defined as the presence of muscular pain that may be generalized or localized. This pain is caused by the presence of hypersensitive spots within the muscle, known as MFTPs as discussed in Section 2.3 (Travell and Simons, 1992; Perez-Palomares *et al.,* 2009; Srbely, 2010 and Rodriguez-Fernandez *et al.,* 2011).

2.4.2 Epidemiology of MPD and MFTPs

The overall prevalence of MPD and MFTPs has not yet been established (Gerwin, 2001). This may be due to the fact that the division between patients with MPD due to active MFTPs from those with MPD as a result of latent MFTPs is extremely difficult and can be a very subjective process (Travell and Simons, 1992 and Gerwin, 2001). Yap (2007) stated that MFTPs and MPD was one of the most common causes of neck and back pain. There have been several studies conducted among specific populations to investigate the prevalence of MPD and MFTPs within these populations (Skootsky *et al.,* 1989, Schiffman *et al.,* 1990, Friction *et al.,* 1990 and Chaiamnuay *et al.,* 1998). A study conducted on patients recruited from a university clinic in 1989 showed that 30% of the recruited patients had MFTPs and MPD (Skootsky *et al.,* 1989). Another study conducted by Han and Harrison (1997), indicated an 85% prevalence of MPD at American pain clinics. Patients who suffered with headaches and neck pain were noted to have 54% incidence of MPD and MFTPs (Friction *et al.,* 1990). A 50% incidence of MFTPs was noted in a study conducted among patients who presented with temporomandibular joint pain and dysfunction (Schiffman *et al.,* 1990). A study conducted in Thailand concluded that 36% of the 431 participants presented with MPD (Chaiamnuay *et al.,* 1998). Fishbain *et al.,* (1986) performed a study which stated that of the 83 participants, 85% were successfully diagnosed with MPD. Gerwin (1995) conducted a study in which 74% of the 96 participants had complaints caused by MFTPs and MPD. Over and above this, he noted that 93% of the cases within this sample had complaints which were at least partially connected to the presence of MPD. From the above-mentioned studies, it can be gauged that MFTPs and MPD are regularly diagnosed by practitioners.

2.4.3 Aetiology and Pathophysiology

The aetiology of MPD is the presence and development of MFTPs (Gerwin, 2001; Cummings and Baldry, 2007 and Delgado *et al.,* 2009), which has been discussed in detail in Section 2.2. MPD comprises of motor and sensory components (Dommerholt *et al.,* 2006). The sensory component consists of local and referred pain as well as peripheral and central sensitization. Peripheral sensitization results in a decreased pain threshold as well as an increased nociceptor responsiveness. Central sensitization causes an increased excitability of the central nervous system (CNS) (Travell and Simons, 1992; Gerwin, 2001 and Dommerholt *et al.,* 2006). The pain felt by the patient in MPD is either felt as hypersensitivity over the area or muscle containing a MFTP, or allodynia, which is the sensation of pain perceived upon non-painful stimulus (Travell and Simons, 1992; Friction, 1994 and Gerwin 2001).

As explained above the causative factor for MPD is the development and progression of MFTPs (Travell and Simons, 1992; Chaitow and DeLany, 2000 and Mense and Simons, 2001). Therefore, the mechanical, traumatic, biochemical imbalances and structural imbalances which have been discussed as contributing factors for MFTPs are relevant for MPD as well.

In addition to the possible aetiological factors mentioned, there are certain perpetuating factors that may contribute to MPD becoming a chronic condition. These factors, if not correctly addressed by the patient and the practitioner will result in a decreased responsiveness to treatment protocols. These perpetuating factors may include (Travell and Simons, 1992; Hong and Simons, 1998 Testa *et al.,* 2003 and Yap, 2007);

- Mechanical stress such as structural anomalies, postural imbalances and prolonged inactivity.
- Nutritional inadequacies such as Vitamin B and C as well as iron, potassium and calcium deficiency.
- Psychological stresses.
- Metabolic and endocrine imbalances such as hypo or hyperthyroidism and hypoglycaemia.
- Unresolved chronic infections.

2.4.4 Types of MPD

Taking into consideration the aetiological and perpetuating factors, it must be noted that patients diagnosed with MPD can be categorised into primary MPD and secondary MPD (Table 2.6).

Table 2.6 Primary and Secondary MPD (Travell and Simons, 1992 and Gerwin, 2001)

Primary MPD (pain that is not related to the presence of underlying or previous medical conditions)	**Secondary MPD** (pain that is as a result of current or previous medical conditions)
• Ankle pain • Piriformis syndrome • Knee pain • Adhesive capsulitis • Shoulder pain • Low back pain • Headaches: cervicogenic, tension-type and migraines • Neck pain	• Chronic unresolved infection • Hypothyroidism • Acute trauma • Vitamin B12 deficiency • Fibromyalgia • Osteoarthritis • Rheumatoid arthritis • Visceral pain (kidney pathology, liver pathology, cardiac pathology) • Structural anomalies (leg length inequalities, scoliosis) • Radicular pain • Post-operative pain • Joint dysfunction

2.5 Treatment of MFTPs and MPD

There are several causes of MFTPs and MPD which have been discussed in detail in Sections 2.2 and 2.3 (Baldry, 1993; Alvarez and Rockwell, 2002). Due to the large range of possible causes of MFTPs, the treatment protocols are also variable (Hains *et al.,* 2010); however, the primary aim of therapeutic measures for MPD is to alleviate the pain, MFTPs cause, to regain muscle length and consistency, thereby decreasing hypersensitivity and relieving pain (Chaitow and DeLany, 2000; Gerwin, 2001; Chaitow and DeLany, 2002; Rachlin and Rachlin, 2002). Many studies have been conducted (Gemmell and Hilland, 2011 and Jeon *et al.,* 2012) to investigate the effectiveness of various treatment modalities for MPD and MFTPs. The non-invasive therapies which have been researched to a great extent are the ones which have been reviewed in the study.

2.5.1 Transcutaneous Electrical Nerve Stimulation (TENS)

TENS is a modality which is commonly used as a part of physical therapy (Gemmell and Hilland, 2011 and Jeon *et al.,* 2012). A study was conducted by Koke *et al.,* (2004) which intended to compare different types of TENS and their effectiveness as a treatment protocol for MPD, this study however, was unable to establish any differences between the types of TENS settings. Another study conducted by Sahin *et al.,* (2011) had similar objectives and produced similar outcomes. TENS was noted to decrease the pain felt on compression of latent trapezius MFTPs in 60 patients. However, the treatment produced similar results to the placebo with regards to cervical ROM (Gemmell and Hilland, 2011). In a study which aimed to compare the effects of: extracorporeal shock wave therapy (ESWT), trigger point injections (TPI) and (TENS), in the treatment of MPD in the trapezius muscle, it was concluded that the ESWT, TENS and TPI were equally effective (Jeon *et al.,* 2012). Smania *et al.,* (2005) looked at another novel therapeutic modality, peripheral repetitive magnetic stimulation (rMS) on myofascial pain compared with TENS. This study reflected that rMS is actually more effective than regular TENS as a treatment modality for MPD in the trapezius muscle.

2.5.2 Ischemic Compression

Another commonly used and investigated modality is ischaemic compression (IC). In a study conducted by Iqbal *et al.,* (2010), it was noted that the combination of ischaemic compression and strain-counterstrain technique produces effective long term relief from MPD in the upper trapezius muscle. Activator trigger point therapy was noted to be more effective than ischaemic compression and sham ultrasound in a study conducted among 45 patients at the Anglo-European College of Chiropractic in the UK (Blikstad and Gemmell, 2008). Gemmell *et al.,* (2008) concluded that ischaemic compression was more effective than trigger point pressure release and sham ultrasound in the treatment of 45 Anglo-European College of Chiropractic students who presented with active upper trapezius MFTPs. Another study conducted on 52 patients with active MFTPs in the upper trapezius muscle concluded that single session ischaemic compression was just as effective as single session activator trigger point therapy in alleviating pain felt due to MPD in the upper trapezius muscle (Gemmell and Allen, 2008). A different study involved 66 patients with latent MFTPs of the trapezius muscle who were divided into 3 groups; one group received ischaemic compression, the second group received ultrasound therapy and the third group received sham ultrasound as a control. This study concluded that both ischaemic compression and ultrasound are effective in the treatment of latent MFTPs in the trapezius muscle (Aguilera *et al.,* 2009).

2.5.3 Ultrasound

Ultrasound has also been compared with other modalities and treatment protocols in order to investigate its efficacy in the treatment of MFTPs and MPD. A study that compared the effectiveness of a combination of high-power pain threshold ultrasound (HPPTUS) and an active muscle stretching programme, versus a combination of dry needling and an active stretching programme, was performed by Bahadir *et al.,* (2006). This study concluded that HPPTUS combined with active muscle stretching was more effective than dry needling and active stretching in reducing local twitch responses in twenty female patients who presented with acute MFTPs in the trapezius muscle. A study conducted by Acar and Yilmaz (2012), which recruited 60 patients and compared the effectiveness of a combination of ultrasound and exercise therapy versus exercise only versus a control group were given two weeks of rest. This study concluded that a combination of ultrasound application and exercise therapy is effective in the treatment of MFTPs and MPD in the cervical region. Sarrafzadeh *et al.,* (2011) conducted a study aimed to

investigate the different efficacies of pressure release (PR), phonophoresis of hydrocortisone (PhH), and ultrasound therapy (US) in patients with latent MFTPs of the upper trapezius muscle. This study found that all three of the investigated modalities are effective with regards to treatment of MPD. A study investigating the effects of low-dose ultrasound resulted in the conclusion that low-dose ultrasound produces a segmental anti-nociceptive effect on MFTPs in the supraspinatus, infraspinatus and gluteus medius muscles (Srbely, 2008).

2.5.4 Laser therapy

Another treatment protocol used to alleviate pain caused by MFTPs is laser therapy. Gur *et al.,* (2004) conducted a study that investigated the effectiveness of low-level laser therapy (LLLT) as a treatment modality for MPD in the neck. The study was conducted on 60 patients and compared actual laser to sham laser treatment. This study concluded that LLLT is an effective treatment for MPD in the neck. With the use of Algometric and Thermographic Evaluation, 62 patients with active MFTPs in the neck were evaluated for the efficacy of LLLT and stretching exercises versus exercise alone. This study concluded that LLLT is effective in the treatment of active MFTPs in the neck region (Hakguder *et al.,* 2003). A study conducted by Yamany and Salim (2011) performed to compare a combination of LLLT with exercise therapy versus placebo laser therapy and exercise concluded that LLLT combined with exercise was more effective than a placebo combined with exercise in the treatment of MPD of the shoulder.

2.5.5 Topical agents

Studies have also been conducted to investigate the efficacy of the use of various topical agents and patches for MFTP and MPD relief. Lin *et al.,* (2012) performed a study to compare the effectiveness of a 5% lidocaine patch versus a placebo patch in the treatment of upper trapezius MPD. This study concluded that the 5% lidocaine patch was more effective than the placebo patch. A study including fifty-two patients with masseter muscle pain and temporomandibular joint pain was conducted to investigate the effectiveness of Theraflex TMJ cream over a placebo cream. The results of this study showed that Theraflex TMJ cream is effective in the treatment of masseter and temporomandibular pain (Lobo *et al.,* 2004). Avarhami *et al.,* (2012) conducted a study to investigate the effectiveness of various over-the-counter topical ointments for the treatment of MPD. The included ointments were; Professional Therapy Muscle Care Roll-on (PTMC roll-on), Motion Medicine cream (MM cream), Bengay Ultra Strength Muscle Pain

ointment (BG), Icy Hot Extra Strength Cream (IH), and Biofreeze roll-on gel (BF) as well as a placebo ointment (PLA). The results of this study indicated that BG, MM and the PTMC roll-on ointment application results in an increased pressure threshold in patients with MPD. PTMC roll-on and BG were more effective than placebo in the short-term reduction of myofascial tenderness. PTMC was also more effective than IH with regards to short-term reduction of MPD. Another study investigated the efficacy of a Diclofenac patch for the treatment of MFTPs in the upper trapezius muscle. Hsieh *et al* (2010b) concluded that the Diclofenac patch was effective in the reducing pain and restoring mobility of the upper trapezius muscle.

2.5.6 Other interventions

Other non-invasive modalities have been noted as possible treatments for MPD include acupressure, interactive neurostimulation as well physical therapy designed to target specific types of MPD (for example temporomandibular pain and dysfunction). MPD in the muscles of mastication was investigated over a one year period among 53 patients, and it was noted that natural progression with occasional education and physical therapy with regular education and follow-ups for 6 weeks were effective to the same extent for long term decrease in pain and increase in functionality (Craane *et al.,* 2012). Kalamir *et al.,* (2010) conducted a study which concluded that intra-oral myofascial therapy (IMT) by itself or in combination with self-care is effective in the short to medium term management of chronic temporomandibular pain. Hsieh *et al.,* (2010a) conducted a study to investigate the efficacy of acupressure versus a muscle relaxant Dorsiflex (Mephenoxalone) as treatment for chronic headaches related to MPD. This study was conducted using 28 patients and concluded that the patients who received acupressure had more relief immediately and at a six month follow-up than those who were given Dorsiflex (Mephenoxalone). A novel modality which has been investigated for its effectiveness in treating MPD is interactive neurostimulation (INS) therapy. A recent study revealed that it may be effective in treating MPD in the neck region. However, this was a preliminary study and more research is required (Schabrun *et al.,* 2012).

2.5.7 Summary of interventions for MPD / MFTPs

As one would gauge from the literature discussed above, the treatment for MPD is a topic that has been investigated intensively. This is beneficial with regards to broadening the knowledge on the subject; however, a problem arises when practitioners need to make a clinical decision on which modality is the most effective. Hence, a systematic review of the studies mentioned in Sections 2.5.1-2.5.6 creates a critical summary of the subject of non-invasive treatment of MPD. This summary provides the information required for; practitioners in clinical decision making with regards to patient care, patients to give proper informed consent, medical aid schemes and health care administrators and it highlights areas where more research is warranted (Williamson *et al.,* 1989; Davidoff *et al.,* 1995; Cook *et al.,* 1997; Shea *et al.,* 2007).

2.6 Systematic Reviews

An essential component of evidence-based medicine (EBM) and 'evidence-based practice' (EBP) as projected by Sackett *et al.,* (1997) and Dagenais and Haldeman (2012), is defined as "clinical decision making based on sound external research evidence combined with individual clinical expertise and the needs of the individual patient" (Bolton, 2001).

In medicine, there exists several different sources of evidence and knowledge with regards to research and thus there are several methods of reporting the above mentioned evidence and knowledge. These could be by means of a narrative report or literature review, a commentary, a systematic review (Lavis *et al.,* 2005 and Buchbinder *et al.,* 2006) or a meta-analysis (Centre for Reviews and Dissemination, 2008; Dagenais and Haldeman, 2008; Hemingway and Brereton, 2009; Cochrane, 2011; Dagenais and Haldeman, 2012). Amongst these sources of knowledge, there is a hierarchy which represents the most scientifically eligible sources (Sackett *et al.,* 1996). This hierarchy places meta-analyses at the top of the hierarchy because such an analysis only accepts stringent data (Sackett *et al.,* 1996; Rothman *et al.,* 2008 and Dagenais and Haldeman, 2012). Narrative reports, in contrast are slightly informal (Babbie and Mouton, 2001). The systematic review is the only source of knowledge which seems to strike a balance and is seen as the most effective way to evaluate and critically analyze the effectiveness of studies (Hemingway and Brereton, 2009; Moher *et al.,* 2009 and Wells *et al.,* 2011). Hence, these evidence sources play significant roles in evaluating health care practice (Figure 2.12). However, (Leach, 2004; Gatterman, 2005; Bergmann and Peterson, 2011) the following associations are sketched on page 35 (Brink, 1996; Sackett *et al.,* 1996; Hemingway and Brereton, 2009; Dagenais and Haldeman, 2012):

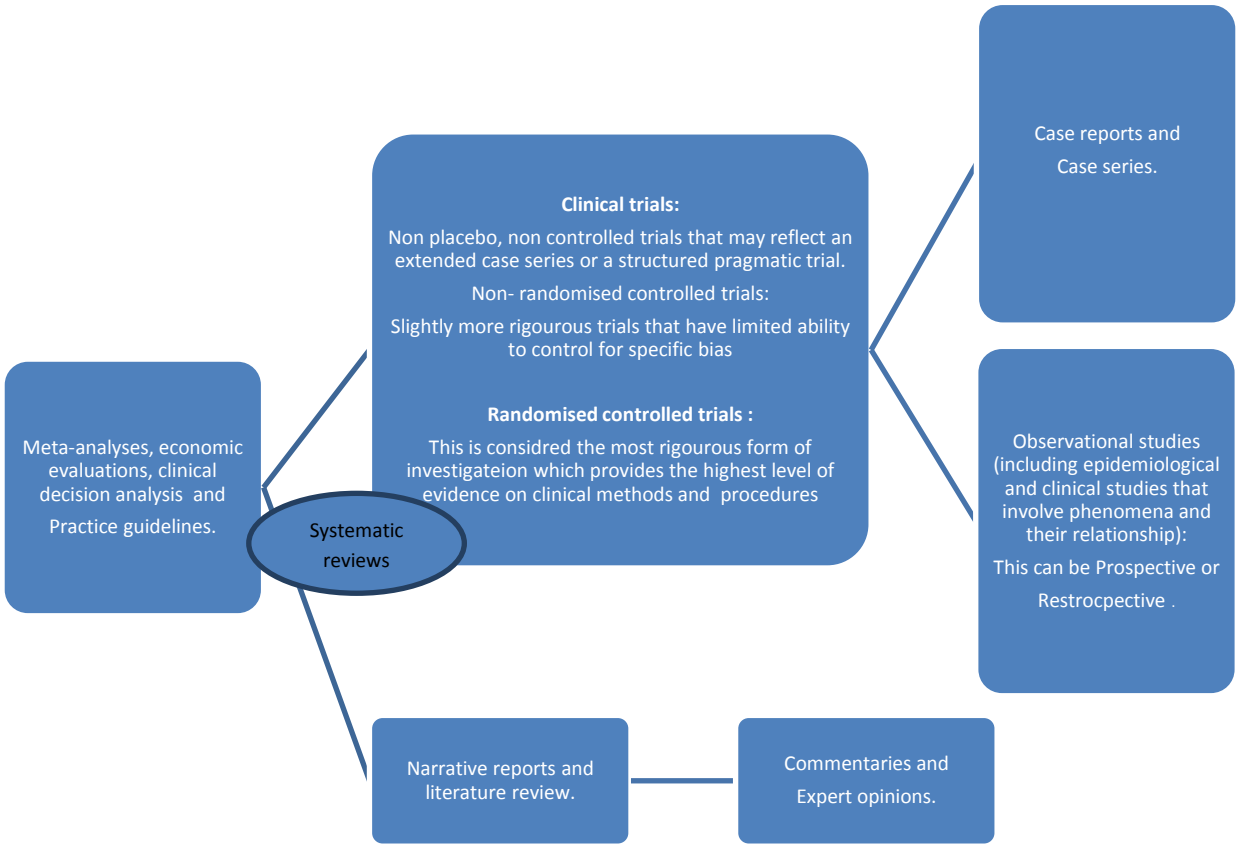

Figure 2.12: Schematic relationship of various literature analyses (Harrison, 2014)

According to the hierarchy of the available sources of evidence depicted in Figure 2.12, the narrative report or literature review and a commentary are examples of literature which has not been exposed to critical review, whereas the meta-analysis is a very critical, strictly analytical examination of the literature which requires extremely specific research skills to both interpret and understand (Brink, 1996; Sackett *et al.*, 1996; Babbie and Mouton, 2001; Rothman *et al.*, 2008; Dagenais and Haldeman, 2012). Hence, the systematic review is left as the singular medium that is able to effectively evaluate evidence within a particular domain by the use of stringent research techniques (Fisher *et al.*, 1990; Mulrow, 1994; Oxman *et al.*, 1993; www.pedro.org.au, 1999; Glasziou 2001; Green and Higgins, 2005; Hemingway and Brereton, 2009; Moher *et al.*, 2009; Wells *et al.*, 2011). Such an evaluation is done without alienating the clinician so as to provide researchers, clinicians and academics with access to information that is readily available regarding the domain in the systematic review (Dagenais and Haldeman, 2012).

2.6.1 Summarised Overview of a Systematic Review

The systematic review has been noted as a retrospective, observational scientific process (Cook *et al.,* 1997) that employs techniques which limit bias and random error, thus, enabling the analysis of the results of many primary investigations (Mulrow, 1987; Cook *et al.,* 1995; Cook *et al.,* 1997; Lavis *et al.,* 2005). The starting point for this process is a well defined clinical question that outlines an objective, which uses eligibility criteria to steer pre-defined outcomes that leads to and encourages a search of the literature (Dickersin *et al.,* 1994; Lavis *et al.,* 2005; Liberati *et al.,* 2009). The question is usually developed while taking into consideration four general variables: specific population and setting, a particular condition, a particular intervention or a combination of these (Cook *et al.,* 1997; Lavis *et al.,* 2005).

When a systematic review is compiled, focus is placed on correctly identifying the appropriate studies, then critically assessing them and finally creating a summary of the evidence found. If these major guidelines of composing a systematic review are properly adhered to, medical professionals are provided with unbiased summaries of the evidence available with regards to specific topics (Lavis *et al.,* 2005; Fox, 2005 and Higgins and Green, 2011). Therefore, electronic and paper based literature which may be published or not is carefully and methodically searched for any references related to the review (in this study, key terms included the non-invasive treatment techniques for MPD) (Cook *et al.,* 1997; Fox, 2005; Lavis *et al.,* 2005). The appropriate literature is then subjected to a screening process based on inclusion criteria developed by the researcher through the objectives of the study (Cook *et al.,* 1997; Fox, 2005; Lavis *et al.,* 2005). Multiple databases are searched and hand searches are conducted in an attempt to limit bias as far as possible (Fox, 2005; Hemingway and Brereton, 2009). The studies which fit the developed inclusion criteria are then analysed by a minimum of two reviewers, which creates a platform for a discussion in the systematic review, referred to as a "synthesis of the best evidence" (Fox, 2005; Liberati *et al.,* 2009). During this process, data is presented in the form of data tables (e.g. Appendix 2.4) by way of reviewer feedback and reported on accordingly (Lavis *et al.,* 2005; Hemingway and Brereton, 2009; Liberati *et al.,* 2009; Higgins and Green, 2011).

The collective feedback received from the reviewers and the synopsis of evidence tables, are then discussed with regards to their related clinical outcomes, efficacy, viability, suitability and correctness. The review of the technique is concluded with a discussion of the results and their

relevance to clinical practice, based on the methodological rigour and outcomes of the reviewed studies (Lavis *et al.*, 2005; Hemingway and Brereton, 2009), including the effect of biases (as outlined in Table 2.7).

Table 2.7 Biases that need to be considered during review of publications in a systematic review

<table>
<tr><th colspan="2">Internal validity</th><th>External validity</th></tr>
<tr><td colspan="2">Selection bias: including randomisation, concealment of allocation</td><td rowspan="3">Patients – age, gender, disease severity and co-morbidities (i.e. homogeneity)
Treatment regimens – dosage, timing, administration route, type of intervention (single / combination)
Setting: primary through tertiary</td></tr>
<tr><td>Performance bias
Detection bias</td><td>Preferential treatment of one group over another, intervention influences outcome measures</td></tr>
<tr><td colspan="2">Attrition bias: including deviations from protocol, loss of patients to follow-up, patient exclusion after allocation, patients not adhering to specific research requirements</td><td>Outcome measures, duration and follow-up measures</td></tr>
</table>

Adapted from: Sackett and Gent, 1979; May *et al.*, 1981; Keirse, 1988; Altman, 1991; Noseworthy *et al.*, 1994; Schulz, 1996; Hollis and Campbell, 1999; Deeks, 2001; Juni *et al.*, 2001

2.6.2 Role of Systematic Reviews:

According to Lavis *et al.*, (2005), a systematic review provides:

- A more accurate source of information in comparison to a single publication related to a particular topic (individual study) (Egger *et al.*, 2001; Blanch, 2004; Hains *et al.*, 2010; The National Institute for Health Research: Systematic Reviews Infrastructure, 2011).
- Confidence in the expectations of a particular intervention (Mulrow, 1994).
- An increased efficacy with regards to time usage (Mulrow, 1994).
- A better structured analysis of data than that provided by a single study (Light and Pillemer, 1984; Mulrow, 1994).

Due to this process, systematic reviews are able to provide updated resources for practitioners (Williamson *et al.,* 1989; Davidoff *et al.,* 1995; Cook *et al.,* 1997; Shea *et al.,* 2007; Blanch, 2004; Hains *et al.,* 2010; The National Institute for Health Research: Systematic Reviews Infrastructure, 2011). In addition, systematic reviews also provide answers to clinical questions that cannot be answered by individual primary studies (Eddy, 1982; Davidoff, 1995; Fox, 2005). This assists the medical community by providing an evidence based list of effective treatment protocols, which is beneficial when constructing treatment plans for patients, as it allows the practitioner to select the most effective treatment protocol based on the collective results of various studies (Blanch, 2004; Hains *et al.,* 2010; The National Institute for Health Research: Systematic Reviews Infrastructure, 2011).

Systematic reviews provide a level playing field for comparison whilst accounting for discrepancies that may be noted within study outcomes (Eddy, 1982; Pedrini *et al.,* 1996; Cook *et al.,* 1997; Moher *et al.,* 2003). A systematic review defines a research agenda and provides summarized information that refines hypotheses and develops research questions (Chalmers and Haynes, 1994; Cook *et al.,* 1997; Lavis *et al.,* 2005). Systematic reviews, also serve to encourage and recommend future research projects as well as to develop future clinical policies. In addition, they are formulated according to scientific methods ensuring limited bias and critical appraisal (Cook, Mulrow and Haynes, 2004). Due to the constant addition of new research in the medical field, systematic reviews are growing in popularity and are seen to be very beneficial to all medical professions (Crombie and Davies, 2009).

Furthermore, systematic reviews assist administrators and third party payers in determining and driving policy (Chalmers and Haynes, 1994; Mulrow, 1994; Cook *et al.,* 1997). They also provide a basis for decisions making (Moher *et al.,* 2003; Fox, 2005). In addition, systematic reviews produce collaboration frameworks (Chalmers and Haynes, 1994) and guide the allocation of resources in terms of both research agendas and socio-economic fronts (Chalmers and Haynes, 1994).

2.6.3 Factors Affecting Systematic Reviews:

It has been noted that the inclusion of "grey literature" (Dickersin *et al.,* 1994) in literature reviews, and particularly systematic reviews, is recommended as a means by which to achieve a comprehensive overview of the literature. However, by including this literature the researcher may potentially increase the possibility of bias, thus, decreasing the credibility of the systematic review. These factors may include:

a. Publication bias: (Dickersin *et al.,* 1994). This is due to the fact that "grey literature" is not always peer reviewed. On other occasions, although this literature may not have been published in a journal, it may have been presented as a dissertation, commentary or other forms of literary publication, which may or may not have had the potential to negatively affect the systematic review.
b. Sensitivity and precision of searching: (Dickersin *et al.,* 1994). An inclusion of "grey literature" requires refined and specified searches. This can prove to be rather difficult and may require adaptations of searching parameters, which then has an effect on the search terms used in the data collection phase. Hence, it has a potential to introduce unwanted bias into the systematic review (Dickersin *et al.,* 1994). Cook *et al.,* (1995) suggest that the use of a variety of search terms may be an appropriate means by which to alleviate this problem, however, it is inconclusive.
c. Indexing constraints / search engine sensitivity and imposed constraints (Dickersin *et al.,* 1994; Cook *et al.,* 1995).
d. Researcher ability to identify and use the correct search terms, as well as the correct screening methods of the literature.
e. Language bias (Dickersin *et al.,* 1994; Sterne *et al.,* 2001) needs to be taken into consideration due to the exclusion of particular languages as a result of restrictions imposed by the review, the reviewer ability or both.

2.6.4 Systematic Reviews for Different Study Types

2.6.4.1 Systematic Analysis of Randomised Clinical Trials

In systematic reviews, which are conducted on randomized controlled trials (RCTs), there are two scales that are popular for the analysis of articles. These are the PEDro Scale and the Jadad scale (Clark *et al.,* 2001; Moher *et al.,* 2009). In regards to the Jadad scale, the literature available

on the efficacy of this scale has been shown to have bias due to the small variation of criteria for evaluation. Bias is also highlighted with respect to the interpretation of the criteria (Clark *et al.*, 1999). The Jadad scale has also been noted to lose its validity in research regarding painful conditions (Clark *et al.*, 2001). The Jadad scale is also not linked with Consolidated Standards of Reporting Trials (CONSORT), whereas the PEDro Scale has been linked to the CONSORT (Altman *et al.*, 2001; Boutron *et al.*, 2008 and Moher *et al.*, 2009). The PEDro Scale consists of eleven yes/no questions. A point is rewarded for each 'yes' question and zero points are rewarded for each 'no' question. The studies which are rewarded with eleven points are seen as being the most reliable, with reliability decreasing as the overall score decreases (PEDro Scale, 2012).

Therefore, Maher *et al.*, (2011) noted that the PEDro Scale is highly accurate for the assessment of RCTs in terms of quality and methodological rigour. The PEDro Scale scored an overall rating of 0.56 ("fair" to "good"), and an individual rating of "fair" to "substantial".

The PEDro Scale (1999) was used to review and assess the RCTs. It comprises eleven specific criteria, with each criterion interrogating the methodological rigour of the study. For each criterion, only one point may be awarded, with a maximum score of eleven points and a minimum score of zero points.

By awarding one point for each criterion, the researcher is able to calculate an average score by tallying the end score for each of the three reviewers. The methodological rigour of a particular study can be analysed by considering the mean score. If a score of eleven is calculated, the highest level of methodological rigour is awarded. Conversely, the lowest level of methodological rigor is awarded should a mean score of zero result.

2.6.4.2 Systematic Analysis of Non-Randomised Clinical Trials

Systematic reviews that analyse non-RCTs use the Newcastle-Ottowa scale (NOS) (Wells *et al.*, 2003). This scale is divided into three basic sections a) selection, b) comparability and c) exposure. Each of these sections have sub-sections, a total of eight sub-sections exist amongst these three sections. Points are rewarded for each sub-section, with a maximum of one point per sub-section under the selection and exposure selections and a maximum of two points per sub-section under the comparability section. A study that is reviewed may be awarded a maximum total of nine points. (Hartling *et al.*, 2010 and Higgins and Green, 2011).

The process of awarding points requires the reviewer to take into consideration whether or not the study in question fulfils each of the individual criteria. This enables the reviewer to calculate mean scores for each section and the scale as a whole. A comparison amongst the reviews generated by the reviewers is then conducted using the above mentioned mean scores. If a mean score of nine is calculated, the highest level of methodological rigour is awarded. Conversely, the lowest level of methodological rigor is awarded should a mean score of zero result.

It has been noted by Deeks *et al.*, (2003) and Higgins and Green (2011) that the NOS is easy to use and suitable for systematic reviews. Wells *et al.*, (2003) and Hartling *et al.*, (2010) presented similar recommendations. They noted good inter-rater reliability (interclass coefficient ICC of 0.94) and showed that there has been continuous review and refinement of the scale.

2.6.4.3 Systematic Analysis of Case Reports, Case Series and Observational Studies

The final category of studies analysed by the means of systematic reviews is case reports and observational studies. The Liddle Scale is the scale most commonly utilised for the analysis of case reports, case series and observational studies (Liddle *et al.*, 1996). This scale was formulated using The Method for Evaluating Research and Guideline Evidence (MERGE) principles (Liddle *et al.*, 1996), which are clear, explicit and standardised guidelines used for the review of studies which fall under the category of case reports, case series and / or observational studies. The standardised approach, created by the New South Wales Health Department, the Cochrane Collaboration and independent contributors, allows for consistent use of this scale by reviewers. The Liddle Scale has been recommended for utilisation by the Scottish Intercollegiate Guidelines Network (SIGN) as the most effective scale for the analysis of case reports, case series and observational studies.

The quality of evidence is established by the explicit evaluation criteria, which require a judgement with regards to the relative importance of bias in all its forms as well as the effects that biases may have had on the results of a particular study (Liddle *et al.*, 1996).
The Liddle Scale is comprised of twelve or thirteen individual criteria. These criteria are as follows (Liddle *et al.*, 1996):

- A description of participants.

- Confirmation that the participants agreed to participate.
- Standardisation, validity and reliability of outcome measures.
- Comparisons between the intervention and a control group.
- Baseline factor differences and their adjusting (statistically) during analysis.
- Loss of participants to follow-up.
- The use of intention to intervene / treat (only applicable to case studies / series and not observational studies).
- If the study is on multiple sites, is there homogeneity between them?
- Bias minimisation.
- Can the effect of the intervention be measured accurately without the influence of an extraneous variable?
- Finally, were any practical / ethical issues noted as to the reason a RCT could not be carried out.

In terms of the ranking specific criteria, if a criterion is awarded an "A", this indicates that it complied with the requirements for that criterion; hence, it had the strongest possible methodological rigor. Conversely if an "I" is awarded, it indicates the weakest possible methodological rigor. Usually the strength of the research rigor is ranked in sequence (from strongest to weakest) from A to B1, B2, C and lastly and "I". If the criterion is considered inapplicable in a specific study, then it can be noted as "n/a" (not applicable) by the reviewer.

2.6.5 Systematic Reviews on Manual Therapy of MPD

With regards to manual therapy, MPD has recently become a common diagnosis in musculoskeletal medicine (Vernon and Schneider, 2008), especially due to the possible connection between MFTPs and joint dysfunction (Mense, Simons and Russel, 2001). Therefore, there is an increasing interest in the area of MPD and the range of modalities available for the treatment of MPD.

Two previous systematic reviews regarding this topic have been completed. Rickards (2006) compiled a systematic review which only rated studies performed on active MFTPs; hence, studies based on latent MFTPs were not included. Vernon and Schneider (2008) compiled a review which included active and latent MFTPs; however, this review included acupuncture

studies, which are invasive in nature. This review also did not include modalities such as proprioceptive neuromuscular facilitative stretching and the use of heat and ice. The systematic review done by Vernon and Schneider (2008) was performed 5 years ago; the articles that were included in this study were articles that were published no later than 2007. Hence clinical trials that were carried out from 2007-2013 have not been reviewed. According to the Cochrane recommendations, systematic reviews should ideally be updated at least every 2 years (Higgins and Green, 2011).

This updated systematic review will aim to identify and critically assess non-invasive studies. It will include studies which were not included in previous reviews as well as those which have been conducted during the period that extends from the end of data collection of previous systematic reviews, to the beginning of data collection of this systematic review. Based on the above analyses of the uses of a systematic review to a practitioner in clinical practice and as a basis for the development of future research, it can be seen that this form of research would be suited to manual therapy techniques that are either in their development or that have limited evidence to allow for further development. This situation is evident in the manual therapies and particularly with modalities utilized to treat MPD and MFTPs, where there seems to be at best only anecdotal evidence. This claim has, however, not been shown to be true and thus this research aimed to evaluate the literature available for this particular technique in order to assist with the validation of its clinical use in practice.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter provides an explanation of the methods and materials that have been used during the study as well as the methodology used to analyze the data. Thus, the study design, methods of data collection (the literature search, identification of the study selection, the inclusion and exclusion criteria) and analysis (evaluation of the studies, and summaries of the findings) (Cook *et al.,* 1995) as well as the ethical considerations are discussed in this chapter. In addition, this chapter has been synthesised for presentation in accordance with the recommendations by Cook, Sackett and Spitzer, (1995), Greenhalgh and Peacock, (2005) and Liberati *et al.,* (2009).

3.2 Study Design

This study was a systematic review of RCTs relating to the effectiveness of the non-invasive modalities used in the treatment of MFTPs in the form of MPD. The design of the study took the form of a systematic review. This required that all publications investigating MFTPs and MPD were systematically and methodically found, screened and obtained in full text format (Cook *et al.,* 1995; Moher *et al.,* 1999). This was completed by means of electronic database searches, reference searches and a secondary hand search (Greenhalgh and Peacock, 2005). Once inclusion compliant articles were found, a process of categorizing the articles followed (viz. RCTs, non-RCTs, observational study and case publications / case series) (Cook *et al.,* 1995). From this grouping, only RCT articles were chosen for inclusion into this study.

Thereafter, the four previously identified reviewers (who had agreed to participate and who had signed the required Memorandum of Agreement (Appendix 3.3) and the researcher were allocated the task of reviewing the included articles (Cook *et al.,* 1995). The reviewers (including the researcher) then assessed and ranked the publications according to the PEDro Scale (www.pedro.org.au, 1999; Maher *et al.,* 2003; de Morton, 2009) (Appendix 3.2). This was done to establish the methodological rigour of the studies presented in the articles and therefore to contextualise the clinical outcomes of their studies in the strength of their conceptual structure (Cook *et al.,* 1995).

Each included article was reviewed by three reviewers (two external reviewers and the researcher) which met the minimum number of reviewers as suggested by Higgins and Green (2011). The feedback from each reviewer was analysed individually and collectively, to establish consensus between individual reviewers (Fox, 2005). The outcomes of this review process were then linked to the clinical outcomes of each of the reviewed studies. This determined the rigour with which particular interventions were performed within a single/ multiple related contexts (Colditz *et al.,* 1989: Miller *et al.,* 1989; Khan *et al.,* 1996; Kleijnen *et al.,* 1997; Moher *et al.,* 1999) and allowed for the outcomes to be assessed in the context of the conceptual framework of the study.

Thus, this systematic review was structured to fulfil the guidelines that have been created and published as per the PRISMA statement (Liberati *et al.,* 2009) and submitted as such to the DUT Research and Higher Degrees Committee and was approved following review by the Institutional Review Board (Appendix 3.1). Thereafter and prior to the commencement of the study, copyright procedures for all the articles sourced and included in this study were completed (Personal communication - Ramika Bansi, Manager: Intellectual Property Management Office DUT, rbansi@dut.ac.za).

3.3 The Research Question

In the context of clinical practice, the research question is: What is the level of evidence with regards to the effectiveness of various non-invasive treatment modalities for MPD?

3.4 Research Methods

The methodology and procedure in this systematic review were structured to address and overcome the weaknesses of previous reviews (Bero *et al.,* 1998; Jadad *et al.,* 1998; Jefferson *et al.,* 2002). Therefore, this review attempted to present:

- A clear research question (Section 3.3)
- Clear conceptual or decision making contexts and reporting of explicit selection criteria for studies (Section 3.6)

- Detailed and clear descriptions (Section 3.5)
- Reporting of explicit criteria for evaluating the studies (Sections 2.5.1 and 3.6.5 and Appendices 3.2 and 3.4)
- Reporting and acknowledging known biases (Sections 1.5, 3.3.6 and Table 2.7)
- Reporting on the validity of the assessment criteria (Sections 2.5.1 and 3.6.5)
- Reporting on the application of the criteria to assess the validity of all the studies (Chapter Four) and
- Transparency of reporting (Chapter Five)

3.5 Research procedure: Article screening and inclusion

An extensive, systematic and thorough search for publications related to the topic was done via identified databases (Moher *et al.,* 1999; Jefferson *et al.,* 2002; Creswall, 2009) subscribed to by the Durban University of Technology; as well as any other available databases available to the researcher. These databases included:

1. PubMed,
2. EBSCOhost,
3. Medline,
4. CINAL,
5. Proquest,
6. Health Source,
7. Sport Discus,
8. Science Direct,
9. Springer Link,
10. Google scholar and
11. Summons[1].

This procedure concurs with that presented by Moher *et al.*, (1999), who suggested that a search of various databases should be conducted in order to avoid indexing and publication bias. The total number of publications identified by citation to the date of the Research and Higher Degrees

[1]The last search engine on the list (Summons) is an institutional search engine that has links to interlibrary and other search facilities that include those listed in Table 3.1. Therefore, this search engine provided a broad scope of searches within established search engines to which Summons is connected.

Committee (RHDC) approval (18 September 2013) (Appendix 3.1) revealed a total of 84 citations. All the citations were arranged into a master list. This resulted in the removal of 27 duplicate publications (leaving 57 citations: Table 3.1). Simultaneously, this process allowed the researcher to include / exclude studies by citation (leaving 25 citations).

Thereafter, a secondary search (reference and hand search) was conducted but this provided no additional citations. After publication / article saturation had been reached and with no further additional articles being found, the researcher obtained all articles that complied with the inclusion criteria of being an RCT (viz. full publication). If an article was not available, the article was requested through inter-library loans (Finlayson, 2013). Once all the required full text articles had been sourced, a further individual review of the publications was done by the researcher in conjunction with the supervisor and co-supervisor (Jefferson *et al.,* 2002), to ensure each publication was in clear compliance with the inclusion criteria. This review therefore included the citation, abstract and full article and these were assessed for inclusion and exclusion against the study criteria as outlined in Section 3.6 (Cook *et al.,* 1997; Fox, 2005; Lavis *et al.,* 2005; Roffey *et al.,* 2010a; Roffey *et al.,* 2010c; Roffey *et al.,* 2010d; Roffey *et al.,* 2010e; Wai *et al.,* 2010a; Wai *et al.,* 2010b). A final number of 25 publications was included. Once all the studies were procured and screened, they were categorized randomly and dispatched to the reviewers. An example of the method used during the data search is indicated in Figure 3.1 on page 47.

Table 3.1: Final no. of articles fulfilling the inclusion criteria

Database	**Number of articles**
PubMed	8
Springerlink	3
Science Direct	13
Ebscohost (includes CINAL, Health Source, Medline and Sports Discus)	7
Proquest	2
Google Scholar	18
Summons	6
TOTAL	**57**

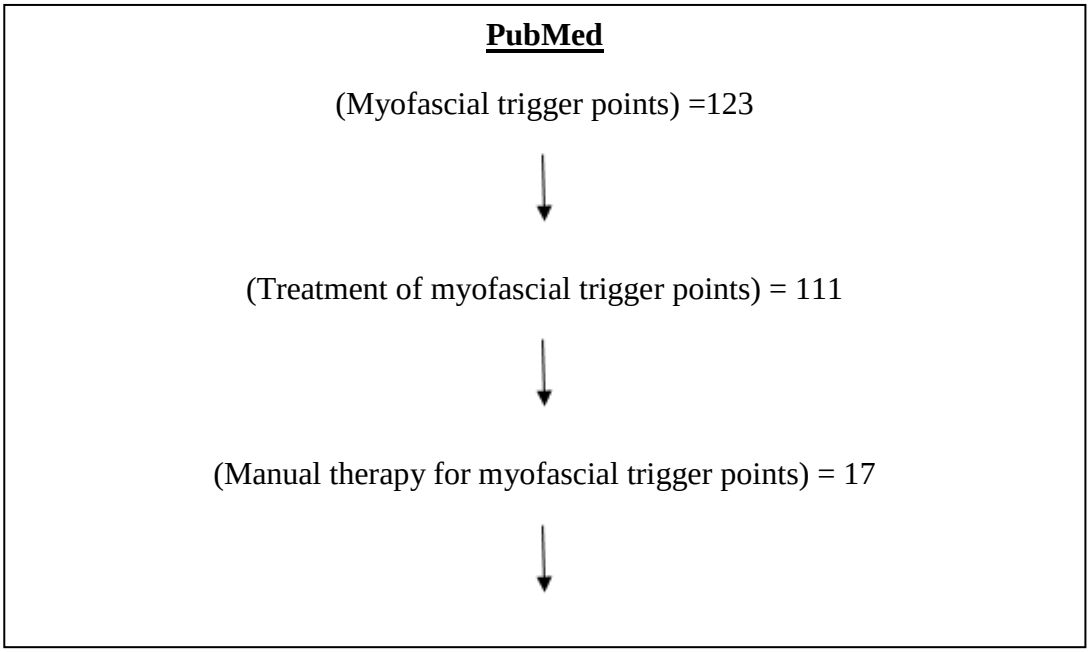

Figure: 3.1: Example of the method used during the database search

To ensure that all articles had been included in this systematic review, an additional search process was utilised. Secondary searches or the pursuit of references from other reference lists, i.e. "snowballing" (Moher *et al.*, 1999; Greenhalgh and Peacock, 2005; Vernon and Schneider, 2009); and using personal knowledge (Greenhalgh and Peacock, 2005), resulted in the inclusion of additional articles, which was found by:

- Reviewing reference list of the included publications (Maher *et al.*, 2003; de Morton, 2009).
- Reviewing and scanning the literature for author(s) names that were found to be common publishers in this area of research.
- Requesting submissions of literature or references from the reviewers / noted authors in this area of research.

Through the process of the secondary searches, citations were identified as per the inclusion and exclusion criteria of this study (Rickards, 2006 and Vernon and Schneider, 2008). These citations were then matched with the consolidated list of citations from the primary search. Even with this additional process, no additional articles were added to the master list of articles.

3.6 Sample inclusion and exclusion criteria

3.6.1 Inclusion criteria for the articles, by citation and abstract (Greenhalgh and Peacock, 2005):

- Only RCTs investigating non-invasive modalities for MPD were included. These studies were considered as clinical trial investigations / a series of investigations consisting of a protocol in which one or more interventions were administered to patients. In addition, these interventions were required to be of a hypothesised benefit to patients. Thus, it was required that the administration of these interventions was to determine whether the extent, and in what contexts the intervention results produced the hypothesised effects (The Medicines Act of 1968, Section 31). In this study, these RCTs were evaluated using the PEDro Scale (www.pedro.org.au, 1999) (Appendix 3.2).
- All included studies were required to have been peer reviewed (the articles have been reviewed by individuals in the same field, who possess knowledge on the subject of MPD)
- Articles were published in or translated into English to minimise misinterpretation (Baynham, 1995; Scollen and Scollen, 1995) and thus inappropriate ranking. (Limitations of this exclusion were noted in Chapter One, Section 1.5 Limitations).
- Keywords: active and latent myofascial trigger points, manual therapy, manipulation, acupressure, massage, muscles stretching exercises, ultrasound, transcutaneous electric nerve stimulation, electric stimulation therapy, ischeamic compression, topical agents, magnetic field therapy, exercise therapy (alone and in combination); irrespective of the search domain (Moher *et al.*, 1999).

It should be noted that where a citation did not contain the above mentioned search terms, but still appeared in the search, the citation was retained and the full abstract or full publication was reviewed. If the article was noted to meet the inclusion criteria of the study, it was included.

All 25 RCTs were divided into 2 groups (Group A and Group B) containing 12 and 13 articles respectively. Each reviewer assessed all the articles in the group allocated to them (Table 3.2), with the use of the PEDro Scale (Appendix 3.2). The articles were randomly allocated to these groups (either Group A or Group B) and reviewers were randomly allocated to either Group A or

Group B, with the researcher (Reviewer Five) included in both groups. It was possible at the time of allocation of the articles to the groups and the reviewers that a reviewer may have been an author / co-author for one of the included articles. Therefore, once the allocations had been made (Table 3.2.), the articles were screened to ensure that no conflict of interest was made to bear on the reviewers, by placing the affected article in a group's allocation that did not include the reviewer in question.

Table 3.2: Allocation of article groups to reviewers

Study type	Reviewers	Numbers of studies
Randomized controlled trials (Group A)	1,2 and 5	12
Randomized controlled trials (Group B)	3,4 and 5	13

3.6.2 Exclusion criteria for the articles, by citation and abstract:

- Narrative reports (Creswall, 2009): studies similar to systematic reviews that analyse articles in a narrative manner were excluded.
- Non-randomized controlled trials (Creswall, 2009; Wells *et al.*, 2011): studies which include participants that were not allocated to groups within the study by the use of random allocation were excluded.
- Case studies (Cassell and Symons, 2005) and Observational studies (Creswall, 2009; Wells *et al.*, 2011; Shaughnessy *et al.*, 2005): studies in which patients are observed before and after receiving specific interventions, without random allocation or control groups were excluded.
- Systematic reviews related to non-invasive therapies for MPD were excluded from the data collection process but were used in the literature review of this dissertation.
- Articles that compared invasive to non-invasive therapies were excluded.
- Unpublished articles were excluded.
- Non-experimental articles were excluded (Creswall, 2009).

3.6.3 Sample size

When reviewing the literature and assessing prior systematic reviews of the literature in terms of the included numbers of articles, it was noted that a range of four (Vernon and Schneider, 2009) to forty two articles (Hoskins *et al.,* 2006, Brantingham *et al.,* 2009) were utilised. This study accepted all the 25 RCT articles up to the date of Research and Higher Degrees Committee approval (18 September 2013) (Appendix 3.1), and therefore, it complied with an average number of 25 articles for review. All articles were obtained via the Durban University of Technology (DUT) library; however, any other articles that were not accessible through DUT were sourced through inter-library loans (Finalyson, 2013) and were also included in the study.

3.6.4 Reviewers

In this study, the reviewers were required to sign a Memorandum of Agreement (MoA) (Appendix 3.3). This MoA served as a foundation between the researcher and the reviewers by outlining the review process and the functions and responsibilities of each reviewer. During the review process, the reviewers were unaware of each other's identities, hence, they were unable to communicate and only the researcher had access to each reviewer. Communication only occurred when conflicting reviews were submitted and a consensus was needed after the reviewers had all submitted their allocated reviews (Fox, 2005).

This study had five appointed reviewers. The reviewers' academic history is outlined as follows:

- Reviewer One: DC, PhD - chiropractic education, academic, researcher and research supervisor.
- Reviewer Two: PhD FBCA, FRCC, FEAC - chiropractic education, academic, researcher and research supervisor.
- Reviewer Three: B.SpSc (Hons) (Biokinetics), M.SpSc, PhD - biokinetics education, academic, researcher and research supervisor.
- Reviewer Four: MSc (Neuroanatomy), MSc: Chiropractic, PhD - chiropractic education, academic, researcher and research supervisor.
- Reviewer Five: Researcher

The above reviewers were selected according to the following criteria:

- Their qualifications, so to attain an appropriate combination of academic experience, clinical experience and research experience for each of the review groups in order to support the researcher's inexperience.
- International experience, so to represent various international geographic regions.
- Their experience, to reflect their experience with systematic reviews, publications and / or research supervision, although the latter two points were optional.

Reviewers were selected according to the following criteria:

Table 3.3: Reviewer qualifications

	Research Experience	Highest qualification		Clinical Experience	Academic Experience
		Master's	PhD		
Reviewer 1	**X**	**X**	**X**	**X**	**X**
Reviewer 2	**X**	**X**	**X**	**X**	**X**
Reviewer 3	**X**	**X**	**X**	**X**	**X**
Reviewer 4	**X**	**X**	**X**	**X**	**X**
Reviewer 5:					**X**

Once the reviewers had completed their allocated reviews, data sheet collection and data analysis was conducted by the researcher. Any disagreement or differences between data sheets from reviewers was analysed to establish such reasons. If the disagreement was significant, a reviewer from a different group was selected to independently review the publication in question. This, in partnership with discussion between the reviewers and the researcher, was used to arrive at a consensus (Fox, 2005). A summarisation of the collected data was then conducted by the researcher (per article -qualitative and quantitative) (Moher *et al.*, 1999). This method of reporting was utilised to contextualise the publication outcomes within the level of methodological rigour noted by the reviewers of the same study (Moher *et al.*, 1999), in order to present the current evidence on this topic and develop recommendations for future research

3.6.5 Review procedure, reviewer's role and scale allocation

The initial steps of the review process involved; signing of Memorandums of Agreement (Appendix 3.3) by the reviewers. Through this process, the reviewers were not linked with their group allocations in the proposal, the dissertation or the publication. This was a measure put into place to ensure that the reviewers and their attached reviews remained anonymous (Mouton, 1996). Further, the allocation of articles and receiving copyright clearance (Bansi, 2013) was also completed.

The included articles, the rating sheets (Appendix 3.2) and the explanation of the rating sheets (Appendix 1.1) were distributed individually to the reviewers electronically. All articles were rated using the PEDro Scale (Appendix 3.2), as this is one of the most commonly used rating scales for controlled trials (PEDro Scale, 2012; Verhagen *et al.,* 1998). The PEDro Scale has been noted to be the most reliable scale for the review of RCTs as it has been linked with CONSORT (Altman *et al.,* 2001; Boutron *et al.,* 2008 and Moher *et al.,* 2009).

Each group of articles was reviewed by three reviewers (including the researcher) to allow for a comparison of ratings. Each group of studies contained approximately the same number of articles as indicated in the allocation table (Table 3.2). Once all articles were critically assessed and rated by all the reviewers, the reviewer feedback was received by the research supervisors. This was done so as not to influence the researcher's reviews as the review outcomes where only given to the researcher once all other reviews had been received.

While the reviews of the included articles were being conducted, they were also individually evaluated by the researcher to establish the clinical outcomes within the respective articles (data property tables, Appendix 2.4). This, in combination with a tabulation of reviewer responses (methodological rigour tables, Appendix 3.4), was utilised to create a foundation for the discussion and review of the article (Moher *et al.,* 1999).

This data was tabulated in order to compare and contrast the ratings (Cook *et al.,* 1997; Fox, 2005; Lavis *et al.,* 2005; Roffey *et al.,* 2010a; Roffey *et al.,* 2010c; Roffey *et al.,* 2010d; Roffey *et al.,* 2010e). Reviewers were allowed 12 weeks to review their allocated articles and return their feedback.

3.6.6 The scales and data extraction

According to the literature it has been noted that most of the scales used in systematic reviews have significant limitations and lack sufficient rigour (Moher *et al.*, 1995; Moher *et al.*, 1999). Furthermore, there are inconsistencies amongst the scales with regards to their levels of development, complexities and sizes (Moher *et al.*, 1999).

The individual rating scales present in the PEDro Scale were noted by Maher *et al.*, (2011) to have a rating of "fair" to substantial", with the overall PEDro Scale attaining a reliability rating of "fair" to "good". Maher *et al.*, (2011), therefore, reported that the PEDro Scale is sufficient for the evaluation of RCT quality in systematic reviews. Hence, the PEDro Scale (www.pedro.org.au, 1999) was utilised in this study to review the RCTs in respect of MPD. This scale consists of eleven individual criteria. Each of these criteria is used to establish the methodological rigour of the study. A maximum of one point can be awarded for each fulfilled criterion; hence, a maximum total score of eleven can be reached. Every unfulfilled criterion receives a zero resulting in a minimum total score of zero.

The criteria are as follows:

1. An explanation of the inclusion criteria / participant selection.
2. A description of participant allocation.
3. A description regarding the concealment of allocation.
4. A description on how the study groups were reported with regards to baseline similarities or differences, with particular emphasis on prognostic indicators / factors.
5. A description of participant blinding.
6. A description of therapist blinding.
7. Whether or not the assessors were blinded.
8. At least one key outcome measure was completed by the majority (85%) of all participants.
9. All participants, received treatment, as intended by group allocation. In the event that this was not the case, data for at least one outcome was analysed by "intention to treat".
10. Statistical comparisons (for at least one key outcome).

11. Point measures (measure of the size of the treatment effect), including measures of variability (standard deviations, standard errors, confidence intervals, interquartile ranges / quartile ranges and ranges) for at least one key outcome.

One point was awarded for each of the above criteria that were fulfilled. A mean score was then computed from a minimum of two reviewers. The mean score indicates the methodological rigor of the study. The mean score of eleven indicates the best possible level of methodological rigor, whereas a zero indicates the worst possible level of methodological rigor.

The articles in the review were rated using the PEDro Scale (Appendix 3.2). This scale has been noted to be the most efficient and most commonly used scale for the rating of RCTs (Verhagen *et al.*, 1998; PEDro Scale, 2012). It consists of 11 carefully constructed questions, which aim to highlight the most important features of a RCT. The questions or criteria are reviewed as either being fully met, in which case the reviewer marks the "yes" box on the rating sheet, and gains 1 point, or not completely met, in which case the reviewer marks the "no" box, and the article gains 0 points. Each randomized controlled study is ultimately rated out of 11. A third rating block for each criterion, stated as "where" requires the reviewer to indicate the page number as a reference. This rating allows for easy comparison should there be inconsistencies between reviewers (Rickards, 2006; Vernon and Schneider, 2008; PEDro Scale, 2012).

3.6.7 Ethical Considerations

- Reviewers' participation in this study was completely voluntary.
- Once the reviewers had accepted the invitation to participate in the study, a Memorandum of Agreement was signed (Appendix 3.3). According to the Memorandum of Agreement:
    1. No reviewer was allowed to communicate with another reviewer.
    2. The names of reviewers would not be associated with their review outcomes (within the context of this dissertation as well as publication). However, names of the reviewers would only be made public in the event of a publication emanating from this dissertation. In the latter context, the reviewers would again not be linked to specific review outcomes pertinent to that publication. Furthermore, they would need to agree to being associated with the publication.

3.7 Statistics

3.7.1 Procedure 1

This process utilised a combination of percentage agreement and majority averages. This was conducted to ensure consistency between reviewers, and if significant discrepancies were noted, the article was independently reviewed by an additional third party (either one of the reviewers from a different group or the research supervisor or co-supervisor). The introduction of a third party was required as it was necessary for any disagreement occurring between reviewers to be evaluated by a neutral third party in order to allow for the establishment of a consensus. This neutral third party could only be another reviewer or a supervisor as the researcher is already a reviewer (Moher *et al.*, 1999). It was hoped that their intervention would determine the reason for inconsistency. Thereafter, based on the additional third party review the article may have been referred back to reviewers for a second analysis.

3.7.2 Procedure 2

The evaluation of articles with regards to clinical outcomes utilised the majority consensus ratings to rank the articles. These rankings were then linked to the clinical outcomes reported by each of the articles. The characteristics of the high versus the low ranked articles were then established with regards to methodological rigor and clinical efficacy in order for the researcher to develop a summary of clinical applicability in terms of the strength of the evidence currently available.

CHAPTER FOUR

RESULTS

4.1 Introduction

This chapter contains the data and results obtained during the study. The results are presented in the form of tables. Each article that was analyzed during the review by the reviewers and the researcher is presented by means of two tables. The first table (example Table 4.1) contains a combination of the PEDro Scales used by each of the reviewers which forms the quantitative component of the review. This table provides the ratings and points rewarded to the article for each criterion, as well as an overall mean score out of 11 (this was calculated by awarding 1 point for each of the 11 questions in the PEDro Scale that received an overall 'yes' answer) and the majority percentage agreement between reviewers for each criterion and the article as a whole. The second table (example Table 4.2) contains the critical analysis of the article, this part of the review is the qualitative component. This table includes the details of the article as well as discussions around the scoring by reviewers and summarizes the general outcome of that particular article's review.

4.2 Results

Table 4 List of table numbers for studies

Tabulated feedback data:	Analysis of article:	Author(s):	Year:	Title:
Table 4.1	Table 4.2	B. Acar and O. T. Yilmaz	2012	Effects of different Physiotherapy applications on pain and mobility of the connective tissue in patients with myofascial pain syndrome

Tabulated feedback data:	Analysis of article:	Author(s):	Year:	Title:
Table 4.3	Table 4.4	F. J. M. Aguilera, D. P. Martin, R. A. Masanet, A. C. Botella, L. B. Soler and F. B. Morell	2009	Immediate effect of ultrasound and ischaemic compression techniques for the treatment of trapezius latent myofascial trigger points in healthy subjects: A randomized controlled study
Table 4.5	Table 4.6	D. Avrahami, A. Hammond, C. Higgins and H. Vernon	2012	A randomized, placebo-controlled double-blinded comparative clinical study of five over-the-counter non-pharmacological topical analgesics for myofascial pain: single session findings
Table 4.7	Table 4.8	C. Bahadir, J. Majlesi and H. Unalan	2006	The effect of high power pain threshold ultrasound therapy on the electrical activity of trigger points and local twitch response
Table 4.9	Table 4.10	A. Blikstad and H. Gemmell	2008	Immediate effect of activator trigger point therapy and myofascial band therapy on non-specific neck pain in patients with upper trapezius trigger points compared to sham ultrasound: A randomized controlled trial
Table 4.11	Table 4.12	B. Craane, P. U. Dijkstra, K. Stappaerts and A. De Laat	2012	One year evaluation of the effect of physical therapy for masticatory muscle pain: A randomized controlled trial

Tabulated feedback data:	Analysis of article:	Author(s):	Year:	Title:
Table 4.13	Table 4.14	H. Gemmell, P. Miller and H. Nordstorm	2008	Immediate effect of ischaemic compression and trigger point pressure release on neck pain and upper trapezius trigger points: A randomized controlled trial
Table 4.15	Table 4.16	H. Gemmell and A. Allen	2008	Relative immediate effect of ischaemic compression and activator trigger point therapy on active upper trapezius trigger points: A randomized trial
Table 4.17	Table 4.18	H. Gemmell and A. Hilland	2011	Immediate effect of electric point stimulation (TENS) in treating latent upper trapezius trigger points: A double blind randomized placebo-controlled trial
Table 4.19	Table 4.20	A. Gur, A. J. Sarac, R. Cevik, O. Altindag and S. Sarac	2004	Efficacy of 904 nm gallium arsenide low level laser therapy in the management of chronic myofascial pain in the neck: A double-blind and randomized controlled trial
Table 4.21	Table 4.22	A. Hakgunder, M. Birtane, S. Gurcan, S. Kokina and F. N. Turan	2003	Efficacy of low level laser therapy in myofascial pain syndrome: an algometric and thermographic evaluation
Table 4.23	Table 4.24	L. Hsieh, H. Liou, L. Lee, T. Chen and A. Yen	2010a	Effect of acupressure and trigger points in treating headaches: a randomized controlled trial

Tabulated feedback data:	Analysis of article:	Author(s):	Year:	Title:
Table 4.25	Table 4.26	L. Hsieh, C. Hong, S. Chern and C. Chen	2010b	Efficacy and side effects of diclofenac patch in the treatment of patients with myofascial pain syndrome of the upper trapezius
Table 4.27	Table 4.28	A. Iqbal, S. A. Khan and M. Miraj	2010	Efficacy of ischaemic compression technique in combination with strain counterstrain technique in managing upper trapezius myofascial trigger point pain
Table 4.29	Table 4.30	J. H. Jeon, Y. J. Jung, J. Y. Lee, J. S. Choi, J. H. Mun, W. Y. Park, C. H. Soe and K. U. Jang	2012	The effect of extracorporeal shock wave therapy on myofascial pain syndrome
Table 4.31	Table 4.32	A. Kalamir, H. Pollard, A. Vitiello and R. Bonello	2010	Intra-oral myofascial therapy for chronic myogenous temporomandibular disorders: A randomized controlled pilot study
Table 4.33	Table 4.34	A. Koke, J. Schouten, M. Lamerichs-Geelen, J. Lipsch, E. Waltje, M. Van Kleef and J. Patijn	2004	Pain reducing effect of three types of transcutaneous electrical stimulation in patients with chronic pain: A randomized crossover trial
Table 4.35	Table 4.36	Y. C. Lin, T.S. Kuan, P. C. Hsieh, W. J. Yen, W. C. Chang and S. M. Chen	2012	Therapeutic effects of lidocaine patch on myofascial pain syndrome of the upper trapezius: A randomized, double blind, placebo controlled study

Tabulated feedback data:	Analysis of article:	Author(s):	Year:	Title:
Table 4.37	Table 4.38	S. Lobo, N Mehta, A. G. Forgione, M. Melis, E. Al-Badawi, C. Ceneviz and K. H. Zawai	2004	Use of Theraflex TMJ topical cream for the treatment of temporomandibular joint and muscle pain
Table 4.39	Table 4.40	N. Sahin, I. Albayrak and H. Ugurlu	2011	Effect of different transcutaneous electrical stimulation modalities on cervical myofascial pain syndrome
Table 4.41	Table 4.42	J. Sarrafzadeh, A. Ahmodi and M. Yassin	2011	The effects of pressure release, phonophoresis f hydrocortisone and ultrasound on upper trapezius latent myofascial trigger points
Table 4.43	Table 4.44	S. M. Schabrun, A. Cannan, R. Mullens, M. Dunphy, T. Pearson, C. Lau and L. S. Chipchase	2012	The effect of interactive neurostimulation therapy on myofascial trigger points associated with mechanical neck pain
Table 4.45	Table 4.46	N. Smania, E. Corato, A. Fiaschi, P. Pietropoli, S. M. Aglioti and TM. Tinazzi	2005	Repetitive magnetic stimulation : a novel therapeutic approach for myofascial pain syndrome
Table 4.47	Table 4.48	J. Z. Srbely, J. P. Dickey, M. Lowerison, A. M. Edwards, P. S. Nolet and L. L. Wong	2008	Stimulation of myofascial trigger points with ultrasound induces segmental anti-nociceptive effects: A randomized controlled study
Table 4.49	Table 4.50	A. A. Yamany and S. E. Salim	2011	Efficacy of low level laser therapy for treatment of myofascial trigger points of shoulder pain

Tables 4.1 to 4.50 represent the results from the study reviews conducted by the reviewers as well as the researcher. Each study has two tables; one is a representation of the PEDro Scale ratings from three reviewers (two reviewers and the researcher), as well as the overall PEDro rating and agreement percentage (e.g. Table 4.1). The second table for each article represents critical analysis and discussion regarding factors that may have affected the quality of the study, taking into consideration factors which could not be assessed by the criteria of the PEDro Scale.

Table 4.1	Tabulated Feedback Data for RCT – Article 1					
AUTHORS:	B. Acar and O. T. Yilmaz					
TITLE:	Effects of different Physiotherapy applications on pain and mobility of the connective tissue in patients with myofascial pain syndrome					
YEAR:	2012					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	NO	NO	NO	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	NO	YES	YES	66%
5	There was blinding of all subjects	NO	NO	NO	NO	100%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	NO	NO	NO	NO	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	NO	YES	NO	NO	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	NO	YES	YES	YES	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	NO	YES	YES	YES	66%
	TOTAL SCORE	4	6	6	6	
		OVERALL PERCENTAGE AGREEMENT				90.73%

Table 4.2	Analysis of Article RCT: Article 1							
AUTHORS:	B. Acar and O. T. Yilmaz							
YEAR:	Effects of different Physiotherapy applications on pain and mobility of the connective tissue in patients with myofascial pain syndrome							
TITLE:	2012							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Short-form McGill Pain Questionnaire. Visual Analogue Scale and six-point Likert-type scale were used to measure pain intensity and quality. The skin roll test was used to evaluate connective tissue mobility.	Measurements were taken pre and post-intervention in the treatment and exercise groups and every fortnight in the control group.	The study was conducted over a two-week period. (The control group was given two weeks rest, but the duration of the study was not mentioned).	The study was conducted using 60 participants.	The evaluation of participants and application of the heat packs and ultrasound were performed by the same investigator, thus, indicating no assessor blinding.	Control group consisted of 20 randomly allocated participants who were given 2 weeks of rest.	Participants were randomly allocated into one of the three groups (treatment, exercise and control) using a randomized allocation program.	6	90.73%
LIMITATIONS:	With regard to the limitations presented in this article, the following were noted with respect to a lack of participant homogeneity: • The participants were described as having had mild pain (viz. the extremes of MPD / MFTPs were excluded); therefore, it is not possible to apply the outcomes of this article to all participants with pain that exceeds a mild nature. • The inclusion criteria with regards to the age of participants were not clearly specified and seemed to allow any participant below the age of 65 to participate. This decreased the homogeneity of the sample, as the likelihood for improvement in the older participants would have been slower and less clinically significant then those participants that had less degenerative diseases and also an increased physiological capacity to respond to treatment and heal effectively (Roberg and Roberts, 1997). Additionally, the age groups comparison between the three intervention groups were not completely comparable and therefore it is possible, although the							

	extent is difficult to quantify, that the outcomes of the study may have been affected by the participants healing response as opposed to the actual intervention that was studied in this article. • Further to the above limitations, the long term effects of treatment were not followed-up and recorded in these participants therefore it is not possible to extrapolate the findings to suggest possible outcomes of long-term intervention. • From a research methodology vantage point, o The apparent lack of a blinded assessor creates the potential for recording and reporting bias. This is particularly true in that the article does not state blinding of the therapist and / or the participant. It is therefore only apparent that there may have been initial assessor blinding with regards to the potential allocation of the participants to the groups. This, therefore, leaves conceptual framework of the research open to bias in terms of the participants' perception of their treatment, the manner in which the therapists interacted with the participants and the actual outcome measures documented in the study. It is therefore apparent that the outcomes of the study had the potential to be either enhanced or be negated dependent on the group in which the participant found themselves. This enhancement and / or negation of the results would therefore have affected the study outcomes both inadvertently (Mouton, 1996 and Mouton, 2006) and / or intentionally if a particular therapy was favoured. o Secondly, from the vantage point of the interventions, it was noted that this study investigated a combination of different interventions per group [Group 1: ultrasound and exercise therapy (which included the use of a hot pack), Group 2: the exercise group (which included the use of a hot pack) who were given an exercise regimen only and Group 3: the control group who were given two weeks of rest]. Therefore, the outcomes of the study can only be limited to the combination of therapies and not to the individual therapies found within the group applications. By assuming that a portion of the treatment was the same in each of the groups does not allow the consideration of the fact that treatment interventions may result in synergistic improvements or cause the beneficial effects to be negated. Therefore, it is not possible to assume that the common interventions provide a stable base by which to compare interventions that are different between the groups.
OUTCOME:	This article concluded that there was a statistical significance between the treatment group (those receiving ultrasound and exercise therapy) and the control group, whereas no significant difference was noted between the exercise group and the control group. It was, therefore, concluded that with regards to pain intensity, pain quality as well as connective tissue mobility, a combination of heat, ultrasound therapy and an exercise program, is more effective than the combination of heat and an exercise program. This combination was also noted to be more effective than the control group who were given two weeks of rest. The combination of heat and an exercise program, although less effective than the combination of heat, ultrasound therapy and an exercise program, was noted to have the same magnitude of effectiveness as the control group.
DISCUSSION:	The authors of this article identified a gap in the literature with regards to the available evidence on the efficacy of a combination of electrotherapy and exercise protocols versus exercise therapy alone. A RCT which consisted of three groups; the treatment group who received a combination of ultrasound and exercise therapy, the exercise group who were given an exercise regimen only and the control group who were given two weeks of rest, was designed to investigate the contrasting efficacy of the combination therapy versus exercise therapy. In the article there was no indication of allocation, therapist, assessor or participant blinding. This had a negative influence on the possibility

	of bias, thus decreasing the accuracy of the results obtained. The inclusion of participants who had a specific level of pain intensity also influenced the results as comparison cannot be applied to the overall population. The article did not include a clear explanation of initial participants who dropped out and the final number present at the end of the duration of the study. This may have been excluded do to the fact that there were no dropouts and 100% of the participants received their intended interventions. However, that cannot be left to assumption, thus the effectiveness of the study can be questioned. There was also no follow-up assessments discussed or intended, therefore, the long-term effects of the interventions remains unclear. The results of this study cannot be applied to individual modalities as the intervention was conducted as combination therapy; therefore, results are only considered valid for this particular combination of modalities. There was also a large age-range between the different age groups who participated in the study and the age groups allocated to each study group varied. This decreases the validity of the comparison and therefore, the results.
CONCLUSION:	This article was rated 6/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 90.73% (noted in Table 4.1 above). Although the overall results of this study were statistically significant, there were limitations as discussed above which increase the possibility of bias and decrease the accuracy of comparison between groups. Therefore, the results of study have been noted as weaker than expressed in the article itself.

Table 4.3	Tabulated Feedback Data for RCT – Article 2					
AUTHORS:	F. J. M. Aguilera, D. P. Martin, R. A. Masanet, A. C. Botella, L. B. Soler and F. B. Morell					
TITLE:	Immediate effect of ultrasound and ischaemic compression techniques for the treatment of trapezius latent myofascial trigger points in healthy subjects: A randomized controlled study					
YEAR:	2009					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	NO	YES	NO	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	NO	YES	YES	66%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	NO	NO	NO	NO	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by "intention to treat"	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	NO	YES	YES	66%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	8	6	9	8	
		OVERALL PERCENTAGE AGREEMENT				90.73%

Table 4.4	Analysis of Article RCT: Article 2
AUTHORS:	F. J. M. Aguilera, D. P. Martin, R. A. Masanet, A. C. Botella, L. B. Soler and F. B. Morell
YEAR:	Immediate effect of ultrasound and ischaemic compression techniques for the treatment of trapezius latent myofascial trigger points in healthy subjects: A randomized controlled study
TITLE:	2009

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Surface electromyography was used to measure basal electrical activity (BEA). A cervical ROM instrument was used to measure active ROM (AROM). Pressure analog algometer was used to measure pressure tolerance. Visual analog scale was used to record the pain felt by participants.	Measurements were taken pre and post intervention in the treatment and control groups.	The study was conducted over the duration of a single treatment. The ischaemic compression(IC) was done for 90secs, the ultrasound (US) was done for two mins on each trapezius, and the sham ultrasound was done over five mins.	This study was conducted using 66 participants.	There was no mention of assessor blinding in this study.	A control group of 22 participants received sham ultrasound. This group was blinded.	All 66 participants were given numbers according to their names; they were then randomly allocated into their groups (IC, US and sham US).	8	90.73%

LIMITATIONS:	Although this study made a brave attempt at approximating the requirements for a highly structured RCT, it is apparent that some criteria were not fully met and reasons for this include one or more of the following: • The inclusion and exclusion criteria noted were specific to the presentation of the MFTP but excluded participant specific details, which would have assisted the reader in being able to identify the population in which this study was done. This information is crucial as it allows for the extrapolation of the results to participants of a similar caliber in clinical practice. It, however, additionally poses a limitation with regards to the comparison of groups as the specific details of groups are unknown and it is therefore not possible to determine whether the groups where homogenous in nature and thus that the outcomes achieved by the groups were

	comparable and as such measuring only the effect of the intervention. An example of this conundrum is that the only measure noted in the study was age and with particular reference to this, the participants allocated to each study group varied. This decreases the validity of the comparison as healing times differ between age groups (Roberg and Roberts, 1997), thus decreasing the reliability of results. • It was further noted that the specific trigger points in the trapezius muscle that were assessed and treated were not recorded. This could result in ambiguous outcomes as the trapezius muscle has at least seven noted regions in which MFTPs can be found. Each of these has the potential to respond differently to different interventions (IC and US) based on their relative depth, fibre type and function (Travell and Simons, 1992; Chaitow and DeLany, 2000). • It is assumed that the study participants only received the stated interventions that were applied to the latent MFTPs in the trapezius muscle and that the results were only for the immediate term [not the short-term as implied by the authors in their conclusion (Aguilera *et al.*, 2009)], as the measurements were taken directly pre and post the intervention application and no additional measures post the intervention were recorded. • A further limitation is that the application was applied to a latent MFTP, which limits the ability of the study to indicate clinical relevance as participants would not normally have sought treatment. Therefore, the outcomes are suggestive of an investigation into the physiological effects that the interventions had and the change that these effects had on active ROM, basal electrical activity and pressure tolerance. Thus, the clinical practicality of the outcomes is limited, although further studies with symptomatic participants may bear out these findings for use in clinical practice. • As is relevant to manual therapies (Dagenais and Haldeman, 2012), this study also battled with the requirement of therapist blinding. As a result of this bias or potential bias, therapist blinding in this study cannot be fully excluded. In addition, it is possible that a lack of naivety of the participants (Mouton, 2006) to the intervention may also have had an impact on the outcomes of the study by introducing the concepts of perception, expectation and satisfaction (Phillips and Pugh 2000; Lessing and Schulze 2003; Armstrong, Allinson and Hayes 2004; Mackinnon 2004; Malfroy 2005; McAlpine and Norton 2006; Cheon *et al.*, 2009; Manathunga 2009; Nulty, Kiley and Meyers 2009; Danjuma and Rasli 2012). • Finally, even though it was noted that the assessor and the therapist were different people, there was no overt discussion as to whether the assessor was blinded to group allocations, treatment interventions and what measure were taken to ensure this. This, therefore, implies that there was a further possibility for the introduction of bias with regards to repeated measure outcomes.
OUTCOME:	This article concluded that both IC and US were effective in the treatment of latent MFTPs in the trapezius muscle. It also concluded that a relationship exists between AROM of the cervical rachis, BEA of the trapezius muscle as well as MFTP sensitivity which received short-term relief from the application of IC.
DISCUSSION:	The authors of this study focused on participants who are susceptible to latent trapezius MFTPs due to their increased computer use. To target this group, the study was done using participants who were apart of the teaching and research staff at a university in Spain. The study authors identified that there had been several other studies investigating the effectiveness of IC and US; however, the novelty in their study was the use of surface electromyography to note the changes that occurred post-treatment. The participants of the study were divided into groups; group one was treated with 90secs of IC, group two was treated with a total of four minutes of US and group three was the control group treated with five minutes of sham US.

	There was no mention of examiner and assessor blinding in the study. This creates an increase in the probability of bias with regards to reporting of overall final results by the authors. Due to the nature of the interventions, the control group was the only group who were kept blinded to their allocated group, thus the results were once again prone a bias. This study was conducted on participants who were asymptomatic and presented with latent MFTPS; therefore, although the results were significant they cannot be applied to the MPD as a whole. The measurements for this study were performed following a single session of treatment for each intervention, - there was no mention of follow-up treatments or measurements, and hence, the effectiveness can only be assumed true for a period immediately following treatment. The groups compared in this study were not of the same age group which decreased the result reliability. There was a lack of participant specific details in the inclusion and exclusion criteria. This decreased the efficacy of group comparison. The results are further questioned due to the lack of information with regards to which MFTPs in the trapezius muscle were assessed and treated. It was not specific whether or not participants were receiving additional therapy during the course of this study, which negatively affected the results as if they were. Therefore, it is difficult to assume that the study intervention was in fact responsible for the change in outcome measures
CONCLUSION:	This article was rated 8/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 90.73% (noted in Table 4.3 above). The authors of the study indicated that the interventions used were effective in the treatment MFTPs; however, the critical analysis of this article has identified the limitations discussed above. Therefore, the accuracy of the results reflected in the study has been noted to be less than originally reported by the authors and rated by reviewers.

Table 4.5	Tabulated Feedback Data for RCT – Article 3
AUTHORS:	D. Avrahami, A. Hammond, C. Higgins and H. Vernon
TITLE:	A randomized, placebo-controlled double-blinded comparative clinical study of five over-the-counter non-pharmacological topical analgesics for myofascial pain: single session findings
YEAR:	2012

CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	YES	YES	YES	YES	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	YES	YES	YES	100%
6	There was blinding of all therapists who administered the therapy	YES	YES	YES	YES	100%
7	There was blinding of all assessors who measured at least one key outcome	YES	YES	YES	YES	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	NO	NO	NO	NO	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	NO	YES	YES	YES	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	NO	YES	YES	YES	66%
	TOTAL SCORE	8	10	10	10	
		OVERALL PERCENTAGE AGREEMENT				93.82%

Table 4.6	Analysis of Article RCT: Article 3							
AUTHORS:	D. Avrahami, A. Hammond, C. Higgins and H. Vernon							
YEAR:	A randomized, placebo-controlled double-blinded comparative clinical study of five over-the-counter non-pharmacological topical analgesics for myofascial pain: single session findings							
TITLE:	2012							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
A manual pressure algometer was used to measure MFTP tenderness. A cervical rangiometer was used to measure bilateral lateral flexion of the c-spine. A verbal satisfaction scale was used to record patient satisfaction with regards to the intervention.	Measurements were taken pre and post application of the topical agents.	The participants received single intervention application of five to seven mins and the entire study was conducted over a period of seven days.	A total of 120 participants participated in this study (20 participants per group).	All creams and roll-ons were placed in generic white containers which were labelled with a code. The translation of these codes was managed by an uninvolved individual who allowed assessor blinding.	A non-medicinal placebo cream was used as a control.	Participants were randomly allocated into groups via the use of a pre-arranged randomized number sequence which was conducted by an uninvolved individual.	10	93.82%
LIMITATIONS:	In the same manner as Acar and Yilmaz (2012) (Table 4.2), this study also reported the inclusion of a wide age range of the participants (18-80 years of age), however in difference to the same study (Acar and Yilmaz, 2012) (Table 4.2), they also included both asymptomatic and symptomatic participants. Both these limitations have an impact on the outcomes of the study in that the older participant is less likely to respond as quickly or effectively as a younger participant (Roberg and Roberts, 1997) in addition to the fact that the symptomatic participants also have additional physiological processes occurring [e.g. arthrogenic muscle inhibition (Roberg and Roberts, 1997)]. This latter assertion							

	is particularly true in participants that also had other degenerative joint processes occurring (i.e. older participants) (Suter *et al.*, 2007). Thus, the lack of stratification for age and symptoms between the intervention groups would have resulted in the potential that the outcomes attained by the groups would potentially have been different for reasons other than the interventions. Further to the above, the study makes no mention of drop-out percentages for each of the groups and why these drop-outs occurred. This is important as drop-out for reasons of adverse reactions or worsening clinical conditions (particularly those under study); alter the context in which the results should be viewed (Moher *et al.*, 2008). Thus, for this study, it is not possible to determine whether a change in context should be considered.
OUTCOME:	Six topical agents were investigated; a non-medicinal placebo cream (PLA), Professional Therapy Muscle Care Roll-on (PTMC roll-on), Motion Medicine cream (MM cream), Bengay Ultra Strength Muscle Pain ointment (BG), Icy Hot Extra Strength Cream (IH), and Biofreeze roll-on gel (BF). The study concluded that there were significant intra-group decreases in MFTP tenderness for BG, PTMC roll-on and MM cream. Inter-group comparisons revealed, PTMC roll-on and BG resulted in a decreased MFTP tenderness when compared to PLA. The topical applications did not result in significant changes with regards to c-spine lateral flexion. The verbal patient satisfaction scales revealed high ratings for each group of topical application and there were no significant differences between groups.
DISCUSSION:	The authors of this study studied the literature and discovered that several studies had been conducted investigating the effectiveness of non-pharmacological topical agents on conditions such as osteoarthritis. However, a gap in the literature was noted with regards to studies conducted to investigate the effectiveness of these agents as treatment for MPD and MFTPs. A RCT was then designed and conducted to investigate this modality as treatment for MPD and MFTPs of the trapezius muscle. The study involved a comparison of the effects produced by three creams, two roll-ons and a placebo cream, on MFTP tenderness and c-spine lateral flexion. There was no mention of the drop-out statistics in the study; therefore, one assumes that 100% of the original included population completed the study. However, this cannot be left to assumption; thus, the accuracy of results becomes questionable. The intervention was applied only to trapezius MFTPs and measurements were only indicative of immediate effect to single application therapy. This indicates that although the results showed a greater decrease in MFTP tenderness amongst the intervention applications versus the control application, the results cannot be applied to MPD generally or to the long-term treatment of MPD and MFTPs. This study involved the a comparison of different topical agents, each of these agents had different compositions which makes a fair comparison and the ability to identify the major contributing factor to pain relief difficult due to the various elements involved. There was a large range between the age groups included in this study, which may negatively affect the results because the physiology and anatomy of an 18 year old is vastly different from that of an 80 year old. Therefore, a comparison between such groups cannot yield valid results.
CONCLUSION:	This article was rated 10/11 according to the criteria provided by the Pedro Scale (Appendix 3.2). The overall percentage agreement for this rating was 93.82% (noted in Table 4.5 above). Although the authors of the study indicated that the topical applications used were effective in the treatment MFTPs, and the critical analysis of this article performed by the reviewers revealed a good overall rating, there were limitations as discussed above, which if taken into

	consideration could have further improved the accuracy of the results.

Table 4.7	Tabulated Feedback Data for RCT – Article 4					
AUTHORS:	C. Bahadir, J. Majlesi and H. Unalan					
TITLE:	The effect of high power pain threshold ultrasound therapy on the electrical activity of trigger points and local twitch response					
YEAR:	2006					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	NO	NO	YES	NO	66%
3	Allocation was concealed	NO	NO	NO	NO	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	NO	NO	NO	NO	100%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	NO	NO	NO	NO	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	NO	YES	YES	66%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	NO	YES	YES	66%
	TOTAL SCORE	6	4	7	6	
		OVERALL PERCENTAGE AGREEMENT				90.73%

Table 4.8	Analysis of Article RCT: Article 4							
AUTHORS:	C. Bahadir, J. Majlesi and H. Unalan							
YEAR:	The effect of high power pain threshold ultrasound therapy on the electrical activity of trigger points and local twitch response							
TITLE:	2006							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual Analogue Scale (VAS). EMG evaluations for the presence and intensity of spontaneous electrical activity (SEA). Measurement of the distance between the tragus and the acromion on lateral flexion of the neck. Frequency of twitch responses.	Measurements were taken before administration of both the therapies and were retaken following each session of therapy.	The study was conducted over five days.	There were initially 23 participants. Following exclusion of those who had no local twitch responses at the second consultation, there were 20 participants; 10 in the intervention group (ultrasound) and 10 in the control group (needling).	Assessor blinding was not mentioned, therefore a comment cannot be made.	Effectively no control group was used as it is technically defined as an intervention group.	Randomization was not mentioned in the study, a comment cannot be made.	6	90.73%
LIMITATIONS:	This study is similar to the study presented in Table 4.4 (Aguilera *et al.*,2009) in that there was no reporting on: • The specific inclusion and exclusion criteria relating to participant inclusion into the study. This decreases the likelihood of participant homogeneity as well as homogeneity between the intervention groups. This ascertion decreases the likelihood that the outcomes in this study were directly related to the interventions as there was no controlling for the extraneous variables that the lack of homogeneity brings to the study (Mouton, 1996 and Mouton, 2006). o To complicate the above further, the inclusion of only female participants (although increasing homogeneity), limits the ability of the study to be able to be extrapolated to male participants.							

	• A unique criterion for this study was the exclusion of participants if they presented with a lack of local twitch response on the second insertion of the EMG needle. This concept and the reason for this exclusion criterion is not explained, although the literature seems to suggest that a local twitch response occurs once per stimulated muscle fiber, but it is not clear whether multiple twitch responses occur in a MFTP where there may be an involvement of multiple muscle fibers. Ultimately, this criterion would seem to suggest that the study results could perhaps only be generalized to participants that have multiple local twitch responses per MFTP. • Thus when looking at the preceding three bullet points, it is possible that this study could have been strengthened significantly with the use of appropriate randomization strategies. However, with the lack thereof, the outcomes of the study cannot exclusively be limited to the interventions utilized and therefore the outcomes become less clinically defined as a result of the bias associated with the lack of this methodology. The sample size of this study was small (ten per group) and no indication was given with regards to the authors having performed an *a priori* analysis. Therefore, the outcomes of this study are potentially only applicable to the select group of people that would fit the exact criteria as found in this study. However, with the limited detail of the participants this would be very difficult to duplicate. Further, in terms of blinding bias, the study makes no mention of participant, assessor or therapist blinding. This, therefore, introduces a range of biases previously discussed in Table 4.4. These biases detract from the measurement outcomes as it results in the reader having increased difficulty in determining whether the improvement / lack of improvement in the outcomes is directly related to the intervention, the lack of sample homogeneity and / or the biases that have not been controlled for in the study. This lack of certainty is also compounded by the fact that the group designated as the "control group" was in fact an intervention group and by the fact that the interventions not only included needling versus ultrasound, but also the participants performed supervised active stretching at the time of the intervention as well as home stretching (which was suggested to the participants for two consecutive days after the intervention was applied).
OUTCOME:	The study consisted of two groups, one group received dry needling and the other received high-power pain threshold ultrasound (HPPTUS). It was concluded that both the modalities had a beneficial effect on the MPD and MFTPs in the upper trapezius muscle. With regards to pain, the group that received HPPTUS was noted to have a greater effect than needling, however, there was no change in the distance between the tragus and acromion on lateral flexion of the neck.
DISCUSSION:	The authors of this study reviewed the literature available on US therapy for MFTPs and MPD, and they discovered that the use of US was common. However, according to their review of the literature, there had been a lack of, "randomized controlled and methodically well-designed studies". A RCT was then formulated and conducted to investigate the effects of HPPTUS on MPD, MFTP electrical activity and the frequency of local twitch responses. Two treatment groups of ten females per group were involved in this study. One group received HPPTUS whilst the other received dry needling. In this study there was no mention of randomization, assessor or therapist blinding or the use of a control group. These factors create an increased possibility for the presence of bias, thus, decreasing the overall reliability of the results. Also, the study was performed using only female participants which indicated that the results cannot be applied to the general population. The groups consisted of ten participants each; this sample size is not significant enough for results to be applied to a general population. There was an absence of participant specific inclusion criteria. This decreased the reliability of the comparison between the groups, thus, having a negative effect on the overall results.

	The exclusion of participants if they presented with a lack of local twitch response on the second EMG needle insertion is not explained in this study. This results in a lack of understanding as to why these participants were excluded. The combination therapy indicates that results can only be applied to this specific combination and does not reflect the efficacy of HPPTUS alone.
CONCLUSION:	This article was rated 6/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 90.73% (noted in Table 4.7 above). Although the authors of the study indicated that HPPTUS was more effective in reducing pain caused by MFTPs in the trapezius muscle than needling, there were limitations as discussed above, which if taken into consideration reflect that the study was of a moderate standard and the results were, therefore, not entirely reliable.

Table 4.9	Tabulated Feedback Data for RCT – Article 5					
AUTHORS:	A. Blikstad and H. Gemmell					
TITLE:	Immediate effect of activator trigger point therapy and myofascial band therapy on non-specific neck pain in patients with upper trapezius trigger points compared to sham ultrasound: A randomized controlled trial					
YEAR:	2008					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	YES	YES	YES	YES	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	NO	NO	NO	66%
6	There was blinding of all therapists who administered the therapy	YES	NO	NO	NO	66%
7	There was blinding of all assessors who measured at least one key outcome	YES	YES	YES	YES	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by "intention to treat"	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	NO	YES	YES	YES	66%
	TOTAL SCORE	10	9	9	9	
		OVERALL PERCENTAGE AGREEMENT				90.73%

Table 4.10	Analysis of Article RCT: Article 5
AUTHORS:	A. Blikstad and H. Gemmell
YEAR:	Immediate effect of activator trigger point therapy and myofascial band therapy on non-specific neck pain in patients with upper trapezius trigger points compared to sham ultrasound: A randomized controlled trial
TITLE:	2008

STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
A numerical rating scale (NRS) was used to measure the pain experienced by the participants before and after treatment. Pain pressure algometer (PPA) was used to measure the amount of pressure required to produce pain. A cervical ROM goniometer was used to measure lateral flexion of the c-spine.	Measurements were taken pre and post treatment.	The study was conducted over a single treatment session of five mins per participant.	This study consisted of 45 participants who were randomly allocated into three groups; MBT + sham activator + gel (15 participants), ATrPT+ gel (15 participants) and sham ultrasound + gel + sham activator / control (15 participants).	The pre- and post treatment readings were taken by the same examiner. This examiner was unaware of the group allocation of participants.	A group of 15 participants were randomly allocated into a group who received sham ultrasound as the control group.	Participants were randomly allocated into one of three groups, by the use of a randomization scheme created according to a randomization website.	9	90.73%
LIMITATIONS:	It is noted in this study by Blikstad and Gemmell (2008), that the participants were selected from the student body (age range was 22.6 – 24.9 years of age) at AECC, which does not allow the generalizability of the results, even though the range (in terms of age) that was accepted into the study was from 18-55 years of age. Additionally, as the AECC is a chiropractic college, it would have been expected that there would have been consideration of and possible exclusion of students that were involved in manipulation technique classes or classes teaching and involving the use of auxiliary therapy technique practicals; as these would have affected the							

	homogeneity of the participants between the groups as well as between the study participants and the general population (the latter resulting in a decrease of the generlizability of the results). To further complicate the inclusion of participants, the study included both unilateral (either side) and bilateral pain. This variance in the clinical presentation of the MFTP, allows for the inclusion of variable factors including that of hand dominance as well as other predisposing factors that may have affected the chronicity of the complaint (particularly as the most painful MFTP was utilised) and therefore the ability of the participant to react to one treatment intervention with the chosen intervention modalities. Additionally, the inclusion criteria required the participants to have neck pain, without delineation as to whether this included or excluded mechanical dysfunctions (as this may potentially have impacted on the ROM outcomes measured). As a result of the lack of stratification of the study participants, in addition to the limitations noted in paragraph one above, it is exceedingly difficult to determine the homogeneity of the sample between the groups and in relation to the general population. These two factors result in the study groups having limited comparability of the outcome as well as the generalizability of the study being limited to patient populations. In terms of bias, the lack of acknowledgement of naivety of the participants is an important consideration, particularly as this study utilised a sham intervention (ultrasound and activator application to the therapist's hands) and because there was an increased likelihood that the predominantly student population (chiropractic students who would have been taught the clinical application of the modality) participating in the study would have had a higher chance of identifying the sham therapy as compared to naïve participants that were not students. This consideration may have resulted in decreased performance of the clinical outcome measures based on perception, expectation and knowledge of the applied therapy (Phillips and Pugh 2000; Lessing and Schulze 2003; Armstrong, Allinson and Hayes 2004; Mackinnon 2004; Malfroy 2005; McAlpine and Norton 2006; Cheon*et al.*, 2009; Manathunga 2009; Nulty, Kiley and Meyers 2009; Danjuma and Rasli 2012) as opposed to its actual clinic effect. This is particularly evident in that, with the nature of the modalities being investigated (Dagenais and Haldeman, 2012), it would not have been possible for participants to be blinded. Therapist bias was also not excluded, as this is an inherent problem with manual therapy studies (Dagenais and Haldeman, 2012) and therefore it needs to be considered as a limitation. The only point in favour of the study was that the person measuring the outcomes was not familiar with the group allocation of the participants and credit must be given to the authors for the extensive process utilised to ensure that this was the case. In terms of the outcomes of the study, it is noted that only one visit / single treatment was applied. Therefore, the implications of the outcomes are only applicable in terms of the immediate effects of one intervention and not of short-term or long-term outcomes. This is an advantage for the study as the immediate effect rules out the possibility of confounding factors influencing the outcome between the intervention and subsequent readings. On the converse however, the fact that participants were asked to rate pain immediately following the treatment may have been complicated by the fact that: • The intervention therapy by virtue of its application may have aggravated the MFTP in the immediate term.

	• The effect of the cold ultrasound gel (if not warmed to room temperature) may have had a positive effect in the immediate term by anaesthetizing the skin. • The effect of touch therapy (by metallic device in all groups) may have resulted in equal improvement in all groups. • Some participants may have found it difficult to report immediate changes and / or they may have remembered the reading that they noted a short time before the intervention either repeated this value (based on their understanding of the intervention groups that they were in) thus basing their report on subjective experience of their understanding of the research as opposed to their clinical reality in terms of pain. The latter of the above bulleted statements may also have been affected by the fact that a female was allocated as the measurement person (as noted in the study), which may also have influenced the male respondents in the study (which were allocated disproportionately between the groups), thereby potentially affecting the clinical outcome measures and thus the post treatment response. Finally, it was noted that the PPT measurements were taken before the ROM measures. This has the potential to affect the outcomes for the ROM, particularly pre-treatment the aggravation of the MFTP by placing pressure on the MFTP may result in unrealistic restriction of movement (this could also have occurred post-treatment if the interventions themselves also aggravated the MFTP). By contrast, the application of the PPT may also be argued to apply a level of treatment in the form of ischemic compression, thus it may have resulted in increased ROM prior to the invention. In either event the changes in the ROM would have caused a narrowing of the window for clinical improvement due to the interventions being tested.
OUTCOME:	The results of this study revealed that ATrPT produced immediate relief for participants with non-specific neck pain, to a greater extent than participants treated with sham ultrasound and MBT.
DISCUSSION:	The authors of this study identified a gap in the literature with regards to MBT and ATrPT. According to the literature, although studies had been conducted on MBT, none of those studies were conducted to assess the effectiveness of MBT on non-specific neck pain. It was reported that ATrPT was used by practitioners for the treatment of non-specific neck pain, however, formal studies regarding the effectiveness of this treatment method was lacking. A RCT was designed and conducted to investigate the effectiveness of both the above mentioned modalities. The study involved three groups; one received MBT, the second received ATrPT and the third received sham ultrasound which was the control group. The study was conducted over single treatment administration periods for each modality; measurements were taken pre and post treatment. There was a lack of therapist and participant blinding; however, the participants who received the control intervention were unaware that they were receiving sham ultrasound instead of therapeutic ultrasound. Due to the fact that the study was conducted using immediate effects and single treatment durations, with no follow-up measurements, the results of this study cannot be applied to the long-term effects of non-specific neck pain. Therefore, further studies are required. The study was conducted using students from AECC as the participants. There were no details provided with regards to whether or not students were receiving additional treatment outside the study intervention. This has a negative effect on the results, because if they were receiving additional treatment it becomes difficult to ascertain whether the effects on outcome measures were purely due to the effects of the study

	intervention. The large age group inclusion difference creates a potential decrease in the reliability of results as the physiology of an 18 year old cannot be compared to that of a 55 year old. Factors that may have a further negative effect on the results include the fact that there was no mention as to whether or not participants had been previously exposed to US. This creates a problem, because if there was previous exposure, the participants would realize that they were in the control group. The activator was applied to the clinician hand in attempt to blind the assessor; however, this would make the other participants aware of their presence in the control group. The ROM readings were taken after the PPT was recorded. This has a potential effect on the readings, because the pressure placed on a muscle during PPT has an immediate effect on the ROM.
CONCLUSION:	This article was rated 9/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 93.82% noted in Table 4.9 above. Although the authors of the study indicated that the use of ATrPT produces immediate relief from non-specific neck pain, and the critical analysis of this article performed by the reviewers revealed a good overall rating, there were limitations as discussed above, which if taken into consideration could have further improved the accuracy of the results.

Table 4.11	Tabulated Feedback Data for RCT – Article 6					
AUTHORS:	B. Craane, P. U. Dijkstra, K. Stappaerts and A. De Laat					
TITLE:	One year evaluation of the effect of physical therapy for masticatory muscle pain: A randomized controlled trial					
YEAR:	2012					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	YES	YES	YES	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	YES	YES	YES	100%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	YES	YES	YES	YES	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	NO	YES	66%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	NO	NO	NO	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	9	9	8	9	
		OVERALL PERCENTAGE AGREEMENT				90.73%

Table 4.12	Analysis of Article RCT: Article 6							
AUTHORS:	B. Craane, P. U. Dijkstra, K. Stappaerts and A. De Laat							
YEAR:	One year evaluation of the effect of physical therapy for masticatory muscle pain: A randomized controlled trial							
TITLE:	2012							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual analogue scale. McGill Pain Questionnaire. Pressure Pain Thresholds of the masseter and temporalis muscles. The mandibular function impairment questionnaire. Active and passive maximal mouth opening.	Measurements were taken post-treatment, at 3, 6, 12, 26 and 52 weeks.	The intervention and control administration was conducted over a 6-month period; measurements were taken until 1 year following commence-ment of the study.	Initially, a total of 53 participants (26 in the therapy group and 27 in the control group) were included, however, following dropouts for various reasons throughout the 52 week duration of the study, a total of 45 participants (22 in the therapy group and 23 in the control group) completed the study.	The treatment and assessor physician were different people. The assessor was of aware of the group to which the participants belonged.	The control group were not given physical therapy. They were only given education at the consultations when measure-ments were recorded.	An electronic randomization plan was used to allocate participants into either the physical therapy or control groups.	9	90.73%

LIMITATIONS:	This study is similar to the study presented in Table 4.8 (Bahadir *et al.*, 2006) and Table 4.4 (Aguilera *et al.*, 2009), where it was noted that the inclusion criteria were not specific with regards to participant characteristics. This creates a problem with regard to the reader being able to identify and compare the outcomes between the study participants and the participants that she/he sees in clinical practice. In addition, it also raises questions about the comparability of the groups as the extraneous variables that the participants bring to the study are not accounted for. This then allows the outcomes to be questioned as the changes from the baseline may not only be related to the intervention, but also participant specific characteristics within the group being reviewed. One example of this in the study is the difference in age between the two groups. The limitations noted under the participant characteristics are further compounded by the small numbers (26 and 27 respectively in each group) and the attrition of participants to 22 and 23 per group respectively by the end of the study. This along with the participant variability has the potential to call the outcomes of the study into question. In terms of bias, it was noted that the therapist was not blinded, which is in keeping with the problem of blinding in the manual therapies (Dagenais and Haldeman, 2012). Therefore, this is an acknowledged flaw of these types of studies and similarly applies to the participants, particularly if no attempt has been made to ensure that the participants are naïve to the interventions being studied. With regards to assessor blinding, there was no mention in the study, so it was assumed that this did not happen and thus, this adds to an increase in the bias present in the study. In terms of the actual interventions, it is noted that the physical therapy group received in office stretching exercises as well as education regarding these exercises. This was supplemented with a "home work" model that required the participant to complete the stretching exercise at home. This is in contrast to the control group which received only education. It is not clear from the presented study whether a difference existed between the groups in terms of the number of follow-up visits outside of those that were used as measurement points. Lastly, in terms of the outcome measures, it was noted in the presented data that the groups were not equal with regards to the baseline PPT measures. This along with the lack of participant characteristics confounds the reader's ability to determine why this would have been possible. A further confounder was the fact that the study does not make mention that statistical controlling was used to avoid the effect of the incongruent baseline measures and their effect on the study outcomes.
OUTCOME:	The study compared the long-term effects of physical therapy on temporomandibular disorders (TMD). Two groups were used: one received physical therapy and the other was allowed to progress through the condition naturally. It was concluded that there was no significant difference after a period of one year between the groups, indicating that over time, TMD caused by MFTPs will resolve even without physical therapy.
DISCUSSION:	According to the authors of this study, the treatment of TMD and their related MPD has included several different approaches with regards to physical therapy. However, the literature lacks evidence produced by well designed controlled studies which investigates the efficacy of physical therapy for the treatment of this condition. A RCT was designed and executed to investigate the long-term efficacy of physical therapy on TMD and related MPD. The study consisted of two groups: the intervention group who received physical therapy and education

	as a part of a six-week regimen and a control group who received only education at the consultations. Due to the nature of the study and the distinct difference in the protocols for the control group and the intervention group, therapist blinding was not possible. This study focused on the long-term effects of treatment, which resulted in participants dropping out over the course of the 1 year period. These factors may have had a negative impact on bias and thus the reliability of the results. The inclusion and exclusion criteria of this study did not include details that were specific to participants. This decreases the validity of results, as one is unaware of the participant types being compared. There was a difference with regards to PPT measurements at baseline which was not accommodated for during statistical analysis, and this results in the outcome measures of PPT post-treatment being questioned with regards to their validity. There was a significant difference between the age groups allocated to the intervention and control groups, which decreases the reliability of the results as the comparison of vastly different age groups creates discrepancies within the comparison.
CONCLUSION:	This article was rated 9/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 90.73% noted in Table 4.11 above. Although the authors of the study indicated that there was no significant difference between the therapy group and the control group, the analysis and rating shows that the study was of a good quality with an exception of the limitations mentioned above.

Table 4.13	Tabulated Feedback Data for RCT – Article 7					
AUTHORS:	H. Gemmell, P. Miller and H. Nordstorm					
TITLE:	Immediate effect of ischaemic compression and trigger point pressure release on neck pain and upper trapezius trigger points: A randomized controlled trial					
YEAR:	2008					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	YES	YES	YES	YES	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	YES	YES	YES	100%
6	There was blinding of all therapists who administered the therapy	YES	NO	NO	NO	66%
7	There was blinding of all assessors who measured at least one key outcome	YES	YES	YES	YES	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	NO	YES	YES	YES	66%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	NO	YES	YES	YES	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	NO	YES	YES	YES	66%
	TOTAL SCORE	8	10	10	10	
		OVERALL PERCENTAGE AGREEMENT				87.64%

Table 4.14	Analysis of Article RCT: Article 7							
AUTHORS:	H. Gemmell, P. Miller and H. Nordstorm							
YEAR:	Immediate effect of ischaemic compression and trigger point pressure release on neck pain and upper trapezius trigger points: A randomized controlled trial							
TITLE:	2008							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual Analogue Scale (VAS). Cervical ROM Goniometer. Pressure Algometer (PA).	Measurements were taken pre and post treatment or control administration.	The study was conducted over the period of time required for single treatment sessions.	There were 45 participants; 15 in the IC group, 15 in the TrPPR group and 15 in the control group.	The examiner was a different individual to the clinician, who was unaware of group allocation, therefore, there was assessor blinding.	There was a control group, they received sham ultrasound.	The forty five participants were randomly allocated to one of the three groups.	10	87.64%
LIMITATIONS:	Similar to Blikstad and Gemmell's (2008) study (Table 4.10), this study also utilised chiropractic students of the AECC as participants. Therefore, the discussion around the limitations of this approach as described in Table 4.10 is also applicable to this discussion and context. The only difference being that the average age of the groups in this study were 24 and 23 for the intervention groups; however, the same principle exists in that the results can only be generalizable to the participant population of similar age ranges to the study outcomes and not those congruent with the stated inclusion criteria (18-55 years of age). In terms of biases in the study, it was noted that there was no: • therapist blinding • participant blinding, which was compounded by the fact that the students would have been able to determine the control group / placebo group intervention based on their education and training. The extent of this was not documented in the study and therefore the effect on the outcomes is not measureable. The use of a chiropractic student known to the study participants, as an assessor, is also questioned as the familiarity between these parties could also have influenced the results, in addition to the relative inexperience of the assessor.							

	In terms of the interventions, it was noted that the results of this study were based on immediate effects. There was no follow-up sessions, therefore, the short-term, intermediate-term and long-term effects of the therapy remain unknown. It was also noted that there was no discussion on the possible impact of the cooling of the US gel that was applied to participants in all groups, as well as the movement and mechanical stimulation of the US head over the muscle and the combined effect of these actions on the overall outcome of the study.
OUTCOME:	The study compared three groups, one received IC, the second received TrPPR and the third (the control) received sham ultrasound. The authors of this study concluded that IC as well as TrPPR were more effective than the control in the alleviation of MPD in the trapezius muscle, however, the results were noted as inconclusive with regards to the comparison between the IC and TrPPR groups.
DISCUSSION:	The authors of this study noted that IC was a MPD treatment modality that had been investigated previously, however, they also noted that there had not been a study conducted previously that compared two different types of IC, namely: IC and TrPPR. A RCT was designed and conducted to investigate this comparison. The study comprised three groups; group one received IC, group two received TrPPR and group three received sham ultrasound (control group). Due to the nature of the therapies it was not possible for there to be therapist blinding, therefore, there was a possibility of increased bias. The examiner was a fourth year chiropractic student who had little experience or practice with regards to the measurements being taken, and as such, this created a question about the quality of those measurements. The study participants were the students of AECC, the study design did not indicate whether or not these students were receiving any additional therapy other than the study intervention. If they were, the results of this study were negatively affected as one is unable to note if the changes in the participants' symptoms were due to the intervention. The large age group inclusion difference creates a potential decrease in the reliability of results as the physiology of an 18 year old cannot be compared to that of a 55 year old. The study included sham US as the control; however, the cooling effect of the US gel and the mechanical effect of the US head were not taken into consideration. This may have a negative effect on the comparison between groups as these factors may potentially produce relief of the MFTP symptoms.
CONCLUSION:	This article was rated 10/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 87.64% noted in Table 4.13 above. Although authors of this study concluded that IC was more effective than the control and that the comparison between IC and TrPPR was inconclusive, the study was rated 'excellently' by the reviewers and with and exception of the limitations discussed above, this study is of a high quality.

Table 4.15	Tabulated Feedback Data for RCT – Article 8					
AUTHORS:	H. Gemmell and A. Allen					
TITLE:	Relative immediate effect of ischaemic compression and activator trigger point therapy on active upper trapezius trigger points: A randomized trial					
YEAR:	2008					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	YES	YES	YES	YES	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	NO	NO	NO	NO	100%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	YES	YES	YES	YES	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	NO	YES	YES	66%
	TOTAL SCORE	9	8	9	9	
		OVERALL PERCENTAGE AGREEMENT				96.91%

Table 4.16	Analysis of Article RCT: Article 8							
AUTHORS:	H. Gemmell and A. Allen							
YEAR:	Relative immediate effect of ischaemic compression and activator trigger point therapy on active upper trapezius trigger points: A randomized trial							
TITLE:	2008							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Patient global impression of change scale. NRS. Pain pressure algometer.	Measurements were taken pre and post single session treatment administration for both groups.	The study was conducted over single session treatments for each participant.	There were a total of fifty two participants. 25 were in the IC group and 27 were in the activator group.	There was assessor blinding as the examiner and the therapist were two different people.	No control was used.	Participants were randomly allocated by means of a randomization program on a website.	9	96.91%
LIMITATIONS:	As seems to be consistent with the previous articles of Gemmell, Miller and Nordstorm (2008) (Table 4.14) and Blikstad and Gemmell (2008) (Table 4.10), this study was noted to have the same limitations concerning the following: • The participants were staff and students from the AECC which resulted in a28/ 29 year average age per group. This limits the studies generalizability and therefore also the applicability of its outcomes to the general population as the study has a defined group of participants that may not share the same characteristics as the general population. • The relatively small sample size per group also limits the likelihood that the study was able to achieve statistical significance indicating that the outcomes achieved were better than those of chance alone. • No attention seems to have been given to the side of hand dominance and how this may have affected the outcome of the study. Further to the above, the following limitations also need to be considered as possible confounders to the study as it was presented: • The inclusion of participants in the pre-study "test/dummy run" was not clearly defined. As a result, it is not clear whether the participants in the pre-study "test/dummy run" were allowed to participate in the main study. This would have allowed unfair advantage in terms of the participants understanding and possible influence of the outcomes. This would have been particularly problematic if the "test/dummy run" participants (if included) also happened to fall into the same group.							

	• The study indicates that participants were only included if they reported sub-acute pain duration. Therefore, the results can only be applied to that part of the population reflecting similar pain characteristics and not the entire population of participants with trapezius trigger point pain. • The lack of a control group within the study indicates that there was no accounting for the natural progression of myofascial trigger point resolution and / or the effect of placebo. In terms of the methodology of the study: • The examiner was a chiropractic student who lacked sufficient experience with regards to the measurements that were taken; this decreases the reliability of the measurements, thus, decreasing the reliability of the results.
OUTCOME:	This study compared two groups; one received IC and the other received activator therapy. The authors concluded that there was no significant difference between the groups and both modalities were equally effective in the treatment of MFTPs and MPD in the trapezius muscle.
DISCUSSION:	The authors of this study searched the literature and discovered that although there was an abundance of studies investigating the effectiveness of IC versus other modalities in the treatment of MPD, there was no previous study that had been conducted to directly compare the difference in effectiveness between IC and activator therapy. They conducted a RCT which consisted of two groups; one group was treated using IC and the second group was treated using activator therapy. In this study there was a lack of both therapist and participant blinding due to the nature of the modalities being compared, which created doubt with regards to bias and placebo that ultimately may have affected the results. The participants were not equally distributed between the groups which may have negatively affected the results especially disadvantaging the IC group which had fewer participants than the activator group. There was no control group in this study which further decreased the reliability of the results due to the lack of elimination of placebo effect. The examiner was an inexperienced student; this makes the measurements records questionable due to inadequate clinical practice. The large age group inclusion difference creates a potential decrease in the reliability of results as the physiology of an 18 year old cannot be compared to that of a 55 year old. There was no mention of hand dominance, this affects results as a participant treated on the dominant side cannot be significantly compared to one who receives the same treatment on the non-dominant side. Prior to the conduction of the trial a group of test participants were exposed to the process to test the way it would work. There was no emphasis on whether or not these test participants were included or excluded from the actual study trial. The study participants were the students and staff of AECC, the study design did not indicate whether or not these students were receiving any additional therapy other than the study intervention. If they were, the results of this study would be negatively affected as one is unable to note if the changes in participants' symptoms were due to the intervention.
CONCLUSION:	This article was rated 9/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 96.91% noted in Table 4.15 above. Although the study received good ratings from reviewers, the limitations mentioned have a great influence on the overall results and decrease the validity of the results.

Table 4.17	Tabulated Feedback Data for RCT – Article 9					
AUTHORS:	H. Gemmell and A. Hilland					
TITLE:	Immediate effect of electric point stimulation (a type of TENS) in treating latent upper trapezius trigger points: A double blind randomized placebo-controlled trial					
YEAR:	2011					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	YES	YES	YES	YES	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	NO	YES	YES	YES	66%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	YES	YES	YES	YES	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	NO	YES	YES	YES	66%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by "intention to treat"	NO	YES	YES	YES	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	NO	YES	YES	YES	66%
	TOTAL SCORE	6	10	10	10	
		OVERALL PERCENTAGE AGREEMENT				87.64%

Table 4.18	Analysis of Article RCT: Article 9							
AUTHORS:	H. Gemmell and A. Hilland							
YEAR:	Immediate effect of electric point stimulation (a type of TENS) in treating latent upper trapezius trigger points: A double blind randomized placebo-controlled trial							
TITLE:	2011							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Pain pressure algometer. Cervical ROM goniometer. Numeric rating scale (NRS).	Measurements were taken pre and post single session treatments.	The study was conducted over single session treatment or control administration.	There were 60 participants. 30 were treated with Electric Point Stimulation (EPS) and 30 were in the control group.	The examiner remained blinded throughout the duration of the study.	A control group received EPS that had and intensity of zero.	Participants were randomly allocated to groups by means of a randomization website.	10	87.64%
LIMITATIONS:	As seems to be consistent with the previous articles of Gemmell, Miller and Nordstorm (2008) (Table 4.14); Blikstad and Gemmell (2008) (Table 4.10) and Gemmell and Allen (2008) (Table 4.16), this study suffered from the same limitations around the following: • The sample consisted of staff and students from the AECC, this is a limitation as the study does not delimit whether these participants were required to limit or eliminate any other treatment options (which would have included practical technique sessions for students). These extraneous variables would have affected the outcomes measured in this study. • Consistent with the above, the age groups of the study were inherently low, even though the inclusion criteria reported to include participants from the ages of 18-60. This limited age range was a direct result of the target population used in the study and results in the study not being generalizable to the general population. • In addition to the above, the hand dominance of the participants was not recorded. As a result, it is not possible to determine whether any intervention was / was not directly related to the sidedness of the trapezius trigger point and its relationship to their hand dominance. • In terms of the interventions, the therapist (researcher) was not blinded, which may have had an effect on increasing bias in the study.							

	In addition to the above, it was also noted that: • The study required immediate post treatment measurements, with no-follow up session. Therefore, the outcomes of the study can only be limited to the immediate effects and not the short-, medium or long-term effects in terms of the application of the TENS to trapezius myofascial trigger points. • Although the participants were required to present with latent MFTPs, it is important to note that the manner in which the exclusion criteria were presented, did not convey a systematic and pragmatic manner of excluding all pathological causes that could allow the participant to present with MFTPs. • The clinical presentation of latent trigger points, does not include the possibility of utilizing all clinical outcome measures, therefore it is necessary to consider the implications of the researchers having used: CROM, NRS and pain pressure algometry. Latent MFTPs would have an effect on ROM (Travell and Simons, 1992) and thus utilizing this as an outcome measure is reasonable. Similarly, the use of the pain pressure algometer is reasonable in that it allows for detecting pressure loads at which the latent trigger point produces discomfort for the participant. However, the use of the NRS is limited as it could only be used to measure the discomfort reported on the pain pressure algometry [which would depend on participant pain thresholds (Dagenais and Haldeman, 2012)], as compared to pain produced by the MFTPs. In latent MFTPs, there is no overt pain (Travell and Simons, 1992) (and the participants were required to be asymptomatic), so the use and comparison of pain readings is not possible. This latter limitation also results in the question as to the applicability of the use of the NRS in participants in this study.
OUTCOME:	The study investigated the comparison between EPS and a placebo, the authors concluded that EPS was effective in decreasing pain ratings but showed no difference in measurements to that of placebo with regards to cervical ROM.
DISCUSSION:	The authors of this study searched the literature and identified a gap with regards to TENS. They noted that several studies had been performed to investigate the effectiveness of traditional TENS; however, no previous study had been conducted to investigate the effectiveness of EPS. They designed and conducted a RCT to investigate this effectiveness. The study consisted of sixty participants who were equally and randomly allocated into the treatment group (EPS) or the control group (sham EPS). The study was noted to be of a high quality with regards to the overall structure and reliability of the results, however, there was no therapist blinding which increased the question of bias. Also, there was no long-term follow-up which meant that these results could only be used as an indication for the immediate effects of EPS. The study participants were the students and staff of AECC, the study design did not indicate whether or not these students were receiving any additional therapy other than the study intervention. If they were, the results of this study are negatively affected as one is unable to note if the changes in participants' symptoms were due to the intervention. The large age group inclusion difference creates a potential decrease in the reliability of results as the physiology of an 18 year old cannot be compared to that of a 60 year old. The study consisted of participants who were asymptomatic and had latent MFTPs, this is indicative that the results obtained cannot be applied to a general population but instead a limited portion of that population.
CONCLUSION:	This article was rated 10/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 87.64% noted in Table 4.17 above. The study received an excellent reviewer rating, and it has been noted that it fulfils the requirements for a study producing reliable results with the exception of the limitations discussed above.

Table 4.19	Tabulated Feedback Data for RCT – Article 10
AUTHORS:	A. Gur, A. J. Sarac, R. Cevik, O. Altindag and S. Sarac
TITLE:	Efficacy of 904 nm gallium arsenide low level laser therapy in the management of chronic myofascial pain in the neck: A double-blind and randomized controlled trial
YEAR:	2004

CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	YES	NO	YES	YES	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	YES	YES	YES	100%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	YES	YES	YES	YES	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	10	9	10	10	
		OVERALL PERCENTAGE AGREEMENT				96.91%

Table 4.20	Analysis of Article RCT: Article 10							
AUTHORS:	A. Gur, A. J. Sarac, R. Cevik, O. Altindag and S. Sarac							
YEAR:	Efficacy of 904 nm gallium arsenide low level laser therapy in the management of chronic myofascial pain in the neck: A double-blind and randomized controlled trial							
TITLE:	2004							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual Analogue scale (VAS). Neck pain and disability scale (NPDS). Beck Depression Inventory (BDI). Nottingham health profile (NHP).	Measurements were taken pre-treatment and at 2, 3 and 12 weeks following intervention.	The study was conducted over a twelve week period.	There were a total of sixty participants with 30 being allocated to the treatment group (actual LLLT) and 30 being allocated to the control group (sham LLLT).	The examiners and participants remained blinded to the group allocation throughout the duration of the study.	There was a control group and they were given laser treatment with a device that was not turned on.	Participants were randomly allocated to one of the two groups.	10	96.91%
LIMITATIONS:	This well thought out study provided good levels of rigour, although some external sources of bias existed, which included the fact that the study was only conducted using participants who had reported pain of duration greater than one year. This limits the generalizability of the study to participants of the same type and calibre of pain presentation. This is, however, complicated by the lack of the description of whether the chronic pain perceived by the participant was intermittent or continuous for the one-year duration of the study. As a result, it is unclear whether participants accepted onto the study were participants with one episode of chronic pain or participants that had chronic neck pain, with intermittent episodes of pain exacerbation or whether the participant was defined as having had chronic pain (as evidenced by several episodes of pain within the given year that were interspersed with periods of no pain) (Chaitow and DeLany, 2000). These different participant presentations elude to different pathomechanical causes and therefore also potential responses to care (Gerwin, 2010).							

	In addition to the above, it is acknowledged that although randomization was used in the study, the method used is not the most effective one in ensuring complete randomisation where each participant had an equal chance of being in either group (Mouton, 1996 and Mouton, 2006). This lack of appropriate randomisation may be partly responsible for the study demonstrating a difference in mean ages between the placebo and intervention groups. This age difference suggests that there may have been an inherent difference between the groups with regards to the participants' ability to respond to care (Roberg and Roberts, 1997 and Suter *et al.,* 2007).Thus the impact of the age difference and the lack of acknowledgement that this was controlled for in the analysis calls into question the outcomes of the results obtained. In addition, the lack of therapist blinding which may have introduced bias into the study, resulting in data skew, which may be another reason for differences in responses to interventions, therefore calling the results into question. Lastly, the trial participant flow diagram shows a drop-out of four participants (one in the treatment group and three in the placebo group) due to what was classified as a "lack of efficacy". This suggested that the participants left the groups as a result that they perceived the treatment was not working. Further extrapolation of this thought, means that there was a likelihood that participants were able to detect whether they were in the active treatment group or not. This may have affected the outcome of the study, although this is not formally acknowledged and it is not known whether the drop-outs would have affected the outcome of the study should an appropriate analysis have included these participants (e.g. intention to treat analysis) (Moher *et al.,* 2008).
OUTCOME:	The study investigated the effectiveness of LLLT versus sham laser on chronic neck pain over a twelve-week period. The authors concluded that LLLT was significantly more effective than sham laser with regards to all the measurement outcomes. Although sham laser produced a decrease in pain, the active LLLT produced a decrease in all parameters measured.
DISCUSSION:	This study was conducted with the intention of filling a gap in the literature that was identified by the authors. They noted that several studies had been done to investigate laser and they did produce positive results but these results were still criticized and not taken seriously. They identified that only a few studies had been conducted to investigate the effectiveness of LLLT on MFTP related neck pain and none had been conducted using the desired settings and measurement outcomes of this study. A RCT was designed and performed to compare two groups of thirty participants. The first group was treated using active LLLT whilst the control group was treated using sham laser. The results for this study were favourable with regards to the use of LLLT, however, there was a lack of therapist blinding which plays a role in increasing the bias involved and the study only included participants with pain of over one-year duration. This indicates that results can only be applied to a specific part of the population. The pain experienced by participants was not specified as being intermittent or continuous for the period of one year. This may have a negative effect on the overall results as it indicates a specific part of the overall MPD population to whom the results are applicable. The study contains a trial profile which states that one participant from the intervention group and three participants from the placebo group dropped out due to a "lack of efficacy"; however, this statement was not discussed further, therefore, it may indicate that these participants dropped out due to a lack of effect or an adverse effect produced during the intervention and placebo. Randomization in this study was conducted by a similar technique to the "hat method" which is not entirely reliable as the participants do not stand equal chances of being allocated into one of the groups. There was

	an age difference between groups which affects the validity of comparison between groups, thus, making the results questionable.
CONCLUSION:	This article was rated 10/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 96.91% noted in Table 4.19 above. Despite the limitations discussed above, this study has been rated as one of excellent calibre and reliable results.

Table 4.21	Tabulated Feedback Data for RCT – Article 11					
AUTHORS:	A. Hakgunder, M. Birtane, S. Gurcan, S. Kokina and F. N. Turan					
TITLE:	Efficacy of low level laser therapy in myofascial pain syndrome: an algometric and thermographic evaluation					
YEAR:	2003					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	NO	NO	NO	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	NO	NO	NO	NO	100%
6	There was blinding of all therapists who administered the therapy	NO	YES	NO	NO	66%
7	There was blinding of all assessors who measured at least one key outcome	YES	YES	YES	YES	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	NO	YES	YES	YES	66%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	NO	YES	NO	NO	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	NO	YES	YES	YES	66%
	TOTAL SCORE	5	9	7	7	
		OVERALL PERCENTAGE AGREEMENT				87.64%

Table 4.22	Analysis of Article RCT: Article 11							
AUTHORS:	A. Hakgunder, M. Birtane, S. Gurcan, S. Kokina and F. N. Turan							
YEAR:	Efficacy of low level laser therapy in myofascial pain syndrome: an algometric and thermographic evaluation							
TITLE:	2003							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual analogue scale (VAS). Pressure algometer (PA). Infrared thermography.	Measurements were taken pre-treatment, post-treatment and at a three week follow-up.	The intervention was administered over ten days but the study only terminated following the three week follow-up.	There were a total of sixty two participants. Group One received LLLT and stretching exercise program whereas Group Two received the stretching program alone.	The examiner and the clinician were different individuals and the examiner was not aware of group allocation.	There was no control group as the intended control group was receiving stretching with is actually an intervention.	The participants were randomly allocated into either the treatment or control group.	7	87.64%
LIMITATIONS:	This study was noted as an efficacy study, which suggests that the second group was a control group (non-intervention group) (Mouton, 2006). However, on reviewing the study, it became apparent that the study actually required the inclusion of an intervention in the control group (stretching). Therefore, it is only possible that the study concluded that a combination of LLLT and stretching is or is no better than, worse than or equal to the implementation of the stretching intervention only. This is complicated by the inclusion criteria which indicate that participants had only one active MFTP in either the trapezius or the levator scapulae. It does not, however, mention that the numbers of the respective trigger points were equal between the groups. This brings a level of bias to the study as these muscles have different actions and different depths; therefore potentially resulting in different responses to the respective intervention outcomes. It may therefore be possible that the responses to treatment were as a result of these anatomical and physiological differences and not the actual intervention. Furthermore, the outcomes of the study would only be applicable to muscles of a similar nature as those represented by the levator scapulae and trapezius muscles. Similar to Gur *et al.*, (2004) (Table 4.20), this study had no therapist or participant blinding with similar sequelae and possible effects on the outcomes of the study. This is further compounded by the lack of drop-outs being noted or the final numbers of participants who completed							

	the study in each group. This lack of reporting does not allow for appropriate contextualisation of the results in terms of outcome, statistical strength and finally the generalisation of the results. Finally, the large age range of the participants who were allocated to each group without a comparison between the groups and the lack of stratification creates the same concerns as noted for Gemmell, Miller and Nordstorm (2008) (Table 4.14); Blikstad and Gemmell(2008) (Table 4.10);Gemmell and Allen (2008) (Table 4.16) and Gemmell and Hilland (2011) (Table 4.18),. In these studies the comparability between groups and between the study groups and the general population become affected by the relative ages of the participants as well as their ability to respond the care options being tested in each of the groups. This lack of age stratification to ensure that reduction of bias as a result of the large age range, may also have affected compliance with regards to the stretching program included in both groups. This is particularly true as the literature notes that older participants tend to be more compliant than younger participants (Roberg and Roberts, 1997 and Suter *et al.*, 2007).
OUTCOME:	The study investigated the efficacy of LLLT and stretching versus stretching alone. The authors concluded that LLLT with stretching produced a more significant decrease in pain experience as that reported by the participants.
DISCUSSION:	The authors involved in this study searched the literature regarding LLLT, they noted that several studies had been conducted to investigate the efficacy of LLLT but none of them used infrared thermography as an outcome measure. This study aimed to investigate the effectiveness of LLLT combined with stretching versus stretching alone by using the usual outcome measures and using infrared thermography. A study was conducted with 31 participants in each group. They received their allocated interventions for a period of ten days. A follow-up session and measurements were scheduled for three weeks following the interventions. Bias and the effects of placebo were negatively affected due to a lack of therapist and participant blinding. The intended control group was actually an intervention; hence, there was no real comparison to a control. There was no mention with regards to drop-outs or exclusion along the course of the study. This may have been due to the fact that all the participants received their intended interventions; however, this cannot be left to assumption. The large age group inclusion difference creates a potential decrease in the reliability of results as the physiology of an 18 year old cannot be compared to that of a 60 year old. The study included participants who had only one MFTP in either the trapezius or the levator scapulae. These factors potentially have a negative effect on the results because they will only be applicable to that specific MFTP, thus it cannot be applied to the general population of MPD. The negative impact also comes from the comparison of two different muscles with different anatomical and physiological features within the same study. Participants were given a stretching program to do at home; there were no measures in place to keep track of patience compliance. There was also no attention given to participant compliance and its effects on the outcome measures and final results.
CONCLUSION:	This article was rated 7/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 87.64% noted in Table 4.21 above. Although the authors of this study concluded that the results of the study were favourable towards the use of LLLT in the treatment of MPD, the study received a moderate rating. If the limitations discussed above are taken into consideration, the study quality and thus the validity of the results become questionable.

Table 4.23	Tabulated Feedback Data for RCT – Article 12					
AUTHORS:	L. Hsieh, H. Liou, L. Lee, T. Chen and A. Yen					
TITLE:	Effect of acupressure and trigger points in treating headaches: a randomized controlled trial					
YEAR:	2010a					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	NO	YES	NO	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	NO	NO	YES	NO	66%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	NO	NO	YES	NO	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	NO	YES	66%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	NO	YES	YES	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	7	6	9	7	
		OVERALL PERCENTAGE AGREEMENT				84.55%

Table 4.24	Analysis of Article RCT: Article 12							
AUTHORS:	L. Hsieh, H. Liou, L. Lee, T. Chen and A. Yen							
YEAR:	Effect of acupressure and trigger points in treating headaches: a randomized controlled trial							
TITLE:	2010a							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Headache quality of life questionnaire. Visual analogue scale.	Measurements were taken pre- treatment, post-treatment, one month following the intervention and six month following the intervention.	The interventions were administered over a period of one month and the last follow-up was conducted six months after, hence the study was conducted over a period of seven months.	There were a total of twenty eight participants. One group of fourteen received acupressure, the second group of fourteen were given muscle relaxant medication and analgesics.	The measurements were conducted by an independent research assistant who remained blinded to the interventions allocated to each group and their pre-treatment assessments.	No control was used.	The participants were randomly allocated by an independent research assistant using a predetermined randomization table.	7	84.55%
LIMITATIONS:	This study assessed the relative effectiveness of two treatment protocols between groups that were of a small number (14 per group). Therefore, this study has a limited ability to be generalized to the population and the ability to reach statistical significance as well as clinical significance was likely to be affected by Type Two errors (Mouton, 1996 and Moher, 2008). This is particularly true in that the groups attrition over the long-term follow-up periods, making the final number of participants per group less than the original fourteen. These small numbers of participants are therefore more likely to be affected negatively by the: • Lack of therapist and participant blinding, which increase the possibility of bias and data skewing. • Heavy reliance on participants who were given the responsibility for controlling and complying with the prescribed medication schedule.							

	• Lack of consistent measurement points that were compared between the groups (viz. the participants in each group rated their post-treatment pain at different times). These different time points would have given one or other group the advantage or disadvantage without the changes necessarily being that of the intervention. • Fact that the participants were not stratified by age between the groups, even with the large age range (24-83). This lack of stratification aggravates the point highlighted in the previous bullet point, as the groups may not collectively had equal amounts of time to enable healing.
OUTCOME:	This study aimed to compare the efficacy of therapeutic acupressure versus a combination of muscle relaxant medication and analgesics. The authors concluded that acupressure was more effective than muscle relaxant medication and analgesics. This conclusion was applied to both the immediate effects of the interventions as well as the long term effects at the six month follow-up.
DISCUSSION:	The authors of this study noted that there had been studies conducted which aimed to prove the efficacy of acupressure in pain relief. However, they identified a gap in the literature with regards to the comparison of the effectiveness of acupressure for treatment of MFTP related headaches versus the effectiveness of muscle relaxant medication and analgesics. They designed a RCT which consisted of two groups. One group received acupressure whereas the other received muscle relaxant medication. The study reliability may have been affected by the absence of therapist and participant blinding, which has a negative effect on the bias and placebo effects on the study. There was also no control group in this study which makes the reader question whether or not the effects of the intervention was influenced by a placebo. The participant drop-out rate was increased due to the duration of the study and the six month follow-up assessment. This created a discrepancy between the numbers of participants in the groups at the end of the study when results were being compared. The large age group inclusion difference creates a potential decrease in the reliability of results as the physiology of a 24 year old cannot be compared to that of an 83 year old. The treatment protocols for each group consisted of a combination of modalities, this is indicative that the results of this study are only applicable for these specific combinations and not the individual modalities. There were initially fourteen participants in each group, which was further decreased to thirteen in the acupressure group and ten in the pharmaceutical group. These numbers are not very significant as sample sizes and larger sample sizes will be required in order to confidently apply the results to the general MPD population. There was no attention given to the measures that may have been put in to place to prevent a lack of participant compliance with regards to the medication that was prescribed to the pharmaceutical group. The study states that post-treatment pain ratings by the participants were performed after one month or six treatment sessions, "whichever came sooner". This creates a discrepancy in the results as participants were not allowed the same amount of recovery time following treatment. The participants in the pharmaceutical group received a single consultation with the therapist clinician, whereas the acupressure group consulted with the therapist for each treatment. This has a negative effect on the results.
CONCLUSION:	This article was rated 7/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 84.55% noted in Table 4.23 above. Although the authors of this study concluded that acupressure was more effective than muscle relaxant medication in combination with analgesics in the treatment of MFTPs which cause chronic headaches, the study received a moderate rating with regards to the Pedro Scale. If the limitations discussed above are taken into consideration, the study quality and thus the validity of the results become questionable and the study may actually be considered to be of a poorer quality than reported by the authors and rated by the reviewers.

Table 4.25	Tabulated Feedback Data for RCT – Article 13					
AUTHORS:	L. Hsieh, C. Hong, S. Chern and C. Chen					
TITLE:	Efficacy and side effects of diclofenac patch in the treatment of patients with myofascial pain syndrome of the upper trapezius					
YEAR:	2010b					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	NO	NO	NO	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	NO	NO	NO	66%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	YES	NO	NO	NO	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	9	7	7	7	
		OVERALL PERCENTAGE AGREEMENT				93.82%

Table 4.26	Analysis of Article RCT: Article 13
AUTHORS:	L. Hsieh, C. Hong, S. Chern and C. Chen
YEAR:	Efficacy and side effects of diclofenac patch in the treatment of patients with myofascial pain syndrome of the upper trapezius
TITLE:	2010b

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual Analogue Scale. Patient pain diaries were used to track patient pain over the duration of the study. Cervical active ROM. Pressure pain threshold. Patient global assessment Neck Disability Index.	Measurements were noted pre- treatment and at days one, four and eight.	Study was conducted over a period of eight days.	There were a total of 153 participants with 97 being allocated to the treatment group and 56 being allocated to the placebo group.	There was no mention of assessor blinding.	There was a non-active menthol patch used as a control in this study.	Participants were randomly allocated into either the control group or the intervention group.	7	93.82%

LIMITATIONS:

In terms of the analysis of the study by Hsieh *et al.*, (2010b) it was apparent that :

- It was seen that the study attempted to recruit an appropriate sample size to obtain a sample size that had the realistic possibility for attaining statistical significance; however, this was done at the expense of equal and comparable group sizes.
- The study presented with stretching in each of the groups, which limits the study's ability to discuss only the outcomes of combination therapies and not pronounce on any single intervention.
- The above combination therapies were further confounded by the use of "rescue medication". The use of these "rescue medications" was at the discretion of the participant and depended on the amount of pain that the participant experienced. This had the potential to affect the outcomes for one or both the groups. Therefore, the impact of this decision on the outcomes of the study is unknown as it was not reported / fully documented. An increase use and reporting of the participant diaries may have assisted in ameliorating the effects of the use of rescue medication and stretching for each of the participants and therefore also the respective groups.

	To complicate the above limitations, there was also mention of assessor, participant or therapist blinding. This lack of blinding increases the likelihood that these respective participants would have been able to affect the outcomes of the study, either positively or negatively in a manner that would detract from the actual intervention being tested. This, therefore, limits the study's ability to be generalised and contextualised in a setting that is dissimilar to the research setting. Lastly, it is not clear from the methodology as to who was responsible for the application of the Diclofenac patch. This calls into question whether the application was consistently and appropriately placed for each treatment interaction. The inability to understand this detail makes the reader unsure as to the degree and level of specificity with which the interventions were employed.
OUTCOME:	The authors of this study concluded that Diclofenac sodium patches were more effective than placebo patches in the treatment of MFTP in the upper trapezius muscles
DISCUSSION:	The authors of this study identified a gap in the literature with regards to the use of Diclofenac as treatment for MPD in the upper trapezius muscle. According to previously conducted studies, Diclofenac is very effective in the treatment of inflammatory conditions; however, the authors of this study noted that no previous study had been conducted to investigate the efficacy of Diclofenac on MFTPs and MPD. A RCT was designed and conducted to compare the effects of a Diclofenac sodium patch versus a control patch. Due to the fact that the difference in the numbers of participants in the intervention versus the control group do not match with the intended 2:1 ratio, the comparison of the final measurements may have been negatively affected, resulting in a decreased reliability of the results. There was also no mention of participant, therapist and assessor blinding. Although this information may have been omitted due to the presence of these factors, it cannot be left to assumption and should have been specified. This negatively affects the reliability of the study further. The application of the patch may have been done by either the clinician or the participant; specific information regarding this is unclear. If it was performed by the participant then the question of participant compliance and use of correct application details becomes pertinent. Results can only be deemed true for the specific combination used for this study and is not applicable for the modality alone. Participants were allowed to take rescue medications which have potential sedative and relaxant effect. This decreases the credibility of results as the effects recorded may have been influenced by the rescue medication.
CONCLUSION:	This article was rated 7/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 93.82% noted in Table 4.25 above. Although the outcome noted by the authors was a favourable, there were limitations as discussed above which decreases the reliability of the results.

Table 4.27	Tabulated Feedback Data for RCT – Article 14					
AUTHORS:	A. Iqbal, S. A. Khan and M. Miraj					
TITLE:	Efficacy of ischaemic compression technique in combination with strain counterstrain technique in managing upper trapezius myofascial trigger point pain					
YEAR:	2010					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	NO	YES	YES	66%
3	Allocation was concealed	NO	NO	NO	NO	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	NO	NO	NO	66%
6	There was blinding of all therapists who administered the therapy	YES	NO	NO	NO	66%
7	There was blinding of all assessors who measured at least one key outcome	YES	NO	NO	NO	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	NO	YES	66%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by "intention to treat"	YES	YES	NO	YES	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	10	6	5	7	
		OVERALL PERCENTAGE AGREEMENT				81.45%

Table 4.28	Analysis of Article RCT: Article 14
AUTHORS:	A. Iqbal, S. A. Khan and M. Miraj
YEAR:	Efficacy of ischaemic compression technique in combination with strain counterstrain technique in managing upper trapezius myofascial trigger point pain
TITLE:	2010

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Pain pressure threshold by the use of pressure threshold meter. Visual Analogue Scale. Neck Disability Index.	Measurements were taken pre-treatment, post-treatment on day one, post treatment on day three, post treatment on day five and one week following intervention.	The study lasted a total of two weeks, the first week was the intervention week, and the second week was the follow-up week.	There was total of forty-five participants. Fifteen were allocated to the group that received heat pack, active stretching, ischaemic compression and strain-counterstrain technique, fifteen were allocated to a group that received heat pack, active stretching and ischaemic compression alone and the final fifteen received heat pack and active stretching alone.	There was no mention of assessor blinding.	The control group received the heat pack and active stretching alone.	Participants were randomly allocated into one of the three groups by the "Chit method".	7	81.45%

LIMITATIONS:

The study as presented by Iqbal *et al*., (2010), was fairly well structured, however:

- The outcomes of the study were limited to only males and thus the results are not generalizable to the general female population.
- There was no explicit description of assessor, therapist or participant blinding. The perceived lack of these attributes to this study indicates that there was a possibility that bias (Mouton, 1996 and Dagenais and Haldeman, 2012) from one or more of these sources has been introduced. This means that the outcomes of the study may have been affected by these biases and therefore are not a true reflection of only the intervention utilized in the study.
- In terms of the participant homogeneity, it was noted that although most measures to achieve homogeneity were recorded in the publication, there were some factors that could have influenced the outcome of the study that were not accounted for. This includes for example, the participants' occupation and the laterality of the trapezius muscle that was treated in each of the participants. This

	can best be depicted by indicating that some participants would have had the trapezius muscles on their dominant side treated and others on their non-dominant side. This has implications for their recovery and therefore has an impact on the outcome measures used and the intervals in which the measurements were taken. The interventions and control groups consisted of protocols which combined more than one therapy. Therefore, the results for this study are limited to a discussion on the outcomes of the combination therapy and not the individual modalities. Thus, the clinical outcomes as regards the individual modalities are therefore lacking.
OUTCOME:	The authors of this study aimed to investigate the effectiveness of ischaemic compression combined with strain-counterstrain technique versus ischaemic compression alone as well as versus a control. They concluded that the combination of ischaemic compression and strain-counterstrain technique is more effective than both ischaemic compression alone and the control.
DISCUSSION:	The authors of this study identified ischaemic compression as a manual therapy often used to treat MFTPs and MPD. They searched the available literature and discovered that although several studies had been conducted to investigate the effectiveness of ischaemic compression, no studies were done previously to investigate the effects of ischaemic compression in combination with other manual therapies, specifically strain-counterstrain. A study was designed and conducted which involved three groups of fifteen participants each. Group One received heat therapy, active stretching, ischaemic compression and strain-counterstrain technique, Group Two received heat therapy, active stretching and ischaemic compression and Group Three (the control) received only heat therapy and active stretching. There was no mention of assessor, therapist or participant blinding. It was noted that although this information may have been omitted on the assumption that blinding was present, the information cannot be assumed true unless it is specified. The study was conducted including only male participants; this indicates that the results cannot be applied to the population as a whole. The therapy was administered unilaterally; there was no attention given to which particular side of the body was treated, which may have negatively affected the results as there were different predisposing and perpetuating factors that affect each side depending on dominance. Each of the three groups received combination therapies. This decreases the efficacy of the results because they cannot be applied to specific modalities; instead they are applicable only for the particular combinations used in this study.
CONCLUSION:	This article was rated 7/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 81.45% noted in Table 4.27 above. The results of this article indicated that the combination of ischaemic compression and strain-counterstrain is more effective than the ischaemic compression alone. However, the limitations mentioned above have a negative effect on the overall reliability of the results.

Table 4.29	Tabulated Feedback Data for RCT – Article 15					
AUTHORS:	J. H. Jeon, Y. J. Jung, J. Y. Lee, J. S. Choi, J. H. Mun, W. Y. Park, C. H. Soe and K. U. Jang					
TITLE:	The effect of extracorporeal shock wave therapy on myofascial pain syndrome					
YEAR:	2012					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	NO	NO	NO	66%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	NO	NO	NO	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	NO	NO	NO	NO	100%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	NO	NO	NO	NO	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	NO	NO	NO	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	7	5	5	5	
		OVERALL PERCENTAGE AGREEMENT				93.82%

Table 4.30	Analysis of Article RCT: Article 15							
AUTHORS:	J. H. Jeon, Y. J. Jung, J. Y. Lee, J. S. Choi, J. H. Mun, W. Y. Park, C. H. Soe and K. U. Jang							
YEAR:	The effect of extracorporeal shock wave therapy on myofascial pain syndrome							
TITLE:	2012							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual Analogue Scale. McGill pain questionnaire. Pain rating Scale Cervical ROM.	Measurements were taken, pre-treatment, one week following first treatment and one week following third treatment.	The study was conducted over a period of three weeks.	There were a total of thirty participants. The first group of fifteen received extracorporeal shock wave therapy (ESWT) and the second group of fifteen received trigger point injection (TPI) and TENS.	There was no mention of assessor blinding.	There was no control group.	Randomization was not outlined in this study.	5	93.82%
LIMITATIONS:	Similar to the study by Iqbal *et al*., (2010) (Table 4.28), this study by Jeon *et al*., (2012) had the following limitations: • There was no reporting on the inclusion or exclusion of therapist, assessor or participant blinding in the study procedure. This negatively affects the outcomes of the study due to the possibility of the lack of these procedures introducing bias (Mouton, 1996 and Mouton 2006). This may have an impact on the outcomes of the study which would reduce the ability of the study to make categorical statements with regards to the interventions alone. • The inclusion and exclusion criteria were not properly outlined; therefore, the homogeneity of the groups cannot be determined. This has an impact on both on the comparability of the groups (and therefore the comparability of the interventions), and also on the ability of the study to be generalized to the patient populations outside of the study. This is further compounded by the lack of reporting of the process of participant allocation and randomization. Both of these factors therefore detract from the study's ability to categorically state that the outcomes were directly as a result of the intervention. In addition to the above similarities to Iqbal's *et al*., (2010) (Table 4.28) study, this study by Jeon *et al*., (2012) also had other limitations with regards to the following methodological contexts: • The study compared two interventions with no control group; therefore their study can only determine the relative effectiveness of the interventions and not the efficacy of the interventions (Moher *et al*., 2008).							

	• The participants in this study had previously been hospitalized for pain they suffered in their neck and shoulders. Therefore, the effect of the previous treatments cannot be ruled out as having influenced the outcomes of this study, particularly as no mention was made with regards to the type and consistency of the hospital treatment that they received. This is further complicated by the lack of clarity on whether the presenting MFTPs were of primary or secondary origin and / or primarily responsible for their neck and shoulder pain that required them to have been previously admitted to hospital. • Each group consisted of fifteen participants, which is a relatively small study sample implying that non-parametric statistics would have been used to calculate comparisons. This, therefore, has an impact on the ability of the study to obtain statistical and / or clinical significance. It was, therefore, noted in the study that a future study with a larger sample size be considered as the generalizability of the study would have been limited. o Lastly, the participants in each group received a different number of treatment sessions (three for the TPI Group and five for the ESWT Group). This has differential effects in terms of exposure to the treating doctor, perception of care received, and therefore, the perceived effectiveness and efficacy of the care as perceived and reported by the participants (Phillips and Pugh 2000; Lessing and Schulze 2003; Armstrong, Allinson and Hayes 2004; Mackinnon 2004; Malfroy 2005; McAlpine and Norton 2006; Cheon*et al.,* 2009; Manathunga 2009; Nulty, Kiley and Meyers 2009; Danjuma and Rasli 2012). This is particularly important as three of the four outcome measures in this study were subjective and had the possibility of being influenced by participant perception (Yeomans, 2000).
OUTCOME:	This study aimed to investigate the difference in efficacy of ESWT versus TPI and TENS in the treatment of MFTPs and MPD. The authors of this study concluded that ESWT was equal in efficacy to TPI and TENS.
DISCUSSION:	The authors of this study studied the literature and discovered that ESWT had been previously investigated with regards to its effect as treatment for specific inflammatory and musculoskeletal conditions. This modality was noted to be effective in the treatment of these conditions; however, a gap in the literature was identified with regards to the efficacy of ESWT as a treatment modality for MFTPs and MPD. A study was designed and conducted that compared ESWT with TPI and TENS as treatment for MFTPs in the trapezius muscle. During the rating of this study, it was noted that there was a lack of clearly defined inclusion and exclusion criteria, which makes it difficult for the results to be applied to the entire population as the reader is unaware of what the parameters of participant inclusion were. There was no mention of assessor, therapist of participant blinding which decreases the credibility of results due to an introduction of bias and placebo affects. There was no control group; hence the effect of a placebo cannot be determined. Although it was mentioned that this study was a RCT, there was no attention given to randomization of participants and as such it cannot be assumed that the participants were randomized to different groups. The groups each contained ten participants; this negatively affects the results as the number of participants is not significant enough, hence a study with larger sample size will be required to confirm the results and make them applicable to the larger population. There is a lack of information with regards to whether the MFTPs present in the participants were the cause of their pain or secondary to their pain. Each group received a different number of treatment sessions. This lack of intervention consistency decreases reliability of results as one group had move exposure to the clinician than the other.
CONCLUSION:	This article was rated 5/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 93.82% noted in Table 4.29 above. Although the authors rated their study favourably, the reviewers of the study concluded that the validity and reliability of results has been

	negatively affected by the limitations discussed above.

Table 4.31	Tabulated Feedback Data for RCT – Article 16					
AUTHORS:	A. Kalamir, H. Pollard, A. Vitiello and R. Bonello					
TITLE:	Intra-oral myofascial therapy for chronic myogenous temporomandibular disorders: A randomized controlled pilot study					
YEAR:	2010					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	YES	YES	YES	YES	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	NO	YES	YES	66%
5	There was blinding of all subjects	YES	NO	YES	YES	66%
6	There was blinding of all therapists who administered the therapy	YES	YES	YES	YES	100%
7	There was blinding of all assessors who measured at least one key outcome	YES	YES	YES	YES	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	11	9	11	11	
		OVERALL PERCENTAGE AGREEMENT				93.82%

Table 4.32	Analysis of Article RCT: Article 16							
AUTHORS:	A. Kalamir, H. Pollard, A. Vitiello and R. Bonello							
YEAR:	Intra-oral myofascial therapy for chronic myogenous temporomandibular disorders: A randomized controlled pilot study							
TITLE:	2010							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual Analogue Scale. Inter-incisal opening range. Jaw pain at rest, upon opening and upon clenching.	Measurements were taken pre-treatment, six weeks following intervention and six months following intervention.	The study was conducted over a period of six months.	There were a total of thirty participants. Ten were allocated to the intra-oral myofascial therapy (IMT) group, ten were allocated to the IMT plus education and exercise group and the final ten were allocated to the control group.	The assessor was an independent individual who remained blinded to the group allocation.	A control group received no treatment.	Randomization was done by an independent individual using a web-based random number generator.	11	93.82%
LIMITATIONS:	By contrast to some of the previous studies reviewed in this chapter (e.g. Gemmell, Miller and Nordstorm (2008) (Table 4.14); Blikstad and Gemmell (2008) (Table 4.10); Gemmell and Allen (2008) (Table 4.16) and Gemmell and Hilland (2011) (Table 4.18), this study was well constructed, with the population being clearly defined to a specific subgroup of participants that had chronic myogenous temporomandibular disorders. Although this becomes a limitation of the study (i.e. the lack of generalizability), it provides a clear outcome for a specific subgroup of participants. Therefore, the only significant limiting factors were those related to the fact that this was a pilot study (with a small sample size). As such, the outcomes cannot be applied to the entire population without further investigation (with larger sample sizes) into the trends noted in this study. Furthermore, the age range in the study consisted of participants from the ages of 18-50 (as per the inclusion criteria). This large age range resulted in the groups having extreme differences in age (although not statistically significant). The impact of this on the outcomes of the study are determinable as a result of the statistical analysis; however, the physiological response of the participants to the interventions may have been very different resulting in a 'data skew' for one or more of the groups. This would have limited the group comparability in terms of realistic values. This 'data skew' could have been avoided had a larger sample size been utilised in the study.							
OUTCOME:	The authors of this study concluded that based on this study, IMT with or without additional education and exercise is effective in the							

	treatment of TMD that is related to MFTPs. They also concluded that a proper RCT needs to be designed and conducted to increase the validity of these results and allow them to be applied to the entire chronic MFTP related TMD population.
DISCUSSION:	The authors of this study identified a gap in the literature with regards to the amount of research that had been previously conducted to investigate the effectiveness of IMT for the treatment of TMD caused by MFTPs. A pilot study was designed and conducted which consisted of three groups: Group One received IMT only, Group Two received IMT and education and exercises and Group Three (the control) received no treatment. The study was well planned and reported on, however, the fact that it was a pilot study indicated that results could not be deemed applicable to the general population without further investigation by means of a full RCT. The large age group inclusion difference creates a potential decrease in the reliability of results as the physiology of an 18 year old cannot be compared to that of a 50 year old.
CONCLUSION:	This article was rated 11/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 93.82% noted in Table 4.31 above. Although the critical analysis and PEDro ratings of this study were extremely positive, the results cannot be applied across the board with regards to MFTP related TMD due to the fact that this study was a pilot study, hence, further investigation into the topic is still required.

Table 4.33	Tabulated Feedback Data for RCT – Article 17					
AUTHORS:	A. Koke, J. Schouten, M. Lamerichs-Geelen, J. Lipsch, E. Waltje, M. Van Kleef and J. Patijn					
TITLE:	Pain reducing effect of three types of transcutaneous electrical stimulation in patients with chronic pain: A randomized crossover trial					
YEAR:	2004					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	NO	NO	NO	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	NO	NO	NO	66%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	NO	YES	YES	YES	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	NO	NO	NO	66%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	8	7	7	7	
		OVERALL PERCENTAGE AGREEMENT				90.73%

Table 4.34	Analysis of Article RCT: Article 17							
AUTHORS:	A. Koke, J. Schouten, M. Lamerichs-Geelen, J. Lipsch, E. Waltje, M. Van Kleef and J. Patijn							
YEAR:	Pain reducing effect of three types of transcutaneous electrical stimulation in patients with chronic pain: A randomized crossover trial							
TITLE:	2004							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual analogue scale. Global assessment (whether or not patient chose to continue with the treatment).	Measurements were taken pre-treatment, at two weeks, at four weeks, at six weeks and at six months.	The study duration was over six months.	180 total participants were randomly allocated into three groups; Group One received high frequency low intensity TENS (HFT), Group Two received high frequency high intensity TENS (HIT), Group Three received control TENS (COT).	There was assessor blinding.	The control group was given regular TENS settings and allowed to use the apparatus whenever they preferred.	Participants were randomized using a computer generated randomization table.	7	90.73%
LIMITATIONS:	This study by Koke *et al.*, (2004) was a fairly well-structured study with a large sample size, however, it has limitations in that it only considered the relative effectiveness of the interventions and not the efficacy of the intervention (as no placebo group was utilised). Although this was not a significant limitation, more significant limitations existed as a result of: the vague and ill-defined age group, the ill-defined pain presentation (duration was greater than six months, of undetermined character (intermittent or continuous pain)) and as a result of the inconsistent use of pain medication by participants (unrecorded and unreported) as allowed during the administration of the interventions in this study. These latter three limitations do not allow for effective interpretation of the outcomes of the study due to the ill-defined clinical presentation of the pain (i.e. lack of identification of which participants would benefit from the interventions as well as contamination of the study outcomes due to varied pain presentations). Additionally, the use of medication (particularly around measurement intervals) may have resulted in inappropriate reporting by the participant based on medication use and not the intervention. This was not recorded, and therefore the impact of medication use could not be determined. The last of the three limitations, as regards the age range being ill-defined, was reported that the groups were not significantly different in even though the age range was large (mean ages were 52:50:49). Therefore, this would have had a lesser impact on the outcomes than the previous two limitations that were discussed.							

	In terms of the outcome measures, this study only utilised subjective outcome measures which negated the possibility of utilising an objective outcome measure to overcome the possibility that participant perception (Phillips and Pugh 2000; Lessing and Schulze 2003; Armstrong, Allinson and Hayes 2004; Mackinnon 2004; Malfroy 2005; McAlpine and Norton 2006; Cheon*et al.*, 2009; Manathunga 2009; Nulty, Kiley and Meyers 2009; Danjuma and Rasli 2012) would or could have played a role in the outcomes of this study and therefore detract from the actual effectiveness of the interventions.
OUTCOME:	The authors of this study concluded that there was no difference amongst the types of TENS used for treatment of MFTPs in participants with chronic pain.
DISCUSSION:	The authors of this study studied the literature and discovered that although there had been several studies investigating TENS, there was a scarcity of research regarding the comparison between different types of TENS. They designed and conducted a RCT which consisted of three groups of approximately sixty participants per group. The first group received HFT, the second group received HIT and the third group received COT. There was no placebo in this study, hence, the efficacy of TENS cannot be remarked upon. The participants were allowed to continue any pain medication that they were on; this may have had a negative effect on the results as the pain medication may have decreased pain, hence applicability of results may have been affected. The study only included participants with pain duration of greater than six months. This creates a problem as the results are then only applicable for participants with pain that falls into this category. Any participant over the age of eighteen was allowed to participate; however, there was an absence of an end-range with regards to age. This makes comparisons questionable.
CONCLUSION:	This article was rated 7/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 90.73% noted in Table 4.33 above. This article received a moderate rating from the reviewers and a relatively favourable conclusion from its authors, however, after considering the limitations discussed above, the reliability of the results significantly decreases.

Table 4.35	Tabulated Feedback Data for RCT – Article 18
AUTHORS:	Y. C. Lin, T.S. Kuan, P. C. Hsieh, W. J. Yen, W. C. Chang and S. M. Chen
TITLE:	Therapeutic effects of lidocaine patch on myofascial pain syndrome of the upper trapezius: A randomized, double blind, placebo controlled study
YEAR:	2012

CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	NO	NO	NO	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	NO	YES	YES	66%
6	There was blinding of all therapists who administered the therapy	YES	NO	YES	YES	66%
7	There was blinding of all assessors who measured at least one key outcome	YES	YES	YES	YES	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	NO	YES	YES	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	10	7	10	10	
		OVERALL PERCENTAGE AGREEMENT				90.73%

Table 4.36	Analysis of Article RCT: Article 18							
AUTHORS:	Y. C. Lin, T.S. Kuan, P. C. Hsieh, W. J. Yen, W. C. Chang and S. M. Chen							
YEAR:	Therapeutic effects of lidocaine patch on myofascial pain syndrome of the upper trapezius: A randomized, double blind, placebo controlled study							
TITLE:	2012							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual analogue scale. Pain pressure threshold. Neck disability index. Cervical ROM.	Measurements were taken pre-treatment, at day seven, day fourteen and day twenty eight.	The study was conducted over a period of three weeks.	The total number of participants was sixty. Group one was treated using lidocaine patches (31participants) and Group Two was treated using placebo patches (29 participants).	The assessing physician remained blinded to the group allocation.	The control group was administered with a placebo patch.	Participants were randomly allocated to one of two groups.	10	90.73%
LIMITATIONS:	Similar to Koke *et al*., (2012) (Table 4.34), Lin *et al*., (2012) also presented a lack of participant specific details with regards to the inclusion criteria. Again, this was seen with regards to the minimum age allowed to participate being indicated as 20 years, but with the omission of the maximum age. This, along with the fact that the study took place at a tertiary medical centre, suggests that a particular patient group was targeted, without this necessarily being explicitly stated. It is, however, clear from the results that the study provided homogeneity with regards to age (35.78; 33.39; 36.19) which was not statistically significant between the groups. It further suggests that the group that participated in this study was older which may be indicative of the venue in which the study took place. This is in contrast to the studies by Gemmell, Miller and Nordstorm (2008) (Table 4.14); Blikstad and Gemmell (2008) (Table 4.10); Gemmell and Allen (2008) (Table 4.16) and Gemmell and Hilland (2011) (Table 4.18), where the location of the study resulted in a very much younger population group. Therefore, the comparability of the outcomes in each of these studies is limited and therefore it is also not generalizable to the general patient population. The above limitations are further impinged upon by the lack of clarity with regards to the randomization processes utilised in the study even							

	though randomization was noted as the technique for participant allocation to groups. This would have assisted in the understanding of the effect of the randomisation process on the differences noted in the demographic and characteristics table (Table 1 in the study) and the potential impact that this would have had on the outcomes of the study. It is also unclear (as analysed in the Iqbal *et al*., (2010) study), if there was a significant difference with regards to the number of participants who had left-sided pain, right-sided pain or bilateral pain and how these presented in each of the three groups. This is particularly important in the context of the predisposing and perpetuating factors for MFTPs (e.g. handedness or dominance would have an impact on the use of a particular arm and therefore impact on the shoulder girdle and the trapezius muscle to a greater extent on the side of use as opposite to the contra lateral side). Lastly, in terms of the intervention, the application of the patch was not discussed. This included whether it was applied by the researcher, another research assistant or the participant as well as whether a particular procedure was used to ensure that each participant received the same application over the same anatomical points.
OUTCOME:	The authors of this study concluded that 5% lidocaine patches are more effective than placebo patches as a treatment for MPD in the trapezius muscle.
DISCUSSION:	The authors of this study aimed to fill a gap in the literature which they noted to be lacking with regards to RCTs performed to investigate the effectiveness of lidocaine patches for the treatment of MFTPs in the trapezius muscle. They designed and completed a study that consisted of two groups; Group One received the 5% lidocaine patches, Group Two received a placebo patch. There was a lack of emphasis on the method of randomization used in this study. This decreased the knowledge with regards to whether or not participants were sufficiently randomized; hence there may have been a negative effect on the results. The comparison of participants may have been compromised by the maximum age group allowed to participate in the study, however, this remains unknown due to a lack of emphasis on this fact. Due to the lack of participants specific inclusion criteria there is difficulty with regards to whether or not the comparison and hence the results are viable. If the patches were applied by the participants instead of the clinician, an issue of participant compliance arises and one begins to question whether the results were affected by this lack of information.
CONCLUSION:	This article was rated 10/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 90.73% noted in Table 4.35 above.

Table 4.37	Tabulated Feedback Data for RCT – Article 19					
AUTHORS:	S. Lobo, N Mehta, A. G. Forgione, M. Melis, E. Al-Badawi, C. Ceneviz and K. H. Zawai					
TITLE:	Use of Theraflex TMJ topical cream for the treatment of temporomandibular joint and muscle pain					
YEAR:	2004					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	YES	YES	YES	YES	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	YES	YES	YES	100%
6	There was blinding of all therapists who administered the therapy	NO	YES	YES	YES	66%
7	There was blinding of all assessors who measured at least one key outcome	NO	YES	YES	YES	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	9	11	11	11	
		OVERALL PERCENTAGE AGREEMENT				93.82%

Table 4.38	Analysis of Article RCT: Article 19							
AUTHORS:	S. Lobo, N Mehta, A. G. Forgione, M. Melis, E. Al-Badawi, C. Ceneviz and K. H. Zawai							
YEAR:	Use of Theraflex TMJ topical cream for the treatment of temporomandibular joint and muscle pain							
TITLE:	2004							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Numerical graphic rating scale.	Measurements were taken pre-treatment, after ten days of treatment, after fifteen days of treatment and after five days following the end of treatment.	The study was conducted over three weeks.	There were a total of fifty two participants; twenty six were allocated to the control group and twenty six were allocated to the intervention group.	There was assessor blinding to the allocation of participants to groups.	The control group used a placebo cream.	Randomization was conducted by means of the hat method.	11	93.82%
LIMITATIONS:	Lobo *et al*., (2004) presented a well-structured and well-presented study with few internal and / or external factors that would have been able to compromise the outcomes as they are reported. To their credit, they utilised a randomization method for participant allocation into their respective groups. The only flaw in this process was the use of the hat method, which would not have allowed each participant an equal chance of being allocated to any of the groups. The use of a computerised randomisation table may have strengthened their study slightly. As noted in the study, the outcomes are only applicable to participants with TMJ and associated muscle pain, with only the muscle pain being treated with the application of a topical cream. One limitation in this is that participants with actual joint pathology / joint dysfunction within the TMJ were not excluded and the presence of joint pathology / dysfunction was not recorded. They may have had an outcome on the participants that presented in this study and therefore the study outcomes. From a methodological vantage point, it was noted that the topical cream was applied by participants at home there was no attention given to participant compliance (as in the use of a diary) in this regard. This may also have had an effect on the outcomes of the study, particularly as the outcomes measure was only one subjective reporting of pain, which can be influenced by participant perception (Yeomans, 2000).							
OUTCOME:	The authors of this study concluded that Theraflex cream is more effective than a placebo cream in the treatment of temporomandibular							

	muscular pain.
DISCUSSION:	The authors of this study identified that no previous study had been conducted to investigate the effectiveness of Theraflex cream on temporomandibular joint and muscle pain. A study was conducted using two groups of twenty six participants each to compare the effects of Theraflex cream with a placebo cream. The randomization process used in this study has not been noted as the most effective method of randomization, because all participants do not stand an equal chance of being allocated into either of the study groups. The creams were given to the participant and he or she was required to apply the cream according to instructions given by the clinician. However, this creates a discrepancy because there was no mention of a record of participant compliance or accommodation for how a lack of participant compliance may have affected the results of the study. The lack of attention placed on temporomandibular joint dysfunction may have had a negative impact on the results because this condition contributes to the muscular pain in the TMJ.
CONCLUSION:	This article was rated 10/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 90.73% noted in table 4.37 above. Although the rating of this article and the authors reached a positive conclusion, the limitations discussed above indicate that this study and its results were not as viable as originally thought.

Table 4.39	Tabulated Feedback Data for RCT – Article 20					
AUTHORS:	N. Sahin, I. Albayrak and H. Ugurlu					
TITLE:	Effect of different transcutaneous electrical stimulation modalities on cervical myofascial pain syndrome					
YEAR:	2011					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	YES	YES	YES	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	NO	YES	YES	66%
5	There was blinding of all subjects	YES	YES	YES	YES	100%
6	There was blinding of all therapists who administered the therapy	YES	NO	NO	NO	66%
7	There was blinding of all assessors who measured at least one key outcome	NO	YES	YES	YES	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	NO	NO	NO	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	9	8	9	9	
		OVERALL PERCENTAGE AGREEMENT				84.55%

Table 4.40	Analysis of Article RCT: Article 20
AUTHORS:	N. Sahin, I. Albayrak and H. Ugurlu
YEAR:	Effect of different transcutaneous electrical stimulation modalities on cervical myofascial pain syndrome
TITLE:	2011

STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
The Visual Analog Scale (VAS) was used to measure pain sensation felt by participants. The Short Form Health Survey (SF-36) was used to measure quality of life.	Measurements were taken pre- and post intervention in all three treatment groups and in the placebo group.	Each group received a total of 10 treatments consisting of three 30mins session weekly (3-4weeks).	The study was conducted using 80 participants.	The pre and post-treatment measurements were taken by the same examiner, whereas all applications of therapy were performed by a different examiner, hence there was assessor blinding in this study.	A group of 20 participants were treated with placebo TENS which served as a control group.	The names of all 80 participants was given to an uninvolved party, who then put the names into an opaque envelope from which names were randomly drawn and allocated into groups.	9	84.55%

LIMITATIONS:	This pre-post evaluation study by Sahin*et al*., (2011), investigated the immediate effect of different TENS modalities on cervical myofascial pain syndrome. The syndrome was a non-specific syndrome which included all MFTPs in the cervical region, but excluded pain of non-soft tissue origin. Given this non-specific diagnosis and the fact that the included participants had pain for more than three months and with pain ratings of greater than three on the VAS, suggested that the comparability of the participants per group may not have been appropriate or possible as the chronicity of the cervical myofascial pain syndrome was not considered for sample homogeneity. This may skew the data as the responses for more "acute" (just over three months may have been very different when compared to those who had a more "chronic" presentation (years). By contrast, the use of a wide age range and a variety of lengths of presentation of cervical myofascial pain syndromes allowed for the results to be more reflective of the general population. However, it does not allow for the identification of participants that would more easily respond to these forms of intervention. In addition to the above, it was noted that the physician who applied the therapy was not blinded, which increases the risk of bias being

	introduced into the study. This lack of delineation in the study may also have affected the outcomes adversely (particularly if the physician behaved differently when interacting with specific groups, based on his / her perceived outcome) (Richardson, 2007). Lastly, the study had a large dropout of 6.25% (5/80) of the total number of participants; however, the reason was not stated. This is important because there is usually no attrition or very few participants drop out in a pre-post intervention study (as the participants are only required to present to the research team once). In addition, the inability of the study to utilise the 'intention to treat' because the study structure would not have allowed for the drop-outs to be accounted for through an analysis process.
OUTCOME:	This article concluded that none of the TENS settings applied produced an effect different to the effect produced by the placebo TENS. Therefore, in this article it was noted that TENS produced no relief with regards to cervical myofascial pain syndrome.
DISCUSSION:	Sahin*et al.,* (2011) identified that there had been several studies conducted using TENS as an intervention for MFTPs and MPD. However, these studies produced erratic results and used different TENS settings. Sahin*et al.,* (2011) then decided to construct a study that would compare the effects of different types of TENS on MFTPs and MPD in the cervical region. The study was a RCT that consisted of 80 participants who were randomly treated with one of four TENS; conventional TENS, acupuncture like TENS, burst TENS and placebo TENS. An increase in the possibility of bias in the results of this study was increased by a lack of therapist blinding. However, the presence of participant and assessor blinding lends to an increased validity of this study. There was a 6.25% drop-out rate at the end of the study. Statistically, there may have been a slight deviation from the reported results if there was a 100% participation of participants who initially qualified or if there was a mention of 'intention to treat' analysis for those who did drop out. This dropout rate was also not specified with regards to explanations as to why participants left the study, which raises the question of whether or not these participants actually deteriorated, hence making the results of the study questionable. The inclusion of participants with specific pain ratings and pain duration created a hindrance with regards to the possibility of applying these results to the broad category of all patients with MPD in the cervical region.
CONCLUSION:	This article was rated 9/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 84.55% noted in table 4.39 above. Although the rating of this article was very good, the limitations discussed above indicated that this study and its results were not as viable as originally thought.

Table 4.41	Tabulated Feedback Data for RCT – Article 21					
AUTHORS:	J. Sarrafzadeh, A. Ahmodi and M. Yassin					
TITLE:	The effects of pressure release, phonophoresis of hydrocortisone and ultrasound on upper trapezius latent myofascial trigger points					
YEAR:	2011					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	NO	YES	YES	YES	66%
3	Allocation was concealed	NO	NO	NO	NO	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	NO	NO	NO	NO	100%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	NO	NO	NO	NO	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	NO	NO	NO	66%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by "intention to treat"	YES	YES	NO	YES	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	NO	YES	YES	66%
	TOTAL SCORE	6	5	5	6	
		OVERALL PERCENTAGE AGREEMENT				87.64%

Table 4.42	Analysis of Article RCT: Article 21							
AUTHORS:	J. Sarrafzadeh, A. Ahmodi and M. Yassin							
YEAR:	The effects of pressure release, phonophoresis of hydrocortisone and ultrasound on upper trapezius latent myofascial trigger points							
TITLE:	2011							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Subjective pain rating. Pain pressure threshold. Lateral flexion of the C-spine.	Measurements were taken pre-treatment and at all six treatment sessions.	The study was conducted over six treatment sessions.	There were a total of sixty participants. Fifteen in each group. There were four groups; Group One received phonophoresis of hydrocortisone (PhH), Group Two received US, Group Three received pressure release and Group Four was the control group.	There was a lack of assessor blinding.	The control group was only evaluated with no treatment.	Participants were randomly allocated to groups, but the randomization method is unknown	6	87.64%
LIMITATIONS:	In contrast to Iqbal *et al.*, (2010) (Table 4.28), this study by Sarrafzadeh *et al*., (2011) included only female participants and therefore the results are limited in terms of their generalizability. Additionally, this study contrasts with Koke *et al.*, (2012) (Table 4.34), but concurs with Gemmell, Miller and Nordstorm (2008) (Table 4.14); Blikstad and Gemmell (2008) (Table 4.10); Gemmell and Allen (2008) (Table 4.16) and Gemmell and Hilland (2011) (Table 4.18), with regards to the average age of the participants in the study. The possible reason for agreement between the studies representing participants with a lower mean age seems to be as a result of the studies having been conducted through a University or in a University setting (therefore recruitment included many students) as compared to Koke *et al*., (2012) (Table 4.34) whose study was in a designated pain clinic (even though it was at a University and hence students are less likely to have made use of the facility). This comparability in terms of the studies show how these individual external factors affect the validity and generalizability of the outcomes obtained. This requires the reader to contextualise the results effectively and therefore it is important that these studies explicitly detail these types of data. In terms of the specifics of the Sarrafzadeh *et al*., (2011) study, it also needs to be recognised that the study included only latent trigger							

	points. This is in contrast to the outcome measures which included the subjective pain rating reporting by the participant. In addition, and unlike Sahin*et al.*, (2011) (Table 4.40), the inclusion criteria in this study allowed for the inclusion of participants with pain duration of between three months and one year. This is better than Sahin*et al*., (2011) (Table 4.40) who specified durations of more than three months without any upper limit because it was more specific to a particular participant presentation. However, this, together with the subjective reporting of pain by the participants is a contradiction in terms as latent MFTPs are inherently pain free, even over a period of time (Lucas, 2007; Lucas, 2008). In addition, there were no objective measures utilised in this study to account for participant perceptions affecting the outcomes of the subjective measures (Yeomans, 2000). The above limitations are further impacted by the lack of clarity with regards to the randomization processes utilised in the study even though randomization was noted as the technique for participant allocation to groups. This would have assisted in the understanding of the effect of the randomisation process on the differences noted in the outcomes of the study. Lastly and possibly most importantly, the manner in which the study is presented lacks emphasis on the: • length of the study • the time between treatment sessions • the time between measurements and • the relationship between treatment sessions and measurement sessions. o This information is vital in enabling the reader to contextualise the presented outcomes and to determine if any external factors have / had the ability to affect the outcomes as they are presented. This lack of clarity is possibly the most important factor that has affected the ranking of this study.
OUTCOME:	The authors of this study concluded that phonophoresis of hydrocortisone, pressure release and ultrasonic therapy were all effective in treating latent MFTPs in the trapezius muscle.
DISCUSSION:	The authors of this study identified a new possible treatment method for latent MFTPs in the trapezius muscle namely PhH. A RCT was then conducted to investigate the effectiveness of PhH in comparison to US, PR and a control group. The study consisted of four groups of fifteen participants each. The participants included in this study were all female, which may create a limitation in that the results cannot be applied to the entire population but instead are only applicable to this very specific part of the population. There was no mention of how randomization was achieved. This may have had a negative effect on the results due to the fact that not all randomization methods are considered viable. Hence, the comparison between groups is a questionable one. The study was conducted only on latent MFTPs; hence the results are only applicable to latent MFTPs and cannot be used in generalization. The inclusion of pain duration between three months and one year is indicative that results only apply to patients struggling with chronic pain, and generalization is not possible. Also, the pain experienced during this period was not described as being either intermittent or continuous and this further affects the results. The time that lapsed between measurements and the overall duration of the study was not clearly noted, and this has a negative impact on the validity of the results.
CONCLUSION:	This article was rated 6/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 87.64% noted in table 4.41 above.

	The authors of this article concluded that they potentially discovered a new modality that is effective in the treatment of latent MFTPs in the trapezius muscle. The article received a moderate rating from the reviewers using the PEDro Scale; however, the limitations discussed above play a negative role that may have decreased the efficacy of the study and its results.

Table 4.43	Tabulated Feedback Data for RCT – Article 22					
AUTHORS:	S. M. Schabrun, A. Cannan, R. Mullens, M. Dunphy, T. Pearson, C. Lau and L. S. Chipchase					
TITLE:	The effect of interactive neurostimulation therapy on myofascial trigger points associated with mechanical neck pain					
YEAR:	2012					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	NO	YES	NO	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	YES	YES	YES	100%
6	There was blinding of all therapists who administered the therapy	YES	NO	NO	NO	66%
7	There was blinding of all assessors who measured at least one key outcome	YES	YES	YES	YES	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	10	9	10	9	
		OVERALL PERCENTAGE AGREEMENT				93.82%

Table 4.44	Analysis of Article RCT: Article 22
AUTHORS:	S. M. Schabrun, A. Cannan, R. Mullens, M. Dunphy, T. Pearson, C. Lau and L. S. Chipchase
YEAR:	The effect of interactive neurostimulation therapy on myofascial trigger points associated with mechanical neck pain
TITLE:	2012

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual analogue scale. Pain pressure threshold. Neck disability index. Patient specific functional scale.	Measurements were taken pre-treatment, immediately post-treatment and at a five day follow up.	The study lasted approximately one week.	There was a total twenty three participants. Twelve were allocated to the treatment group and eleven were allocated to the control group.	There was blinding of assessors to group allocation throughout the duration of the study.	The control was a sham interactive neurostimulation therapy (INS).	Randomization was carried out by the use of a random numbers table.	9	93.82%

LIMITATIONS:	This pilot study included a small sample size, which suggests that the study was too underpowered to detect significant changes. Credit is, however, given to the authors for identifying this limitation and suggesting that a larger study be done to confirm the outcomes of the study. In terms of participant homogeneity, it was noted that in terms of the condition that there was a lack of homogeneity with participants included as long as they had pain duration of longer than two weeks (no limit was seen to be set). This has the possibility that participants would have responded differently based on the chronicity of their condition (Gerwin, 2010). This coupled with the small sample size may have had the result that the groups had inherent differences in their ability to respond to the intervention and therefore were not entirely comparable with regards to the outcome even though the noted baseline characteristics were not statistically and significantly different. With the relative novelty of this treatment, it should also have been a consideration as to the naivety if participants to this intervention. The lack of similar exposure between the groups may have been factors that affected the study outcomes without due consideration. This external factor that may have had an effect on the validity of the study outcomes along with the lack of explicit instructions to participants regarding activity between the last treatment and the final follow-up measurements, both place a question on the outcomes and the degree to which they were affected by factors external to the study. A future study may seek to control these aspects of this study.

OUTCOME:	The authors concluded that this new modality has the potential to be effective in the treatment of MFTPs; however, they did also note that a larger more in depth study is required so that the results can be applied to the general population.
DISCUSSION:	The authors of this study identified a relatively new modality for the treatment of MFTPs associated with mechanical neck pain, namely INS. They designed and conducted a study aimed at investigating the effectiveness of this therapy versus a sham therapy (the control). The study consisted of two groups of twelve (intervention) and eleven (control). The authors of the study included participants who had a pain complaint of greater than two weeks. This presents as a limitation because the results obtained cannot be applied to the population of acute pain. The duration of pain inclusion criterion also does not state a maximum duration. This indicates the possibility of inclusion of participants who have had pain for a number of years, which changes the grounds for comparison to participants who may have only, had pain for two weeks. Also, there was no specification as to whether or not this pain was continuous over the duration or intermittent, which further decreases the validity of comparison. The authors do not clearly specify whether or not there was previous exposure of the included participants to INS. If there had been previous exposure, the participants would have been able to identify that they were in the control group, hence, affecting the results due to the lack of proper control. The lack of avoidance measures for extraneous variables during the five days awaiting follow-up has a negative effect on the results, as there may have been unwanted or unusual activity carried out by the participants, which may have affected the final readings but would not have been a true indication of the effects of treatment.
CONCLUSION:	This article was rated 9/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 93.82% noted in table 4.43 above. Although the rating of this study was very good with regards to the PEDro Scale, the limitations discussed above have a negative effect on the efficacy of the study and its results, hence, the results are noted to be significantly less viable than assumed initially.

Table 4.45	Tabulated Feedback Data for RCT – Article 23					
AUTHORS:	N. Smania, E. Corato, A. Fiaschi, P. Pietropoli, S. M. Aglioti and TM. Tinazzi					
TITLE:	Repetitive magnetic stimulation : a novel therapeutic approach for myofascial pain syndrome					
YEAR:	2005					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	YES	YES	YES	YES	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	YES	YES	YES	100%
6	There was blinding of all therapists who administered the therapy	YES	YES	YES	YES	100%
7	There was blinding of all assessors who measured at least one key outcome	NO	YES	YES	YES	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	NO	NO	NO	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	10	10	10	10	
		OVERALL PERCENTAGE AGREEMENT				93.82%

Table 4.46	Analysis of Article RCT: Article 23
AUTHORS:	N. Smania, E. Corato, A. Fiaschi, P. Pietropoli, S. M. Aglioti and TM. Tinazzi
YEAR:	Repetitive magnetic stimulation : a novel therapeutic approach for myofascial pain syndrome
TITLE:	2005

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Neck pain and disability visual analogue scale. Algometric evaluation. Evaluation of trigger point characteristics. Cervical ROM.	Measurements were taken pre-treatment, immediately post-treatment, one month following end of intervention and three months following intervention.	The study duration was a total of three months.	There were a total of fifty three participants. They were divided into three groups: Group One (17) received repetitive magnetic stimulation (rMS), Group Two (18) received TENS and Group Three (18) received a placebo.	The assessor remained blinded throughout the duration of the study.	There was a control group (Group Three and they received placebo.	Participants were allocated via a simple randomization scheme.	10	93.82%

LIMITATIONS:

This study by Smania *et al*., (2005) consistently reflects problems with the participants' homogeneity. Examples of this include the following:

- The mean age for the placebo group was higher than the two treatment groups.
- There was a larger ratio for females to males in the placebo group.
- The group receiving TENS was noted to have more years of education than the other two groups.
- The group receiving TENS also had more MFTPs than the other groups.
- The rMS group had a higher incidence of a history of cervical trauma.
- The TENS group had a higher incidence of previous exposure to physical therapy.

None of the above differences were seen to be accounted for in terms of their significance (statistical significance) between the groups and therefore the impact on the outcomes of the study. This is important for a number of reasons, but the principle consideration is that if these external factors changed the manner in which the participant was physiologically able to respond to the intervention(s) (Dagenais and Haldeman, 2012), changed the perception of participants with regards to the interventions (s) and / or influenced the participant as a result of

	the novelty of an intervention (Phillips and Pugh 2000; Lessing and Schulze 2003; Armstrong, Allinson and Hayes 2004; Mackinnon 2004; Malfroy 2005; McAlpine and Norton 2006; Cheon*et al.*, 2009; Manathunga 2009; Nulty, Kiley and Meyers 2009; Danjuma and Rasli 2012); these would all have had the potential to affect either the object and / or subjective outcomes, detracting from the study results that may have explained the effect attributable only to the intervention. The above discussion would further have been compounded by the fact that no explanation was given with regards to the missing data or dropouts. This is important as larger numbers of dropouts from one group are likely to reflect negatively on that group as a result of: • The results only reflecting the select group that remained. • The exclusion of participants that deteriorated as a result of the treatment has the ability to skew the data, indicating a more favourable outcome than is necessarily the reality. • Lastly, there is also the possibility that there was no effect on the outcomes based on the dropouts if the reasons for their exclusion were not related to the study at all. o However, it is not possible to determine this from the current review and therefore it is possible that these external factors had a greater impact than one is currently able to understand from the publication.
OUTCOME:	The authors of this study concluded that rMS may be more effective than TENS and a placebo in the medium to long-term treatment of MFTPs.
DISCUSSION:	The authors of this study noted that no previous study was conducted to investigate rMS versus TENS and a placebo in the treatment of MFTPs. They designed and conducted a study that compared these modalities. The study consisted of three groups, Group One received rMS, Group Two received TENS and group three received placebo. During analysis of this study, it was noted that there was a difference between the groups with regards to mean age, gender ratios, years of education, number of trigger points, history of trauma and previous exposure to physical therapy. These between group differences create a negative effect on the results of the study as they change the grounds for comparisons; hence, the validity of the results is affected. The missing data or dropouts were not specified. This makes the results questionable as this missing data may have been due to participant symptoms deteriorating because of the treatment.
CONCLUSION:	This article was rated 10/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 93.82% noted in table 4.45 above. Although the article received a very good rating from the reviewers and a favourable outcome from the authors, the limitations as discussed above indicate that the quality of the study and the results could have been improved.

Table 4.47	Tabulated Feedback Data for RCT – Article 24
AUTHORS:	J. Z. Srbely, J. P. Dickey, M. Lowerison, A. M. Edwards, P. S. Nolet and L. L. Wong
TITLE:	Stimulation of myofascial trigger points with ultrasound induces segmental anti-nociceptive effects: A randomized controlled study
YEAR:	2008

CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	NO	YES	NO	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	NO	YES	YES	66%
6	There was blinding of all therapists who administered the therapy	YES	YES	NO	YES	66%
7	There was blinding of all assessors who measured at least one key outcome	NO	NO	YES	NO	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	NO	YES	66%
	TOTAL SCORE	9	8	9	9	
		OVERALL PERCENTAGE AGREEMENT				84.55%

Table 4.48	Analysis of Article RCT: Article 24							
AUTHORS:	J. Z. Srbely, J. P. Dickey, M. Lowerison, A. M. Edwards, P. S. Nolet and L. L. Wong							
YEAR:	Stimulation of myofascial trigger points with ultrasound induces segmental anti-nociceptive effects: A randomized controlled study							
TITLE:	2008							
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Pain pressure threshold.	Measurements were taken pre-treatment and post-treatment.	The duration of the study spanned single treatment sessions.	There were a total of fifty participants. With twenty five in each group. Group One was the intervention group and Group Two was the control.	There was no assessor blinding noted.	Control group was the group that had participants gluteus medius MFTPs.	There was randomization but the method by which this was conducted is unknown.	9	84.55%
LIMITATIONS:	The study by Srbely *et al*., (2008) utilised objective measures to include participants with MFTPs and thus the criteria of an active MFTP or latent MFTP was not utilised. This is consistent with Gerwin *et al*., (1997), who indicated that not all the subjective clinical parameters of MFTP identification are reliable. This positive approach, was however, confounded by the inclusion of the infraspinatus, supraspinatus and the gluteus medius muscles. These muscles lie at different depths from the skin (Standring, 2008), have different actions (Standring, 2008), and predisposing and perpetuating factors (Gerwin, 2010). Therefore, it is not consistent for a study to be comparing outcomes between these muscles or utilise on as a control for another. Another factor that would have been directly affected by the use of the objective measures for inclusion would have been the measurement tool, as the only one outcome measure was the measure of pain pressure threshold. This threshold is directly related to the participants' pain tolerance (Travell and Simons, 1992), thus it is likely that participants with a pain tolerance would have been able to allow for the inclusion of only those participants that had a lower pain tolerance – limiting the outcomes to this particular participant population. Perhaps an attempt to standardize the muscles chosen was the fact that the study used only right hand side readings. However this is also affected by dominance / handedness, which was not mentioned as a confounding variable and was not listed as a factor that had been controlled.							

	Lastly, the study did not accommodate for the possibility of a systemic response to treatment that may have allowed for changes that also affected the "control" muscle.
OUTCOME:	The authors concluded that US results in a short-term segmental anti-nociceptive effect on MFTPs
DISCUSSION:	The authors of this study aimed to show the segmental nociceptive effect of MFTP US stimulation. A study consisting of two groups was conducted. One group of twenty five participants received US whilst the other group of twenty five was a control group. The analysis of this study resulted in the identification of several limitations. The study group compared infraspinatus, supraspinatus and gluteus medius muscles - all in the same context. This is not viable as the anatomy, physiology, predisposing factors and the perpetuating factors involved in the MFTP development of these muscles are all very different from one another, therefore, comparing them without taking these factors into consideration results in a decreased validity of study results and design. The use of only one outcome measure severely affects the extent to which the results can be regarded as reliable. The use of right hand sided measurements only has a negative effect on the results as there are certain factors that affect MFTP formation on the dominant side more than the non-dominant side. The study did not make any reference to the possibility of a systemic effect as a response to the treatment which may have been the result of the outcomes yielded; this cannot be assumed to be due to a local effect. Hence, the results are further diminished with regards to viability. The study also notes that the baseline readings were taken on the infraspinatus and gluteus medius muscles; however, the application of US was conducted on the supraspinatus muscle. This creates a difference on the grounds of comparison for pre- and post-treatment measurements.
CONCLUSION:	This article was rated 9/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 84.55% noted in table 4.47 above. Although the article received a very good rating from reviewers and a favourable outcome from the authors, the limitations as discussed above show that the study consisted of several factors which severely decrease it validity.

Table 4.49	Tabulated Feedback Data for RCT – Article 25					
AUTHORS:	A. A. Yamany and S. E. Salim					
TITLE:	Efficacy of low level laser therapy for treatment of myofascial trigger points of shoulder pain					
YEAR:	2011					
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified	YES	YES	YES	YES	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	YES	YES	YES	YES	100%
3	Allocation was concealed	NO	NO	NO	NO	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	YES	YES	YES	YES	100%
5	There was blinding of all subjects	YES	YES	YES	YES	100%
6	There was blinding of all therapists who administered the therapy	NO	NO	NO	NO	100%
7	There was blinding of all assessors who measured at least one key outcome	NO	NO	NO	NO	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	YES	YES	YES	YES	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”	YES	YES	YES	YES	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	YES	YES	YES	YES	100%
11	The study provides both point measures and measures of variability for at least one key outcome	YES	YES	YES	YES	100%
	TOTAL SCORE	8	8	8	8	
		OVERALL PERCENTAGE AGREEMENT				100%

Table 4.50	Analysis of Article RCT: Article 25
AUTHORS:	A. A. Yamany and S. E. Salim
YEAR:	Efficacy of low level laser therapy for treatment of myofascial trigger points of shoulder pain
TITLE:	2011

STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
Visual analogue scale. Active shoulder flexion and abduction via an electrogoniometer. Pain pressure threshold Trigger point identification and threshold.	Measurements were recorded pre-treatment and after four weeks of treatment.	The study duration was four weeks.	There was a total of forty participants with twenty allocated to each group. Group One was the intervention group and Group Two was the control group.	There was no assessor blinding.	The control group consisted placebo LLLT and exercise.	Randomization was conducted but the mechanism was not mentioned.	8	100%

LIMITATIONS:	From the outset, this study included the use of combination therapies as part of the intervention; therefore, it is not possible to comment directly on the effect of any one intervention. To confound this, the participants recruited into the study were required to have shoulder pain (MTFPs and / or MPS) with MFTPs from the deltoid and / or the trapezius muscles. The use of these muscles falls into the same category of concern as Srbely *et al*., (2008), where these muscles lie at different depths from the skin (Standring, 2008), have different actions (Standring, 2008), predisposing and perpetuating factors (Gerwin, 2010) and therefore it is not consistent for a study to be comparing outcomes between these muscles. Therefore, if the presentation between the groups is different (i.e. more trapezius MFTPs in one group as compared to deltoid MFTPs in the other group), this would affect the ability to compare the two groups. Similar to Aguilera *et al.,* (2009) (Table 4.4), Bahadir *et al.,* (2006) (Table 4.8) and Gemmell and Hilland (2011) (Table 4.18), there was no mention of assessor or therapist blinding, which increases the possibility of bias being introduced into the study

	(Mouton, 2006). Therefore, the study strength has been weakened by the lack of this component. In terms of the intervention, it was noted that the exercises were aimed at targeting principally the capsules of the shoulder joint which are not muscular related components, so it is unclear whether these exercises were meant to aid in the reduction of the MTFPs, act as an exercise ensuring consistent and equitable use of the shoulder (then it is necessary to also have included handedness as a consideration) and / or as an activity for participants to perceive that they are receiving an active care modality so to decrease the effects of perception on the outcome of the study. These questions are not sufficiently answered in the publication and therefore detract from its ability to contextualise the intervention and its necessity and the impact on the outcomes obtained.
OUTCOME:	The authors of this study concluded that LLLT and exercise is more effective than placebo LLLT and exercise in the treatment of MFTPs related to the shoulder joint.
DISCUSSION:	The authors of this study aimed to investigate the effectiveness of laser therapy combined with an exercise program as a treatment modality for MFTPs. They conducted a RCT which consisted of two groups of twenty participants each who were allocated to a treatment group and a control group. Analysis of this article revealed the investigation was conducted using a combination of therapies; this indicates that results cannot be applied to the individual modality; hence, generalization is not possible. There was a lack of blinding with regards to the assessor or the therapist which decreases the reliability of results due to the increased effects of the bias on the study. The sample of participants included in this study did not include members of the public which limits the extent to which results are applicable. Due to the lack of specification, with regards to inclusion and exclusion criteria, the results may have been negatively affected because there may have been an inclusion of participants who did not have MFTP related primary complaints. The exercises involved in the intervention were aimed at having an effect on the capsules of the shoulder joint which is not related to MFTPs and introduces variables which decrease the validity of the results.
CONCLUSION:	This article was rated 8/11 according to the criteria provided by the PEDro Scale (Appendix 3.2). The overall percentage agreement for this rating was 100% noted in table 4.47 above. Although the article received a good rating from reviewers and a favourable outcome from the authors, the limitations as discussed above are indicative of a study with decreased reliability with regards to the study design and results.

CHAPTER FIVE
DISCUSSION OF RESULTS

5.1 Introduction

This chapter is designed to show the level of evidence regarding non-invasive treatment modalities used for MPD, which has been ascertained from the analysis discussed in Chapter Four.

5.2 Review and classification of articles as per the interventions investigated

Following the review of the included studies in Chapter Four, it was noted that the studies may be grouped according to the modality which was investigated as indicated in Tables 5.2.1-5.2.6.

Table 5.2.1 Studies investigating TENS

Authors and Year	Title	Interventions compared
Gemmell and Hilland, 2011	Immediate effect of electric point stimulation (TENS) in treating latent upper trapezius trigger points: A double blind randomized placebo-controlled trial	EPS Sham EPS
Jeon, Jung, Lee, Choi, Mun, Park, Soe and Jang, 2012	The effect of extracorporeal shock wave therapy on myofascial pain syndrome	ESWT TPI and TENS
Koke, Schouten, Lamerichs-Geelen, Lipsch, Waltje, Van Kleef and Patijn, 2004.	Pain reducing effect of three types of transcutaneous electrical stimulation in patients with chronic pain: A randomized crossover trial	HFT HIT COT
Sahin, Albayrak and Ugurlu, 2011	Effect of different transcutaneous electrical stimulation modalities on cervical myofascial pain syndrome	Conventional TENS Acupuncture like TENS Burst TENS Placebo TENS
Smania, Corato, Fiaschi, Pietropoli, Aglioti and Tinazzi, 2005	Repetitive magnetic stimulation : a novel therapeutic approach for myofascial pain syndrome	rMS TENS Placebo

Table 5.2.2 Studies investigating IC

Authors and Year	Title	Interventions compared
Aguilera, Martin, Masanet, Botella, Soler and Morell, 2009	Immediate effect of ultrasound and ischeamic compression techniques for the treatment of trapezius latent myofascial trigger points in	IC US Sham US

	healthy subjects: A randomized controlled study	
Blikstad and Gemmell, 2008	Immediate effect of activator trigger point therapy and myofascial band therapy on non-specific neck pain in patients with upper trapezius trigger points compared to sham ultrasound: A randomized controlled trial	MBT ATrPT Sham US
Gemmell, Miller and Nordstorm, 2008	Immediate effect of ischeamic compression and trigger point pressure release on neck pain and upper trapezius trigger points: A randomized controlled trial.	IC TrPPR Sham US
Gemmell and Allen, 2008	Relative immediate effect of ischeamic compression and activator trigger point therapy on active upper trapezius trigger points: A randomized trial	IC Activator
Iqbal, Khan and Miraj, 2010	Efficacy of ischeamic compression technique in combination with strain counterstrain technique in managing upper trapezius myofascial trigger point pain	Heat, active stretching, IC and strain-counterstrain technique Heat, active stretching and IC Heat and active stretching

Table 5.2.3 Studies investigating US

Authors and Year	Title	Interventions compared
Acar and Yilmaz, 2012	Effects of different Physiotherapy applications on pain and mobility of the connective tissue in patients with myofascial pain syndrome	US and exercise Exercise only Rest for two weeks
Bahadir, Majlesi and Unalan, 2006	The effect of high power pain threshold ultrasound therapy on the electrical activity of trigger points and local twitch response	HPPTUS Dry needling
Sarrafzadeh, Ahmodi and Yassin, 2011	The effects of pressure release, PhH and ultrasound on upper trapezius latent myofascial trigger points	PhH US PR No treatment
Srbely, Dickey, Lowerison, Edwards, Nolet and Wong, 2008	Stimulation of myofascial trigger points with ultrasound induces segmental anti-nociceptive effects: A randomized controlled study	US Sham US

Table 5.2.4 Studies investigating Laser

Authors and Year	Title	Interventions compared
Gur, Sarac, Cevik, Altindag and Sarac, 2004.	Efficacy of 904 nm gallium arsenide low level laser therapy in the management of chronic myofascial pain in the neck: A double-blind and randomized controlled trial	Active LLLT Sham Laser
Hakgunder, Birtane, Gurcan, Kokina and Turan, 2003	Efficacy of low level laser therapy in myofascial pain syndrome: an algometric and thermographic evaluation.	LLLT and stretching exercise program Stretching and exercise only
Yamany and Salim, 2011	Efficacy of low level laser therapy for treatment of myofascial trigger points of shoulder pain.	Active LLLT and exercise Placebo laser and exercise

Table 5.2.5 Studies investigating Topical Agents

Authors and Year	Title	Interventions compared
Avrahami, Hammond,	A randomized, placebo-controlled double-blinded	Professional Therapy Muscle

Higgins and Vernon, 2012	comparative clinical study of five over-the-counter non-pharmacological topical analgesics for myofascial pain: single session findings	care (roll on) Motion Medicine (cream) Bengay Ultra Strength Muscle Pain (ointment) Icy Hot extra strength cream Biofreeze (roll on) Placebo (ointment)
Hsieh, Hong, Chern and Chen, 2010b	Efficacy and side effects of diclofenac patch in the treatment of patients with myofascial pain syndrome of the upper trapezius	Diclofenac-sodium patch Placebo patch
Lin, Kuan, Hsieh, Yen, Chang and Chen, 2012	Therapeutic effects of lidocaine patch on myofascial pain syndrome of the upper trapezius: A randomized, double blind, placebo controlled study.	5% lidocaine patch Placebo patch
Lobo, Mehta, Forgione, Melis, Al-Badawi, Ceneviz and Zawai, 2004	Use of Theraflex TMJ topical cream for the treatment of temporomandibular joint and muscle pain	Theraflex cream Placebo cream

Table 5.2.6 Studies investigating Other Modalities

Authors and Year	Title	Interventions compared
Craane, Dijkstra, Stappaerts and De Laat, 2012	One year evaluation of the effect of physical therapy for masticatory muscle pain: A randomized controlled trial	Physical Therapy and education – six week regimen Education at consults only
Hsieh, Liou, Lee, Chen and Yen, 2010a	Effect of acupressure and trigger points in treating headaches: a randomized controlled trial.	Acupressure Muscle relaxant medication
Kalamir, Pollard, Vitiello and Bonello, 2010	Intra-oral myofascial therapy for chronic myogenous temporomandibular disorders: A randomized controlled pilot study.	IMT IMT, education and exercises No treatment
Schabrun, Cannan, Mullens, Dunphy, Pearson, Lau and Chipchase, 2012	The effect of interactive neurostimulation therapy on myofascial trigger points associated with mechanical neck pain.	INS Sham INS

5.3 Ranking Criteria for the evidence available per treatment modality

The studies discussed and evaluated in the preceding chapters have been categorized according to the type of interventions used as seen in Tables 5.2.1-5.2.6. These articles were rated using the PEDro Scale based on their efficacy on MPD.

These articles can be ranked with regards to the level of evidence they provide by the use of a criteria outlined by Dagenais and Haldeman (2012). According to these criteria, a group of studies can be ranked as follows to determine the level of evidence available for a particular intervention:

- **Strong:** Generally consistent findings documented by systematic review of multiple, high quality RCTs (ranked between 9-11/11 on the PEDro Scale).

- **Moderate:** Generally consistent findings documented by systematic review of at least four low quality RCTs (ranked between 0-5/11 on the PEDro Scale) or at least two high quality RCTs (ranked between 9-11/11 on the PEDro Scale).
- **Limited:** One RCT, of either low or high quality, or inconsistent findings of at least four RCTs.
- **None:** No RCTs.

Note: RCT rankings between 6-8/11 are ranked as average on the PEDro Scale and therefore weigh neither strongly nor weakly into the evaluation equation as they provide ambivalent results.

5.4 Evaluation and Ranking of evidence for each intervention

5.4.1 TENS

Table 5.3 Level of Evidence for TENS

Author and Year	Type of Study	PEDro Ranking	Level of evidence			
			STRONG	MODERATE	LIMITED	NONE
Gemmell and Hilland, 2011	RCT	10/11				
Smania, Corato, Fiaschi, Pietropoli, Aglioti and Tinazzi, 2005	RCT	10/11				
Sahin, Albayrak and Ugurlu, 2011	RCT	9/11			X	
Koke, Schouten, Lamerichs-Geelen, Lipsch, Waltje, Van Kleef and Patijn, 2004.	RCT	7/11				
Jeon, Jung, Lee, Choi, Mun, Park, Soe and Jang, 2012	RCT	5/11				

The above table (Table 5.3) reflects the RCTs that have been reviewed with regards to the effectiveness of TENS as a treatment for MPD in various settings, as well as the combined level of evidence provided by these studies. The various conclusions reached by the authors (Tables 4.18, 4.46, 4.40, 4.34 and 4.30) and the quality of the studies (Tables 4.17, 4.45, 4.39, 4.33 and 4.29) were major factors used in the ranking of the level of evidence.

Gemmell and Hilland (2011) concluded that EPS decreased pain but had no effect on ROM in the cervical spine. Although this study yielded a positive outcome, the results are considered to be questionable due to the limitations caused by external factors influencing the study as discussed in Chapter Four (Table 4.18). Therefore, the quality of the evidence produced by this study has been ranked as being moderate to low in partial support of EPS, notwithstanding the high methodological rigor that the study achieved when reviewed by the reviewers.

The well-structured study by Smania *et al.,* (2005) investigated the effectiveness of rMS and concluded that this modality "may" be clinically effective in the treatment of MPD. However, the study only produced a moderate level of evidence in support of TENS. This was due to significant contribution that the lack of homogeneity of the participants in the various intervention groups and a few methodological limitations discussed in Chapter Four (Table 4.46). This resulted in an otherwise good study providing only moderate levels of evidence with regards to rMS.

By contrast, Sahin *et al.,* (2011), concluded that there was no difference in effectiveness between therapeutic TENS and placebo TENS; in the context of a moderate level of evidence as described in Chapter Four (Table 4.40).

Similarly, Koke *et al.,* (2004), reached the conclusion that there was no significant difference amongst different TENS settings in terms of their effectiveness on MPD. However, this conclusion may have been different if the limitations of this study discussed in Chapter Four (Table 4.34) had not resulted in the study being ranked in methodologically providing a poor quality design and thus a low level of evidence supporting its outcome.

Lastly, the study conducted by Jeon *et al.,* (2012) concluded that ESWT was equally as effective as TPI and TENS. The level of evidence obtained from this study was ranked as being of a low quality due to the many significant limitations (both internal and external factors) and this has an impact on the study design and the outcomes achieved. This was discussed in Chapter Four (Table 4.30).

Based on the criteria suggested by Dagenais and Haldeman (2011), and in the context of the available evidence for TENS and TENS like interventions, it seems to be apparent that the level of evidence regarding the effectiveness of these interventions is limited due to the

inconsistencies present between the outcomes of the publications and the variations in the rigour of the studies. Therefore, the effectiveness of TENS as a treatment intervention for MPD is inconclusive and practitioners should be cautious in clinical practice when recommending its use in this regard. Further, more in depth and more rigorously structured research is required to ascertain a higher quality and therefore better levels of evidence with regards the clinical effectiveness of TENS.

5.4.2 Ischaemic Compression

Table 5.4 Level of Evidence for IC

Author and Year	Type of Study	PEDro Ranking	Level of evidence			
			STRONG	MODERATE	LIMITED	NONE
Gemmell, Miller and Nordstorm, 2008	RCT	10/11			X	
Blikstad and Gemmell, 2008	RCT	9/11				
Gemmell and Allen, 2008	RCT	9/11				
Aguilera, Martin, Masanet, Botella, Soler and Morell, 2009	RCT	8/11				
Iqbal, Khan and Miraj, 2010	RCT	7/11				

Table 5.4 reflects the reviewed studies which aimed to investigate the effectiveness of IC as a treatment for MPD, as well as the overall level of evidence created by these studies in support of IC as a clinical intervention. As discussed in Table 5.3 above, the major contributing factors for the ranking of the level of evidence created are: the conclusions made by the authors of the respective studies (Tables 4.14, 4.10, 4.16, 4.4 and 4.28) and the quality of the RCT and the manner in which it was conducted (Tables 4.13, 4.9, 4.15, 4.3 and 4.27).

In a study where Gemmell *et al.,* (2008) investigated the efficacy of IC versus TrPPR as well as the use of a control group, it was concluded that IC was more effective than the control, however, the comparison between IC and TrPPR yielded no difference. The significant effect of external limitations in this study was described in Chapter Four (Table 4.16). These collectively had a negative effect on the ranking with regards to the level of evidence produced by this study, resulting in this study contributing only a moderate to a low level of

evidence in support of IC being better than placebo and comparable to another form of MFTP therapy.

Similarly, Blikstad and Gemmell (2008) investigated the difference in efficacy between MBT (a type of IC) and activator therapy as treatment for MPD. They concluded that MBT was less effective than activator therapy. However, due to the significant limitations as a result of predominantly external factors which were identified in this study (Chapter Four, Table 4.10); the reliability of the conclusion was brought into question. Therefore, the level of evidence presented in this study was ranked as being of a low quality and not in favour of MBT.

A different study conducted by Gemmell and Allen (2008) aimed to establish the difference efficacies between IC and activator therapy concluded that there was no significant difference between these modalities and their therapeutic effects on MPD. With this study also having succumbed to similar limitations as the Blikstad and Gemmell (2008) and Gemmell *et al.,* (2008) studies, this study was also ranked as having a moderate to low level of evidence in support of the interventions studied (Chapter Four: Table 4.18).

In a similar manner, Aguilera *et al.,* (2009) aimed to compare IC versus US; they concluded that IC was equally as effective in the treatment of MPD as US. However, the results of this study may have been flawed due to the limitations related to some structural problems within the design of the study as well as external factors with respect to participant recruitment both of which were discussed in Chapter Four (Table 4.4). This resulted in the study being evaluated as providing a moderate to low level of evidence in support of IC as an intervention therapy.

A final study investigating the efficacy of combination therapies was conducted by Iqbal *et al.,* (2010). This study focused on comparing a combination of IC and strain-counterstrain exercises with IC alone as well as the use of a control. It was concluded that the combination of IC and strain-counterstrain exercises was more effective in the treatment of MPD than IC alone as well as more effective than the control. However, this study was ranked as being a low level of evidence as the quality of the study was hampered by several limitations that were identified in Chapter Four (Table 4.28). In addition, the outcomes of the study did not

favour IC, but the combination of IC and strain-counterstrain as an intervention therapy. Therefore this study does not provide direct support for the use of IC alone.

To conclude the discussion on IC, it has been noted that the outcomes of the individual studies are inconsistent with the level of rigour being excellent to average. The significant impact of the external factors in this series of studies seem to negate the attempts of the researchers to provide appropriate levels of evidence in support or not of IC like therapies. Hence, the level of evidence available for the effectiveness of IC as MPD treatment has been ranked as limited. Therefore, further studies which are succinctly structured in terms of controlling external factors and conducted more soundly are required in order to reveal the clinical effectiveness of IC.

5.4.3 Ultrasound

Table 5.5 Level of Evidence for US

Author and Year	Type of Study	PEDro Ranking	Level of evidence			
			STRONG	MODERATE	LIMITED	NONE
Srbely, Dickey, Lowerison, Edwards, Nolet and Wong, 2008	RCT	9/11			X	
Acar and Yilmaz, 2012	RCT	6/11				
Bahadir, Majlesi and Unalan, 2006	RCT	6/11				
Sarrafzadeh, Ahmodi and Yassin, 2011	RCT	6/11				

Table 5.5 shows the reviewed studies that aimed to investigate the effectiveness of US, for use in patients with MPD. These studies investigated US alone and in combination with other modalities as a treatment method for MPD.

A study conducted by Srbely *et al.,* (2008), intended to investigate whether or not US produced short-term segmental anti-nociceptive effects on MFTPs. A conclusion in support of US was reached; however, despite the positive outcome, the limitations discussed in Chapter Four (Table 4.48) of this study resulted in the evidence produced as being of a moderate quality in support of the US in MPD.

Acar and Yilmaz (2012) conducted a study that compared two groups of combination therapies (US, heat and exercise versus heat and exercise) with each other as well as with a control group who received rest. They concluded that a combination of US, heat and exercise is more effective than a combination of heat and exercise, as well as being prescribed rest. The combination of heat and exercise was noted to have the same effectiveness as the control. Therefore, the outcomes of this study were in favour of the combination; however there is no specific evidence that links to indicating that the US was the key factor in facilitating the success of the combination therapy. Thus, although this study yielded a positive outcome, the reliability of these outcomes were the several limitations that was noted and discussed in Chapter Four (Table 4.2). As a result of these internal and external limitations, the evidence created by this study has been ranked as being of a low quality.

By contrast, Bahadir *et al.,* (2006) conducted a study that compared the pain relief effects of only US to that of dry needling. The conclusion of this study was that US created better pain relief in patients with MPD than dry needling, however, is does not improve ROM. Therefore, this study also produced limited positive results. In a manner similar to the study by Acar and Yilmaz (2012), the limitations present and discussed in Chapter Four (Table 4.8) resulted in a negative effect on the quality of evidence. As such, notwithstanding the positive outcome, the overall effect ranked the study as low level in quality, but that which is in partial support of the clinical effectiveness of US.

Similar to Bahadir *et al.,* (2006), the study conducted by Sarrafzadeh *et al.,* (2011) aimed to compare US, PR and phonophoresis of hydrocortisone to a control group. This study concluded that all three of these modalities were successful (better than the control group) in the treatment of MPD. Therefore, without looking at the limitations, the study provided positive support for US. However, when evaluating the limitations noted in Chapter Four (Table 4.42), these limitations provided a context in which the interpretation of the study indicated that the level of evidence was actually of a low standard.

As it may be noted in the discussion above on US, the studies reviewed for US and its effectiveness as a treatment for MPD all yielded positive results; however, the quality of these studies ranged between moderate to low. Therefore, upon taking into consideration the study outcomes and limitations, the resultant level of evidence provided by the combination of these articles noted that collectively the evidence in support of US has been ranked as

limited. Studies which implement corrective measures for the limitations discussed in Chapter Four (Tables 4.2, 4.8,4.42 and 4.48) and the collective discussion of the studies in Chapter Five are required to improve the quality of evidence available with regards to the effectiveness of US as MPD therapy.

5.4.4 Laser

Table 5.6 Level of Evidence for Laser

Author and Year	Type of Study	PEDro Ranking	Level of evidence			
			STRONG	MODERATE	LIMITED	NONE
Gur, Sarac, Cevik, Altindag and Sarac, 2004.	RCT	10/11				
Yamany and Salim, 2011	RCT	8/11				
Hakgunder, Birtane, Gurcan, Kokina and Turan, 2003.	RCT	7/11		X		

Table 5.6 is an indication of the studies which have been reviewed during this dissertation which investigated the efficacy of laser therapy as a treatment modality for MPD.

The study by Gur *et al.,* (2004) was conducted to compare the efficacy of LLLT versus a control group who received sham LLLT. The authors of this study concluded that LLLT was more effective as a treatment method for MPD than sham LLLT. Although the control did decrease the pain experienced by participants, LLLT brought about a decrease in all the measurement parameters. While this study did show LLLT as being clinically effective, it was ranked as having produced a moderate quality of evidence due to the several limitations identified Chapter Four (Table 4.20).

The study by Yamany and Salim (2011) compared LLLT and exercise with placebo LLLT and exercise. They concluded that LLLT with exercise was more effective than placebo LLLT and exercise in the treatment of MPD. This outcome is similar to Acar and Yilmaz (2012) where the outcomes, although favourable do not allow for the reader to determine whether LLLT is effective in its own right when dealing with patients presenting with LLLT. Therefore, in line with this and the previous discussion of the study limitations (Chapter

Four: Table 4.50); it is that this study was ranked as having a no evidence in support of LLLT and moderate to low evidence in support of a combination therapy.

Hakgunder *et al.,* 2003 aimed to compare a combination of LLLT and stretching exercises with exercise alone. The conclusion was that a combination of LLLT and stretching was more effective in treating MPD than stretching alone. The positive result of this study also falls prey to the pitfalls of Yamany and Salim's (2011) study and Acar and Yilmaz's (2012) study, as the combination therapy does not allow for the interpretation of the individual therapy's effect. Therefore, this study provides no support for LLLT in its own right. The combination therapy seems to have a positive outcome, however the significant limitations identified (Chapter Four: Table 4.22) result in the study being ranked as providing a moderate to low level of evidence in support of the combination therapy.

Therefore, based only on the study of Gur *et al.,* (2004), LLLT for MPD seems to be moderately effective. The remaining studies have limited capabilities in providing evidence on the effect of LLLT as a result of the combination of therapies used in each treatment group. After taking into consideration the discussion on LLLT, it was ranked as having moderate level of evidence to support its efficacy as MPD treatment.

5.4.5 Topical Agents

Table 5.7 Level of Evidence for Topical Agents

Author and Year	Type of Study	PEDro Ranking	Level of evidence			
			STRONG	MODERATE	LIMITED	NONE
Lobo, Mehta, Forgione, Melis, Al-Badawi, Ceneviz and Zawai, 2004	RCT	11/11		X		
Lin, Kuan, Hsieh, Yen, Chang and Chen, 2012	RCT	10/11				
Avrahami, Hammond, Higgins and Vernon, 2012	RCT	10/11				
Hsieh, Hong, Chern and Chen, 2010b	RCT	7/11				

The information is Table 5.7 lists the studies which have been reviewed according to the category of topical agents as utilised in the clinical treatment of MPD. These studies all

aimed to investigate the effectiveness of various topical creams and patches as treatments for MPD.

Firstly, Lobo *et al.,* (2004) conducted a study that investigated the effectiveness of Theraflex cream versus that of a placebo cream. The authors concluded that Theraflex cream was indeed more effective (in support) than the placebo as a treatment for MPD. These results can be questioned though, due to the presence of several internal and external limitations within the study noted in Chapter Four (Table 4.38). As a result of these limitations, this study was ranked as having a moderate quality of evidence.

This methodologically rigorous study by Lin *et al.*, (2012) compared a 5% lidocaine patch with a placebo patch. This study concluded that the 5% lidocaine patch was more effective (in support) than the placebo patch; however, the external limitations (Chapter Four: Table 4.26) of this study decreased the ability of the study to provide a strong level of support. Therefore, the level of evidence in support of the 5% lidocaine patch was ranked as being moderate.

By contrast to Lin's *et al.,* (2012) study, Avrahami *et al.,* (2012) compared six different topical creams and roll-ons. The inter-group results concluded that PTMC roll-on and BG decreased MPD more than PLA. However, these topical agents did not have an effect on ROM. The evidence in this study after consideration was given to the external limitations (Chapter Four, Table 4.6) and as such this study provided partial support and moderate evidence in favour of PTMC roll-on, MM and BG interventions.

Lastly, Hsieh *et al.,* (2010b) compared a Diclofenac patch to a placebo patch and they concluded that the diclofenac patch was more effective than to the placebo patch. Thus, notwithstanding the limitations (Chapter Four: Table 4.6) of this study, it was noted that the diclofenac patch is positively supported. However, when including the external and internal limitations it becomes apparent that the level of evidence is of a low quality.

The discussion of topical agents shows positive results collectively with the quality of the evidence remaining high with a moderate ranking. This supports the use of specific topical applications in the treatment of MPD. Although all the studies showed topical agents that had positive clinical effects in the treatment of MPD, the topical agents themselves were all

different; hence further research is required, firstly, to strengthen the quality of the level of evidence and secondly to investigate the individual types of topical agents in a more thorough and systematic manner.

5.4.6 Other Modalities

Table 5.8 Level of Evidence for Other Modalities

Author and Year	Type of Study	PEDro Ranking	Level of evidence			
			STRONG	MODERATE	LIMITED	NONE
Kalamir, Pollard, Vitiello and Bonello, 2010	RCT	11/11			X	
Craane, Dijkstra, Stappaerts and De Laat, 2012	RCT	9/11			X	
Schabrun, Cannan, Mullens, Dunphy, Pearson, Lau and Chipchase, 2012	RCT	9/11			X	
Hsieh, Liou, Lee, Chen and Yen, 2010a	RCT	7/11			X	

Table 5.8 shows a list of studies that could not be categorized based on the modalities they investigated. Each of these studies investigated different modalities.

Kalamir *et al.,* (2010) compared a control to IMT with / IMT without additional education and exercise. They concluded that IMT in both instances has the potential to be effective as treatment option for MPD. In addition to this and based on the noted limitations (Chapter Four, Table 4.32), this pilot study provided strong evidence in favour of IMT. To support this, the authors noted that more research into this topic is necessary in order to achieve a true reflection of efficacy. However, because there is only one such study in this domain and relating to MPD, it is unfortunate that within the greater picture, this single study only provides a limited level of evidence in favour of IMT.

Craane *et al.,* (2012) investigated the difference in efficacy between physical therapy and natural progression of MPD over a period of one year. They concluded that there was no significant difference and that after a period of one year a patient was most likely to improve with or without physical therapy. This study was ranked as having created a level of evidence that was of a moderate (after accounting for limitations and quality and rigour of the methodology) (Chapter Four, Table 4.12).

A similar conclusion was reached by Schabrun *et al.,* (2012) who investigated the effectiveness of a novel therapy, INS. This study was ranked as having moderate rigour that provided a moderate level of evidence. This ranking may have been higher if the limitations discussed in Chapter Four: Table 4.44 were addressed.

Lastly, the study conducted by Hsieh *et al.,* (2010a) aimed at comparing the effects of acupressure versus muscle relaxant medication and analgesics. It was concluded that acupressure was more effective than medication as treatment for MPD. However, due to the limitations of the study and their effects on the rigour of the study as discussed in Chapter Four (Table 4.24); this study was ranked as having contributed a limited level of evidence to the literature.

The discussion above reveals that there are several modalities which still require systematic and structured research. The overall level of evidence ranking in this miscellaneous category was noted as 'limited' as these individual studies addressing particular aspects of possible interventions for MPD stand alone in their provision of evidence and have not been supported by further studies.

5.4.7 Combination of modalities in the treatment of MPD

After reviewing the literature to determine the effect of non-invasive interventions for the treatment of MPD, it became apparent that approximately 25% of these studies actually constituted combination therapies, yet in some instances, claims were made with regards to a particular form of intervention. This is a cause for concern, but also provides a nidus for the development of future research that is well structured and rigorous in nature.

In addition, it was noted that; Iqbal *et al.,* (2010), provided evidence in favour of their combination, even though the quality of the study was low. Acar and Yilmaz (2012); provided evidence in favour of their combination, even though the quality of the study was low. Hakgunder *et al.,* (2003), provided evidence in favour of their combination, even though the quality of the study was low. Yamany and Salim (2011); provided evidence in favour of their combination, even though the quality of the study was low.

The only two studies that broke this trend were those of:
Kalamir *et al.,* (2010), who found in favour of the combination therapy with a strong quality pilot study and Craane *et al.,* (2012) who did not find in favour of combination, with a moderate quality study.

These outcomes suggest that further research is necessary in order to support the practical application of combination therapies in the context of MPD, particularly as combination therapies are often utilised in clinical practice.

5.5 Conclusion

Based on the analysis of the individual studies in Chapter Four (by rigour and outcome) and then the collective groupings of the interventions in Chapter Five (by rigour and outcome) of the individual studies as well as by reviewing the collective outcomes in the context of the criteria supplied by Dagenais and Haldeman, (2011), it becomes apparent that the level of evidence that is currently available in the peer-reviewed literature in support of interventions for MPD is at very best limited.

Table 5.9 Level of evidence for non-invasive modalities for treatment of MPD

Modalities	Level of Evidence			
	Strong	**Moderate**	**Limited**	**None**
TENS			**X**	
IC			**X**	
US			**X**	
LASER			**X**	
TOPICAL AGENTS		**X**		
OTHER			**X**	

The outcomes of this study are reflected in Table 5.9, which is a summarized representation of the level of evidence presented for the various non-invasive modalities used as treatment options for MPD.

This Table clearly indicates that there is a lack of strong, high quality methodologically rigorous studies. Therefore, on the topic of non-invasive myofascial therapies, specifically, clinical effectiveness still requires more in depth and well-structured research in order to create a greater body of knowledge with good quality in order to enable the provision of appropriate evidence for use in clinical practice. It has also been noted that combination therapies are the most supported amongst the treatment protocols investigated, hence, there is a lack of studies that investigate the effectiveness of individual modalities and further research into this topic is required. The above conclusion is limited to the literature that was included in this study. Hence, it can only be applied to the literature that includes studies that were:

- Published in English
- Published before September 2013 (The end of data collection for this study)
- RCTs
- Peer-reviewed

Future systematic reviews conducted with regards to the effectiveness of non-invasive modalities as treatment for MPD may yield different conclusions if the above mentioned limitations are taken into consideration.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Introduction

This chapter discusses the conclusion of the study as well as recommendations for future research and practitioners.

6.2 Conclusion

The aim of this study was to locate and critically analyze the available body of knowledge around the effectiveness of non-invasive myofascial therapeutic modalities. Initially, a search was performed to gather all potentially relevant studies; the identified studies were then screened according to a pre-structured set of inclusion and exclusion criteria. After review and screening, the final number of studies included in this systematic review was twenty five.

Following the search and inclusion of studies, five reviewers (four professionals in the field and the researcher) performed a review process using the recommended PEDro Scale (PEDro Scale, 2012; Verhagen *et al.*, 1998). Each study was reviewed by three reviewers, which was followed by the researcher thoroughly analysing and tabulating each study. Each study was reviewed for methodological rigour as well as the impact of limitations on the outcomes of the study so as to reflect the overall quality of the study. Therefore, the level of evidence it provided within its domain. This process was then repeated for the collective evidence that was provided by multiple studies in the context of a particular form of intervention. The results of this analysis provided an outcome (quality and level of evidence) that either supported the particular type of intervention or not.

The quality of evidence created by each study was noted to range between moderate to low, whereas the overall level of evidence for each modality was generally ranked as limited with the exception of Topical Agents which received a moderate ranking. It was also concluded that approximately 25% of the studies investigated combination therapies; therefore, although the outcomes of these studies may have been positive they cannot be applied to individual modality effectiveness. The lack of strong levels of evidence as noted in Chapter Five and the presence of numerous limitations as noted in Chapter Four, indicate that further research is required in order for one to gauge the true effectiveness of these modalities on MPD.

6.3 Recommendations

6.3.1 Recommendations for improvement of this review

This study only reviewed articles that were RCTs and although the literature regarding systematic reviews state that RCTs are the ideal source of evidence, inclusion of non-RCT, case studies and observational studies may have had the potential to alter the results. This systematic review also included only those studies which had been either published in or previously translated into English. Studies that were not available in English were excluded; however, an inclusion of these studies may also have had an effect on the conclusion. Finally, this study only included peer-reviewed and published studies, which creates a possible discrepancy in results as the unpublished articles and theses may have had an impact on the data, which in turn would have had an impact on the results.

6.3.2 Recommendations for practitioners

As it has been discussed in the Conclusion (Section 6.1), the level of evidence for non-invasive myofascial therapy needs to be strengthened by further research. However, according to the results from this study, Topical Agents ranked the highest with regards to their level and quality of evidence and therefore, it can be assumed that this modality is more effective than TENS, IC, US, Laser and Other modalities. It has also been noted that combination therapies seem to produce positive outcomes and may in fact be more effective in patient care than the use of individual modalities.

6.3.3 Recommendations for future research

This systematic review has highlighted several limitations within the present body of knowledge regarding non-invasive myofascial therapy. Further RCTs are required that take into consideration the limitations discussed in Chapter Four for each study and modality used and aim to correct those limitations thereby creating studies of a higher quality. Further systematic reviews will also be beneficial and may add a clearer perspective to the subject of MPD and its therapy. Studies investigating individual modalities are also recommended.

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Appendix 1.1

An explanation of the PEDro Scale

The PEDro scale is used for the review of the validity of randomized controlled trials. It consists of 11 criteria, which are reviewed as either being fully met in which case the reviewer marks the "yes" box on the rating sheet, a criterion which scores a "yes" rating gain 1 point. In the event that the criterion is not completely met, the reviewer marks the "no" box, and the article gains 0 points. Each randomized controlled study is ultimately rated out of 11. A third rating block for each criterion "where" requires the reviewer to indicate the page number as a reference. This rating allows for easy comparison should there be inconsistencies between reviewers.

Each criterion is explained below;

Criterion 1: is satisfied if there is a clear list of inclusion and exclusion criteria for subjects who were considered eligible to participate in the study. A second requirement for the satisfaction of this criterion is clear indication of the source of subject included in the related study.

Criterion 2: is satisfied provided there is clear indication in the study stating that the allocation of subjects was random, methods such as 'drawing from a hat', 'tossing of a coin', etc is regarded as randomization. However, methods which may create personal links with subjects, such as dates of birth, is regarded as quasi-randomized and does not satisfy Criterion 2.

Criterion 3: is satisfied in the instance when subjects' inclusion or exclusion was decided by a person who was unaware of the groups to which the included subjects will be allocated.

Criterion 4: is satisfied if the study describes one or more measures of severity of the related condition as well as at least one measure of effectiveness at a baseline level. The groups should not be different from each other with regards to the prognostic variables.

Criterion 5: is satisfied if all the subjects included in the study remain unaware of the group they are in throughout the study.

Criterion 6: is satisfied if administrator of treatment remains unaware of which group each subject has been allocated to.

Criterion 7: is satisfied if the assessors involved in the study are unaware of the groups to which included subjects have been allocated.

Criterion 8: is satisfied if the study states clearly the initial number of subjects allocated to the groups and the number of subjects from whom the measures of effectiveness was obtained. The measures of effectiveness must be obtained from at least 85% of the initial number of subjects in the events where measures of effectiveness are obtained at various intervals throughout the study.

Criterion 9: is satisfied when the study clearly indicates that all subjects received the intervention they were planned to receive. This is considered satisfactory with or without a mention of an 'intention to treat'. An 'intention to treat' is relevant when a subject scheduled to receive specific interventions within a specific time frame, does not receive the intervention due to unforeseen circumstances. The results in this situation are recorded according to what they would have been if the subject had received the planned interventions.

Criterion 10: is satisfied if there is clear indication of 'between groups' statistical comparison of one or all of the measures of effectiveness. A 'between groups' statistical comparison refers to the process of analyzing and comparing the results yielded during the study

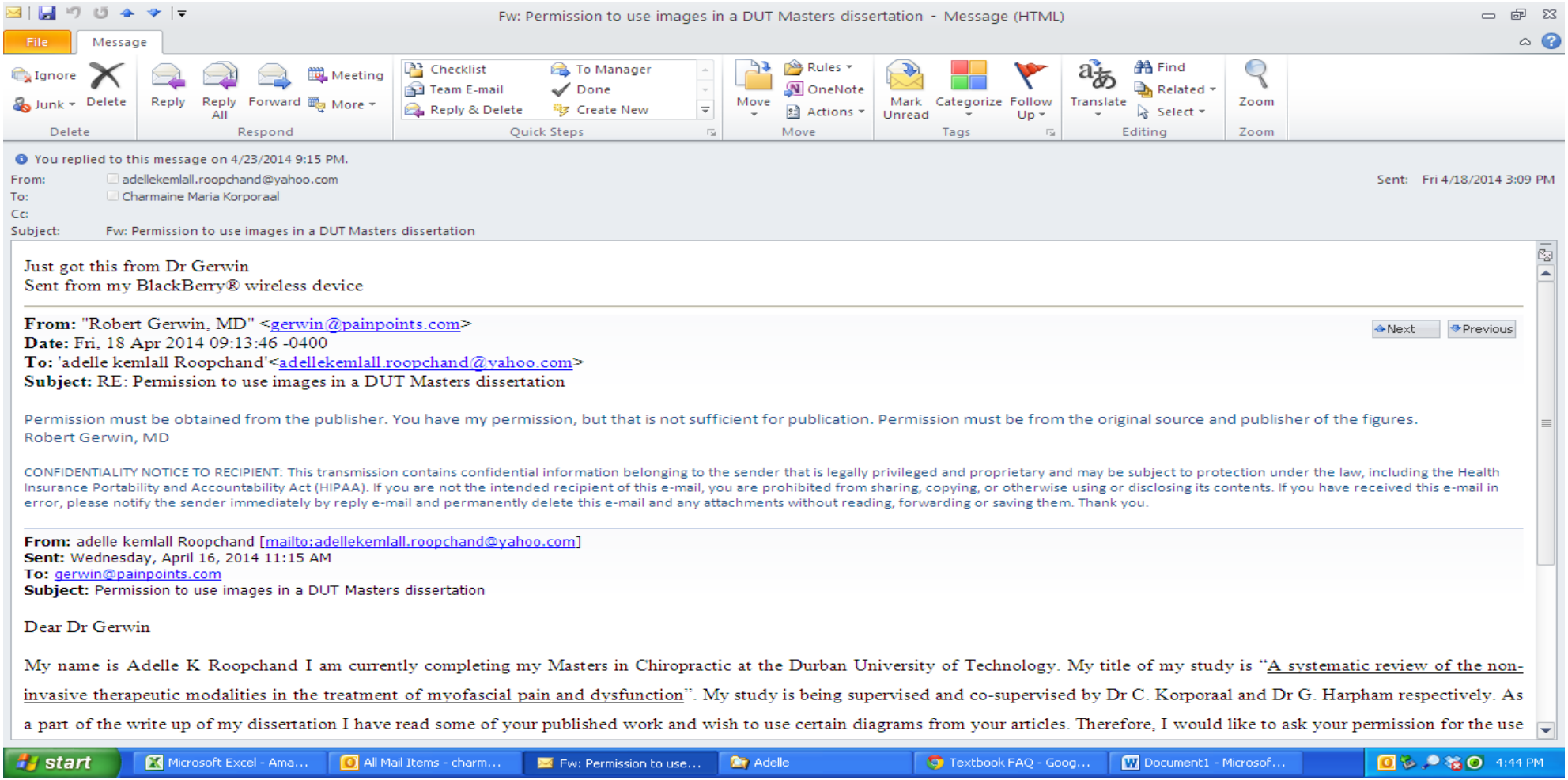
within the groups of subjects. This comparison should occur after the data collection of the study is completed and the results from each group can be easily generated and analyzed.

Criterion 11: is satisfied if the study clearly provides measures of the magnitude of the effects created by the investigated modality. The measures of variability may be; standard errors, confidence intervals, standard deviations etc. These must be clearly depicted; the depiction may be graphic, numerical or otherwise.

Adapted from; *PEDro Scale* (online). 2012. Available at www.pedro.org.au (Accessed on 13 September 2012).

Appendix 2.1

Permission for the Use of Images – Dr Gerwin



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Date: Fri, 18 Apr 2014 09:13:46 -0400
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Robert Gerwin, MD

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From: adelle kemlall Roopchand [mailto:adellekemlall.roopchand@yahoo.com]
Sent: Wednesday, April 16, 2014 11:15 AM
To: gerwin@painpoints.com
Subject: Permission to use images in a DUT Masters dissertation

Dear Dr Gerwin

My name is Adelle K Roopchand I am currently completing my Masters in Chiropractic at the Durban University of Technology. My title of my study is "A systematic review of the non-invasive therapeutic modalities in the treatment of myofascial pain and dysfunction". My study is being supervised and co-supervised by Dr C. Korporaal and Dr G. Harpham respectively. As a part of the write up of my dissertation I have read some of your published work and wish to use certain diagrams from your articles. Therefore, I would like to ask your permission for the use

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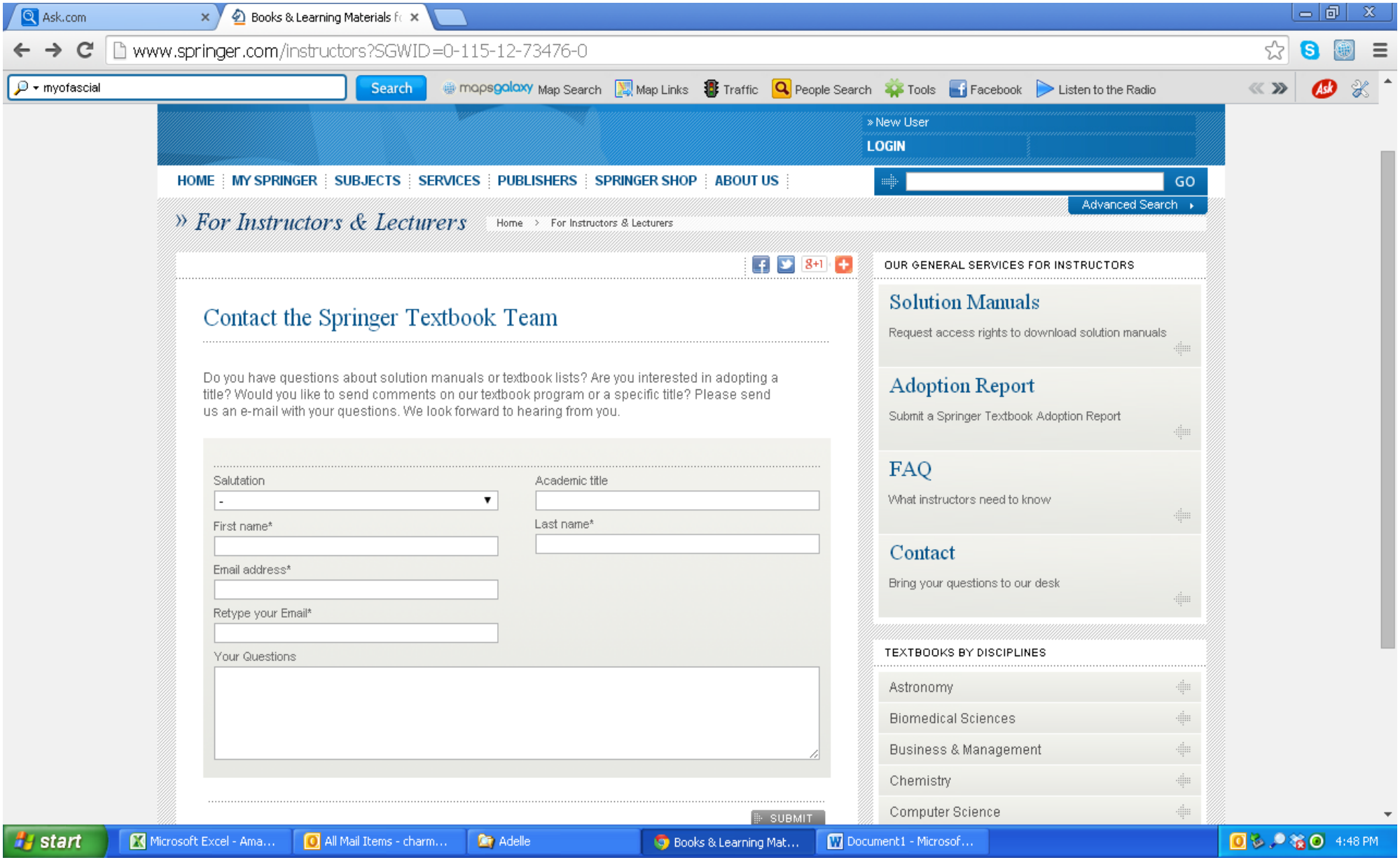
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Total	0.00 USD

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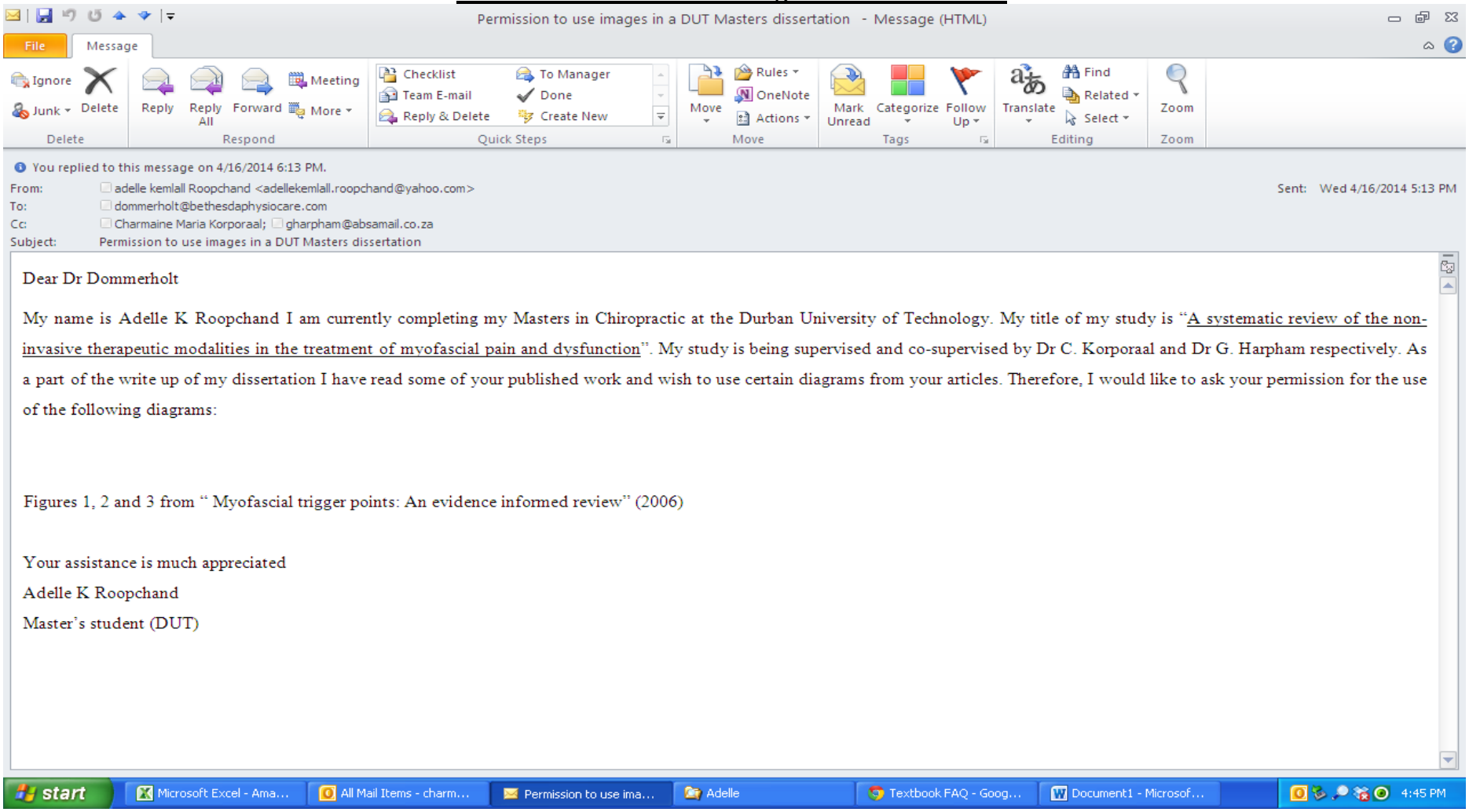
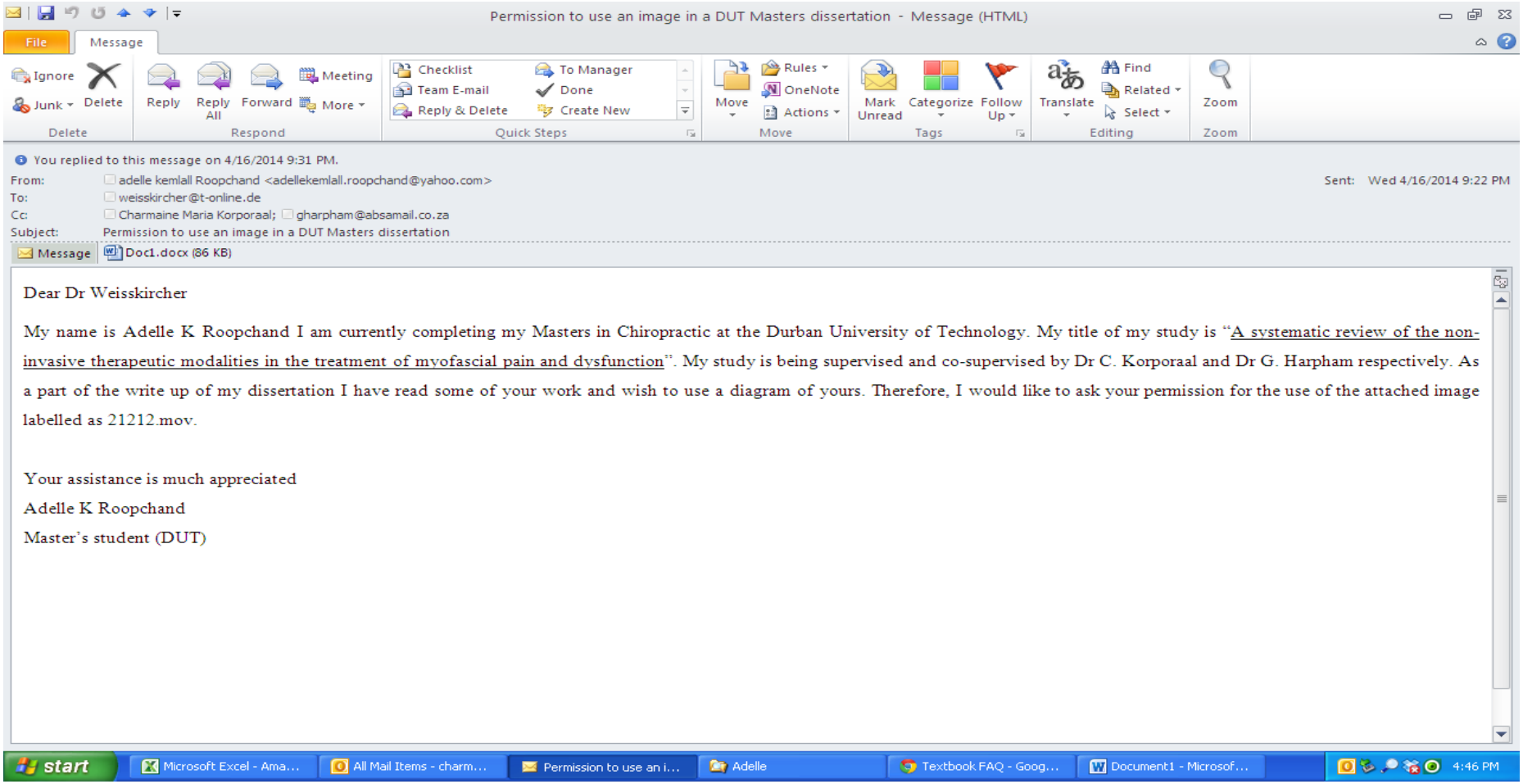
Appendix 2.2

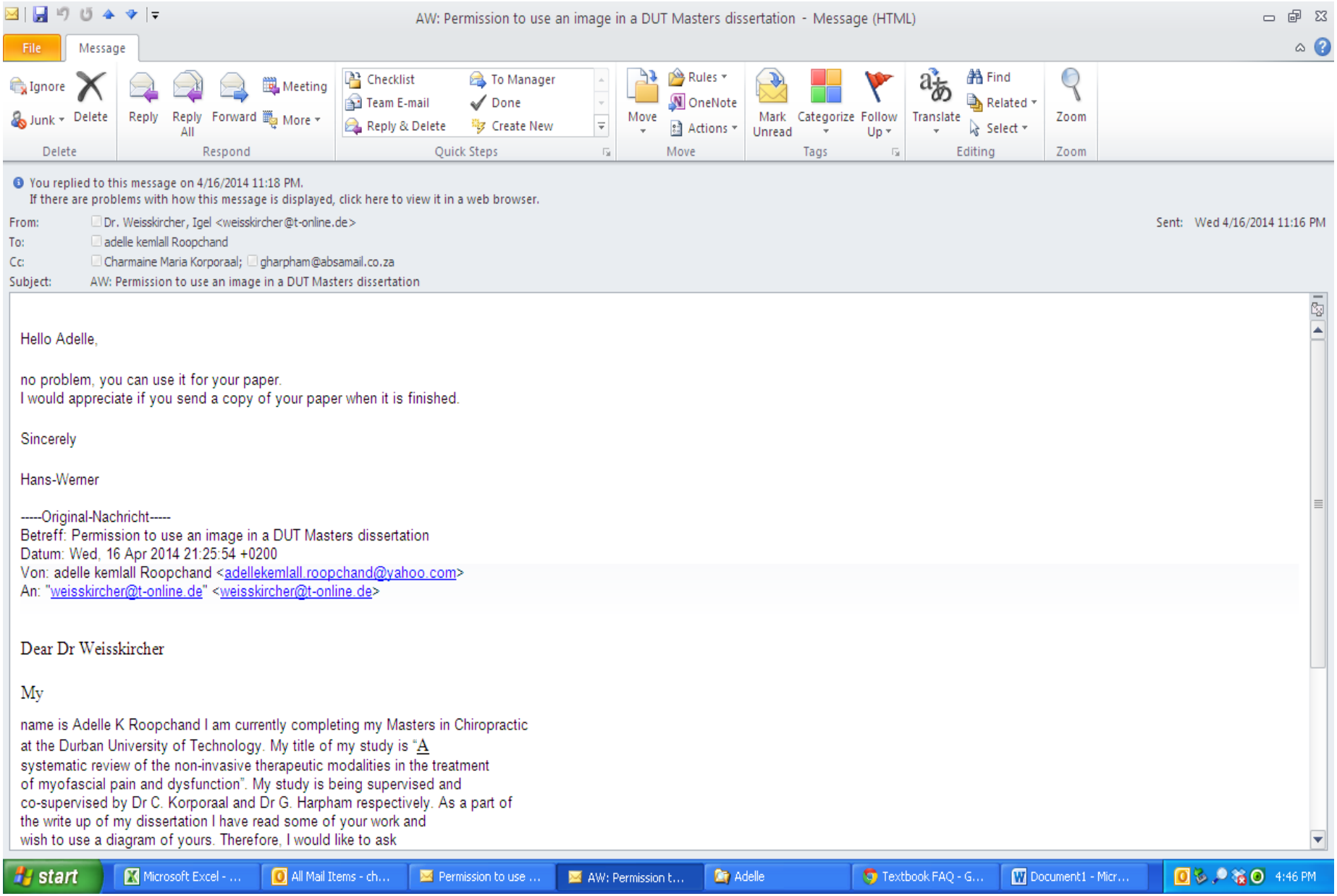
Permission for the Use of Images – Dr Dommerholt



Appendix 2.3

Permission for the Use of Images – Dr Weisskircher

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Von: adelle kemlall Roopchand <adellekemlall.roopchand@yahoo.com>
An: "weisskircher@t-online.de" <weisskircher@t-online.de>
Dear Dr Weisskircher
My
name is Adelle K Roopchand I am currently completing my Masters in Chiropractic at the Durban University of Technology. My title of my study is "A systematic review of the non-invasive therapeutic modalities in the treatment of myofascial pain and dysfunction". My study is being supervised and co-supervised by Dr C. Korporaal and Dr G. Harpham respectively. As a part of the write up of my dissertation I have read some of your work and wish to use a diagram of yours. Therefore, I would like to ask
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Appendix 2.4

Data Property Table

Table	Analysis of Article RCT							
AUTHORS:								
YEAR:								
TITLE:								
STUDY PROPERTIES:								
Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking out of 11	Total Percentage Agreement
LIMITATIONS:								
OUTCOME:								
DISCUSSION:								
CONCLUSION:								

Appendix 3.1

Letter of Approval from DUT Research and Higher Degrees Committee

18 September 2013

Student No: 20800062

Ms A Roopchand
17 Flamingo Road
Duffs Road
Durban
4051

Dear Ms Roopchand

MASTER'S DEGREE IN TECHNOLOGY: CHIROPRACTIC

I am pleased to advise that:

1. The Research and Higher Degrees Committee approved the following:

    (i) Your research proposal and dissertation title, being:

A systematic review of the non-invasive therapeutic modalities in the treatment of myofascial pain and dysfunction.

Please note: ANY PROPOSED CHANGES in the DISSERTATION TITLE require the approval of your supervisor and the Research and Higher Degrees Committee.

(ii) Supervisor – **Dr C. Korporaal**

A Research budget of R5 000 has been approved. Please note that this funding is not paid directly to you but is controlled by your Head of Department. Any proposed changes to this funding allocation needs the approval of your supervisor, and Faculty Research Committee

The Institutional Research Committee has stipulated that:

(a) The funding for the Research budget allocated to you is subject to compliance with the Intellectual Property Rights from Publicly Financed Research and Development Act No. 51, 2008 (including the Regulations) in force from time to time;
(b) This University retains the ownership of any Intellectual Property (patent, design, etc.) registered in respect of the results of your Masters/Doctoral Degree in Technology studies as a result of the award and the provisions of the above Act;
(c) Should any amounts accrue to you in respect of the disposal of any tangible assets developed or created during the course and scope of your Masters/Doctoral Degree in Technology, such amount will first be directed towards repaying the University the funding investment which the University has made in approving your request for funding, with the balance being retained by you;
(d) If the University provided the equipment/materials for the creation of artefacts, this cost must be refunded to the University if such artefacts are sold;

May we remind you that in terms of Rule G25(2)(b), if you fail to obtain the Masters/Doctoral degree within the maximum time period allowed after first registering for the qualification, Senate may refuse to renew your registration or may impose any conditions it deems fit. You may apply to the Faculty Research Committee for an extension.

Please note that you are required to re-register each year.

Should you experience any problems relating to your research, your supervisor must be informed of the matter as soon as possible. If the difficulties persist, you should then approach your Head of Department and thereafter the Executive Dean of the Faculty.

Please refer to the 2012 General Rule Book concerning the rules relating to postgraduate studies, which include *inter alia* acceptable minimum and maximum timeframes, submission of thesis/dissertations, etc. You are also advised to read the Postgraduate Students' Guide which is available on the DUT website http://research.dut.ac.za.

Please do not hesitate to contact Research and Postgraduate Support office for any assistance. We wish you success in your studies.

Yours sincerely

[redacted]

Prof T Puckree
EXECUTIVE DEAN: FACULTY OF HEALTH SCIENCES
DURBAN UNIVERSIT OF TECHNOLOGY

Appendix 3.2

PEDro Scale

Reviewer:
Article Title:
Authors:
Year of publication:

Please clearly indicate YES or NO for each criterion:

CRITERION			WHERE
1. Eligibility criteria were specified	**YES**	**NO**	
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	**YES**	**NO**	
3. Allocation was concealed	**YES**	**NO**	
4. The groups were similar at baseline regarding the most important prognostic indicators	**YES**	**NO**	
5. There was blinding of all subjects	**YES**	**NO**	
6. There was blinding of all therapists who administered the therapy	**YES**	**NO**	
7. There was blinding of all assessors who measured at least one key outcome	**YES**	**NO**	
8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	**YES**	**NO**	
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by "intention to treat"	**YES**	**NO**	
10. The results of between-group statistical comparisons are reported for at least one key outcome	**YES**	**NO**	
11. The study provides both point measures and measures of variability for at least one key outcome	**YES**	**NO**	

Adapted from; *PEDro Scale* (online). 2012. Available at www.pedro.org.au (Accessed on 13 September 2012).

Appendix 3.3

Memorandum of Agreement

Title of Research: A systematic review of the non-invasive modalities in the treatment of myofascial pain and dysfunction.

Researcher: Adelle Kemlall Roopchand

Supervisor: Dr. C. Korporaal (MTech:Chiropractic, CCFC, CCSP, ICSSD)

Co-Supervisor: Dr. G. Harpham (MTech:Chiropractic)

Introduction and purpose of the study:

This study is a systematic review of the various non-invasive treatment modalities used in the therapy of myofascial pain and dysfunction, where “non-invasive” refers to any modality applied to the surface of the skin but does not physically penetrate the skin. This study aims to review and summarise the evidence available on these modalities and ultimately develop an evidence based list of which modalities are most effective and which are least effective.

Outline of the procedure

This study involves the collection of the related articles from electronic databases. These articles have been either included or excluded based on specific criteria. The final list of randomized controlled trials has been randomly allocated into 4 groups. Each group will be randomly allocated to 2 separate reviewers. The articles will then be reviewed using the PEDro scale. Reviewers will be allowed a maximum of 12 weeks to complete the review of all studies allocated to them (average number of articles per reviewer is 13).

Benefits

Should this study be published all reviewers will each be named as authors. Should you choose to opt out of this possibility please draw a line through this paragraph and initial alongside it.

Remuneration

An honorarium of R850.00 will be awarded to each reviewer as a token of appreciation for the time and effort you will contribute to the completion of this study.

Should you have any questions or uncertainties please do not hesitate to contact one of the following people;

- Adelle K Roopchand-078 2912 406/ adellekemlall.roopchand@yahoo.com
- Dr. C. Korporaal -083 246 3562/ charmak@dut.ac.za
- Dr. G. Harpham -084 545 2345/ Dr.Graeme@chiropractordurban.com

Statement of Agreement to participate in the study

I_____ (Full Name), _____(ID no.), have read and understand this document completely.

I hereby volunteer to be a part of this study as a reviewer.

Reviewer's Name: Signature: _____
Date: _____

Researcher's Name: Signature: _____
Date: _____

Supervisor's Name: Signature: _____
Date: _____

Appendix 3.4
Methodological Rigor Table

Table	Tabulated Feedback Data for RCT					
AUTHORS:						
TITLE:						
YEAR:						
CRITERION:		Reviewer 1	Reviewer 2	Reviewer 3	Majority	Percentage Agreement
1	Eligibility criteria were specified					
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)					
3	Allocation was concealed					
4	The groups were similar at baseline regarding the most important prognostic indicators					
5	There was blinding of all subjects					
6	There was blinding of all therapists who administered the therapy					
7	There was blinding of all assessors who measured at least one key outcome					
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups					
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by "intention to treat"					
10	The results of between-group statistical comparisons are reported for at least one key outcome					
11	The study provides both point measures and measures of variability for at least one key outcome					
	TOTAL SCORE					
		OVERALL PERCENTAGE AGREEMENT				