A systematic review to determine the evidence to support the use of flexion distraction Chiropractic technique.

By

Dillon Cuppusamy

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

Durban University of Technology

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

Dillon Cuppusamy	Date

Approved for Final Submission

Dr. C. Korporaal M.Tech: Chiropractic, CCFC, CCSP, ICSSD	Date
Dr. L. O'Connor M.Tech: Chiropractic, CCEP	Date

Dedication

I dedicate this dissertation to my father,

I can only wish that you were here to see me today.

Acknowledgements

I cannot express my gratitude enough to say how much I owe to my family, Mum, Chentell and Kyle. Thank you for everything that I am today. My grounding has been all because of you!

To my fiancé, Riona, my source of inspiration and beacon of motivation. Thank you for being there for me in the good times and more so in the bad times.

To Dr. Charmaine Korporaal, how can I even put into words as to how much I am indebted to you? Thank you for the enormous amounts of time and continuous guidance through this project.

To my co-supervisor, Dr. Laura O'Connor. Thank you for all the help, especially through those frustrating times and moments, and allowing me to vent frustration while you kept a level head.

Thank you to my reviewers, thank you for your time and dedication towards this project.

To Bronwyn Jones, a big, big thank you for proof-reading this dissertation so efficiently

And finally, to my peers, it has been a long, long journey. We have had some great times and some not so great times. I am so looking forward to practicing together, as professionals in the field of Chiropractic.

Abstract

Background: Flexion distraction chiropractic technique (FDCT) is a commonly used manual therapy technique which is purported to address various clinical pain syndromes. However, it lacks the credibility of appropriate evidence-based guidelines. An analysis of the literature would be able to inform the development of guidelines.

Objectives: The aim of this systematic review was to determine the evidence to support the use of FDCT in clinical practice.

Data sources: A systematic review of PubMed and Summons was conducted, using the following search terms: chiropractic, flexion distraction, protocol and / or technique.

Study selection: All electronic or paper, English articles, which possessed the required key indexing terms and represented randomised and non-randomised controlled study designs were included.

Data extraction: Blinded review of the articles was conducted by three independent reviewers utilising the PEDro (for randomised controlled trials) and NOS for (non-randomised controlled trials). This allowed the methodological rigour of the article to be ranked. This ranking was compared to a critical appraisal of the article in order to achieve an overall decision with regards to the contribution of the article to the level of evidence for FDCT.

Data synthesis: 18 review outcomes were aggregated around four clinical categories; two articles each on neck pain, chronic pelvic pain, and physiological outcomes and the remaining twelve on low back pain. There was agreement that the evidence for pelvic pain and physiological function was limited to no evidence and limited respectively. Conflicting evidence existed for neck and low back pain (single and multimodal treatment) with limited and moderate evidence respectively.

Conclusion: FDCT is clinically advocated for many conditions. The evidence provided in this review indicates that practitioners should be guarded in their use of FDCT, as the evidence to its widespread use is limited to only those conditions noted in this review. Therefore, further high quality and rigorous studies are required to develop appropriate treatment guidelines for use by practitioners to adequately provide evidence based care in clinical practice.

Key words: systematic review, flexion distraction, chiropractic, low back pain, neck pain, pelvic pain, physiological mechanisms

Table of Contents

Chapter Four: Results

Chapter Five: Discussion of Results

Chapter Six: Conclusion and Recommendations

List of Appendices

List of Tables

CHAPTER FIVE

List of Figures

Glossary of Terms

Adjustment (chiropractic reference):

Manipulative therapy and especially chiropractic manipulative therapy has a unique characteristic as it is involves the practice of controlled velocity, amplitude and directional thrust which is dynamic in nature; and characterised by a specific contact and controlled depth and speed of thrust (Schafer and Faye, 1990). This type of manipulation has been coined the chiropractic adjustment (Leach, 2004; Bergmann and Peterson, 2011). The procedure is frequently related to a distinct articular click (cavitation - particularly in synovial joints) that is delivered within the integrity of the joints anatomic boundary (Sandoz 1976; Leach, 2004; Mrozek and Vernon, 2005).

Therefore, in the context of the above definition of manipulation, spinal manipulation refers to the skilled realignment of articulations of the spine by means of a corrective force (Schafer and Faye, 1990; Gatterman, 1995; Leach, 2004).

An adjustment can be imparted by means of an instrument assisted device, low amplitude Chiropractic techniques, pelvic blocks or by hand (Cooperstein and Gleberzon, 2000).

Cavitation:

According to Unsworth et al., (1971), a cavitation is the audible release of pressure / gas as a result of an accompanying chiropractic adjustment. It was further stressed that this cavitation may not necessarily occur after all chiropractic adjustments due to the patient's muscle guarding or muscle spasm (Unsworth, 1971).

Distraction manipulation:

Bergmann and Peterson (2011), describes the distraction manipulation procedure whereby patients are placed on specifically designed tables for the application of these forces. While a distraction force is being applied, the zygoapophyseal (facet) joints are motioned and manipulated through their physiologic ranges of motion at particular spinal levels. The purpose of this procedure is to restore normal joint positioning and motion.

Flexion Distraction:

Is a non-propriety therapeutic method that is commonly used by other health care professionals i.e. manual therapists, with its application being described in Chapter 2 (Cooperstein and Gleberzon, 2000).

Joint mobilization:

This occurs when a joint is moved through the physiological range of movement and is typified by being a non-thrust passive in nature joint mobilization (Maitland, 1986; Isaacs and Bookhout, 2002). These can range from being segmental (specific) to general (non-specific) in nature for the purpose of mobilizing either single or multiple joints (Haldeman, 2005).

Manipulation:

By applying a therapeutic manual force (chiropractic adjustment), a joint can be moved across the physiological barrier into its paraphysiological space. This occurs without the joint exceeding its anatomical integrity (Bergman, Petersen and Lawrence, 1993; Gatterman, 1995; Haldeman, 2005).

Manual traction/distraction:

This form of manipulation refers to the practitioner's ability to manually impart a pulling or tractional force to a patient's joints (Bergman, Petersen and Lawrence, 1993). This process has in more recent years become characterised by the use of tables, mechanical devices or a combination of these to reduce injury to the practitioner whilst he/she is applying the treatment to the patient (Cooperstein and Gleberzon, 2004; Lennard et al, 2011).

Traction: Refers to a non-specific, unassisted traction-force that is applied to affect a joint (Bergman, Petersen and Lawrence, 1993).

Distraction: Refers to an applied traction force that is doctor-controlled to specific spinal levels (Bergman, Petersen and Lawrence, 1993).

Massage:

This technique involves the application and use of therapeutic kneading, stroking, friction and percussion to the body (Travell, Simons and Simons, 1999; Chaitow and DeLany, 2000).

Muscle energy technique:

This is a technique whereby a muscle is used in a precisely controlled manner in order for a restrictive barrier to become actively engaged and the joint mobilised. This is performed against an operator applied counterforce (Goodridge, 1981; Chaitow, 2006; Isaacs and Bookhout, 2002; Ferguson and Gerwin, 2005).

Muscle stretching:

This means that through the deliberate flexing and/or stretching of a specific tendon or muscle, the elasticity and tone of that structure can be improved (Prentice, 2003; Weerapong, Hume and Kolt, 2004; Ferguson and Gerwin, 2005).

Range of motion:

Range of motion refers to the degree and range of movements (rotation and translation) that occurs to a joint segment (Gatterman, 1995), and in particular with regard to the structure of the joint, and its six degrees of freedom.

Soft tissue manipulation:

This term describes the physical techniques that are designed to stimulate soft tissue, by imparting stretch, massage, point pressure and visceral manipulation to the body (Isaacs and Bookhout, 2002; Ferguson and Gerwin, 2005; Haldeman, 2005).

Trigger point therapy:

This term is also known as ischaemic compression. This therapy requires the application of point pressure to reduce the blood flow to an area, in order to increase blood flow when pressure is released in order to achieve clinical outcomes (Travell, Simons and Simons, 1999; Isaacs and Bookhout, 2002; Montanez-Aguilera et al, 2010).

Vertebral motion segment:

This term describes the relationship between articulating surfaces (the disc and the facet / zygopophyseal joints), together with the associated soft tissue structures (Haldeman, 2005; Dagenais and Haldeman, 2012).

Visceral manipulation:

This manipulative technique encompasses the use of gentle and specific forces, to manually restore the mobility of organs (Plaugher, 1993; Barral, 2005; Haldeman, 2005; Masarsky and Todres-Mararsky, 2008; Byfield, 2012).

Chapter One
Introduction

1.1 Introduction to the study

Chiropractic is a non-allopathic health care profession, which places emphasis on neural disorders as a result of structural dysfunction of the vertebral column and its contiguous structures (Chapman-Smith, 2000; Haldeman, 2005). Chiropractic techniques are used to treat neuro-musculoskeletal complaints, ranging from back and neck pain, to pain in the joints of the arms or legs, and headaches (Haldeman, 2005; Bergmann and Peterson, 2011; Dagenais and Haldeman, 2012). In order to achieve this, the most commonly performed procedure by chiropractors is that of a "spinal manipulation" which is also known as the "chiropractic adjustment" (Gatterman, 2003; Haldeman, 2005).

The manner in which the chiropractic adjustment is delivered to a patient can vary from practitioner to practitioner with many Chiropractic technique systems existing (Cooperstein and Gleberzon, 2004). Ndetan *et al*., (2009) found that there was a plethora of techniques being taught to chiropractic students at various universities in the United States of America (USA). In contrast, in other countries like South Africa, Chiropractic curriculums focus on one technique (diversified) with other techniques only available as post-graduate courses (University of Johannesburg, 2011; Durban University of Technology, 2013). A reason why so many technique systems exist, is that as a practitioner gains experience they seek new or alternative techniques to assist with the management of different types of patients (i.e. body size and age), their presenting complaints or how to manage co-morbid pathologies (Davies, 2000; Gatterman, 2003). Often practitioners may choose to mix these techniques (Cooperstein and Gleberzon, 2004) and modify them as they gain clinical experience (Haldeman, 2005). According to Christensen and Kollasch (2005), the top six adjusting procedures practiced by chiropractors in the USA were diversified, extremity adjusting, activator methods, Thompson Derifield technique, Gonstead and Cox / flexion distraction.

Some of the technique systems are step-by-step protocols that are followed to locate a patient's primary problem and presenting complaint. The protocol also includes information concerning the type and what treatment should be administered to solve the patient's pain (Cooperstein and Gleberzon, 2004). Many of these technique systems are a source of corporate income for patent holders (Cox, 1990; Fuhr, 2009; Activator®, 2012; Cox® Technic, 2012).

Gleberzon (2001a) conducted a literature review of "chiropractic named techniques" and found that there was a lack of literary evidence to support the more common techniques and even less to verify their clinical efficacy. With particular reference to flexion distraction Chiropractic technique (FDCT), this is a commonly used technique in chiropractic practice (Christensen and Kollasch, 2005). According to Gleberzon (2001a), only one descriptive study was found when he conducted a review of the literature on Chiropractic "named" techniques; which described the intra- and inter-examiner reliability of the FDCT procedure, rather than the effectiveness of the technique.

This presents a clinical conundrum for chiropractors, when they are required to decide on an appropriate chiropractic technique to use in the care of their patients (Sackett *et al*., 1997). Haldeman (2005) recommended that systematic reviews be conducted on chiropractic techniques to determine their clinical effectiveness and the practical value of these chiropractic techniques in clinical practice and specifically for the patient (Liberati *et al.,* 2009). This approach to chiropractic techniques would support an evidence based medicine (EBM) requirement, in so far as clinical practice protocols and treatment intervention would have evidence against which to base their choice of techniques (Sackett *et al*., 1997; Liberati *et al.,* 2009; Dagenais and Haldeman, 2012).

Since Gleberzon's (2001a) literature review, there has been increased investigation into this technique (See Table 5.1 for a summary of all publications in this regard). However, to this researcher's knowledge, there has been no systematic review determining the level of evidence to support the use of this technique in the clinical setting. As the Chiropractic profession grows and places more emphasis on validating its treatment modalities (Haldeman, 2005), systematic reviews like this will

assist chiropractors in making educated decisions about the use of chiropractic techniques such as FDCT, aiding evidence based practice (Dagenais and Haldeman, 2012).

Therefore, it is important to perform a systematic review of chiropractic techniques as findings could improve patient outcomes, quality of care and educational standards (Hemingway and Brereton, 2009). In addition, it may also contribute to the research agenda, by indicating areas where further research is required (Hemingway and Brereton, 2009). Furthermore, a systematic review may also assists practitioners by summarising vast amounts of information in a concise manner, allowing practitioners to keep up to date more easily (Mulrow, 1994; Oxman *et al.,* 1994; Green, 2005; Hemingway and Brereton, 2009).

Moreover, in the context of practice, a systematic review will provide the chiropractor with accurate and unbiased information based on current scientific evidence (Khorsan *et al*., 2009), clinical experience and patient preference (Murray *et al.,* 2007), thus allowing a sustained trend, where the majority of chiropractors practice evidence-based chiropractic (Haneline, 2007).

Therefore, this study aimed to critique the clinical outcomes of FDCT studies, by means of a systematic review design.

1.2 Aims

The aim of this study was to conduct a systematic review to determine the evidence to support the use of FDCT in clinical practice.

1.3 Objectives

Objective One

To determine the rigor of the various studies done on FDCT, by utilising the PEDro and Newcastle – Ottawa Quality Assessment Scale.

Objective Two

To determine in which conditions FDCT has been utilised as a treatment method.

Objective Three

To determine the level of evidence to support the use of FDCT in the various conditions.

Objective Four

To make recommendations with regards to future investigations utilising FDCT.

1.4 Rationale and benefits for the study

Sackett *et al.,* (1997) proposed that the trend in medicine should be to focus on EBM. The majority of chiropractors have followed this trend over recent years, leading to the development of evidence based chiropractic practice (Haneline, 2007; Dagenais and Haldeman, 2012). In this context, it is required that the chiropractor provide accurate and unbiased information, based on current scientific evidence (Khorsan *et al*., 2009), clinical experience and patient preference (Murray *et al.,* 2007) in order for the patient to make an informed decision with regard to their treatment options (Dada and McQuoid-Mason, 2011).

There are, however, many different chiropractic techniques (including FDCT) that have evolved since the inception of chiropractic, over 117 years ago (Keating, 1992; Chapman-Smith, 2000; Redwood and Cleveland, 2003). The myriad of techniques has made the chiropractor's role more difficult because of the various choices they have to make in choosing the most appropriate intervention. This is compounded by the findings of Gleberzon (2001a), who found that most of the published literature on chiropractic techniques were descriptive in nature rather than on verifying the treatment efficacy of the technique(s).

Many chiropractic educational institutions teach a selection of chiropractic techniques either as part of the core curriculum or as adjunct courses. Ndetan *et al*., (2009) reported that several techniques were used by students at universities in the USA. It is, therefore, important to critically review these techniques (including FDCT), as this information could aid South African academic officers in making rational decisions, regarding the inclusion of these techniques into an institutions' curriculum.

1.5 Limitations

Within the constraints of time and cost, a notable limitation in this methodology was that only English articles or articles that have been translated into English were used (Clarke, 2007; Higgins and Green, 2008). Thus, an unknown percentage of articles may not have been included in this systematic review (Clarke, 2007). To reduce the potential for bias in future systematic reviews it is suggested that translation be accounted for and utilised, in order to ensure the greatest potential for the inclusion of all articles within this particular context and thus into a future systematic review (Liberati *et al.*, 2009; Moher *et al.,* 2009).

There may also be a potential for publication bias in this systematic review. This limitation may therefore exclude some evidence in support of or not in support of FDCT. This limitation was however, viewed as a "desirable bias", meaning that it included only articles which had previously been peer-reviewed (thus demonstrating a higher level of evidence). Additionally, the exclusion of unpublished articles, excluded articles that presented studies with small sample sizes, case reports and other publications with a high potential for susceptibility to error and bias in their conclusions (Clarke, 2007; Higgins and Green, 2008; Liberati, 2009) and potentially unfavorable results (Liberati, 2009).

Lastly, this study was not intended to be a meta-analysis (Dagenais and Haldeman, 2012). This study was structured in order to collect, review and present available evidence in the context of FDCT evidence (Green, 2005), so that it only addressed methodological rigor of previously published articles. This contrasts with a meta-analysis, which refers to the use of statistical techniques in extracting and combining data to produce a summary of the statistics from which a conclusion is then drawn

(Sackett *et al*., 1996). Therefore, previous meta-analyses are useful for understanding an article's conceptual and statistical relationship when completing a systematic review. However, it must be noted that their actual process is not evaluated (Clarke, 2007).

1.6 Outline of Chapters

This chapter presents a summary of the literature, and indicates the area of study in this dissertation, while offering objectives, rationale, and aims behind the study.

Chapter Two will discuss a detailed literature review pertaining to this study, with Chapter Three defining the methodology and design of this research. Chapter Four presents the acquired results. A discussion of these results is presented in Chapter Five. Chapter Six offers conclusions and recommendations which draws this study to an end.

Chapter Two
Literature Review

2.1 Introduction

This chapter gives a brief insight into the history of chiropractic and focuses on the flexion distraction Chiropractic technique (FDCT). It further defines this technique in reference to this study, while discussing the clinical use of FDCT.

Any limitations of the available literature as well as information specific to conducting a systematic review such as publication types (literature review, literature synthesis, systematic reviews and meta-analyses) are included in the discussion in order to contextualise the methodology presented in Chapter Three.

2.2 Brief history of manipulation

Manual therapy, in particular the use of manipulation has been recorded as far back as the ancient Egyptians and the American Indian tribes (Gatterman, 1995). The oldest recorded document, the "*Corpus Hippocrateum*" written by Hippocrates outlines simple, but crude manipulative techniques utilising traction, specific contact points and the application of thrusts to particular joint segments. The use of manipulation in these early days centred around restoring normal motion to the locomotor system and to positively influence the function of the nervous system (Schiotz and Cyriax, 1975; Basmajian and Nyberg, 1993) and health to the body (Ligeros, 1937; Basmajian and Nyberg, 1993; Haldeman, 2005). This form of healing was based on the conservative ethic of medicine around the time of Hippocrates, which is best reflected in the statement "at least do more good than harm" (Basmajian and Nyberg, 1993) and was seen at that time to be on par with drug therapy and surgery (Haldeman, 2005).

This integrated method of medicine proposed by Hippocrates was the basis for the inclusion of manipulation into Islamic and other healing systems (Anderson, 1992;

Haldeman, 2005), whereas in the western world (principally Europe), a decline in the use of manipulation occurred due to:

- fear of physicians contracting contagious diseases (Anderson, 1983),
- fear of harming patients, particularly with the endemic proportion of tuberculous disease at that time (Tuscon, 1841; Lomax, 1975) and
- the possible association of manipulative practices with dogmatic or cultic beliefs that did not conform to the development of medicine (Keating, 1992).

These latter fears were, however, overridden by several physicians, such as Galen (Gatterman, 1990) to the bonesetters of Europe and Britain (Anderson, 1983; Gatterman, 1990; Basmajian and Nyberg, 1993; Haldeman, 2005), who continued to practice manipulation through family tradition, as well as outside the realm of that which was referred to as traditional medicine (Keating, 1992; Basmajian and Nyberg, 1993). These physicians were instrumental in maintaining the conservative ethic of medicine through a period in which their practices were frowned upon.

It was not until the works of Hippocrates, Gaucher and Schultetus were revived in the 1800's that patients started to demand increased accountability from the medical practices of their day, and therefore the conservative ethic of medicine started to receive attention (Keating, 1992; Haldeman, 2005). This renewed interest in manual and complementary alternative therapies (Wardwell, 1987; Wardwell, 1992) resulted in the development of several different forms of manual therapy that reflected the Hippocratic tradition (Keating, 1992).

These manipulative arts included a revival of bonesetting (Keating, 1992; Basmajian and Nyberg, 1993; Gatterman, 1995) and the beginnings of magnetic healing (Keating, 1992; Haldeman, 2005), osteopathy (World Health Organisation, 2010a), chiropractic (World Health Organisation, 2005), physical therapies and later such therapies as naprapathy (World Health Organisation, 2010b). This growth in the western world was in part, paralleled by similar developments in the Orient, with the growth of such disciplines as Tuina (World Health Organisation, 2010c) and Shiatsu and Nuad Thai (World Health Organisation, 2010d).

With this sudden growth and development of the various manual therapy disciplines responsible for the treatment and management of conditions that affect the human body (Dagenais and Haldeman, 2012); there became a need for a classification of the various intervention types and their effect on the musculoskeletal system (Bergmann, Peterson and Lawrence, 1993; Plaugher, 1993; Bergmann and Peterson, 2011). This classification (**Figure 2.1**) was further refined by classifying interventions as having a principle effect on soft tissues (viz. massage, stretching, point pressure and visceral manipulation) or joints (mobilisation, manipulation, traction, distraction, muscle energy techniques) (Maitland, 1986; Chaitow and Delany, 2000; Isaacs and Bookhouts, 2002; Hammer, 2007; Bergmann and Peterson, 2011).

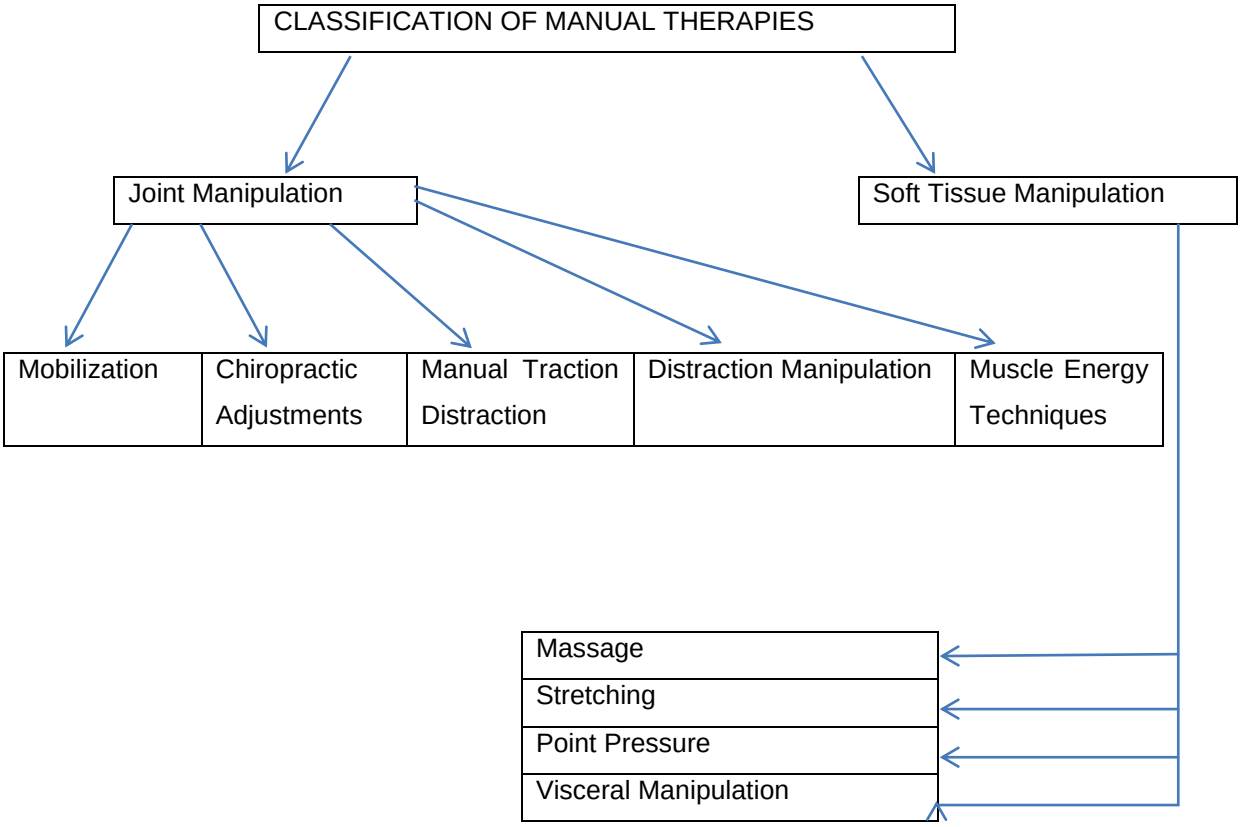

Figure 2.1 Classification of manual therapies (Bergmann and Peterson, 2011)

2.3 Joint manipulation

Joint manipulation is directed at a motion segment (Bergmann and Peterson, 2011) which, as depicted in **Figure 2.2**, constitutes two juxtaposed osseous structures between which there are one or more articulations and intervening soft tissues that lie between them.

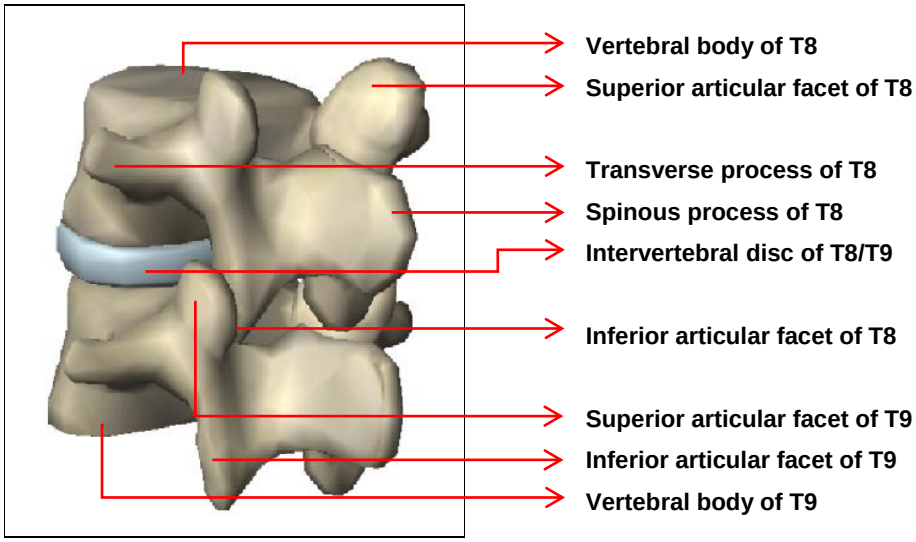

Figure 2.2 The anatomy of the posterior joint and capsule of two spinal segments (Adapted from Visible Body (2013))

Each motion segment has an active range of motion and a slightly larger passive range of motion as depicted in **Figure 2.3.** The passive range of motion is bound by the elastic barrier associated with the physiological limits of joint movement. When joint manipulative techniques are applied to spinal joints [technique dependent] it will result in movement in either the physiological (mobilisation) or the para-physiological space (manipulation) (Sandoz, 1976; Leach, 2004; Bergmann and Peterson, 2011).

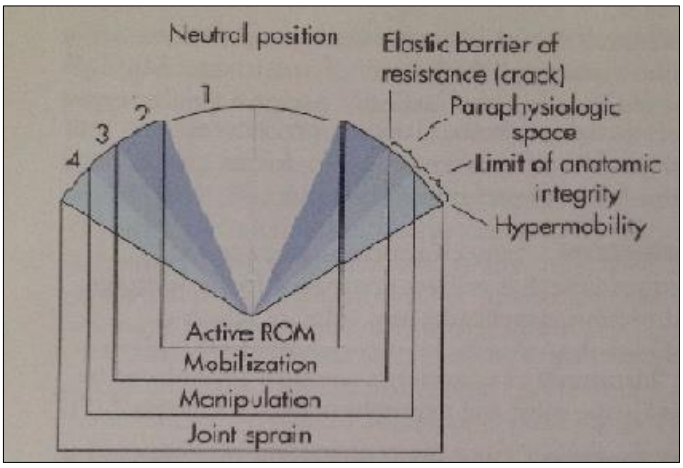

Figure 2.3 Range of motion of a joint (with permission, Gatterman, 2005)

Therefore, joint manipulation aims to restore or increase the range of movement in a motion segment (Schafer and Faye, 1990; Mrozek and Vernon, 2005), by means of joint manipulation techniques. These manipulative techniques are categorized by grading the amplitude and velocity of the therapy (Grades I – V) (Maitland, 1986; Bergmann, Peterson and Lawrence, 1993; Bergmann and Peterson, 2011). In this grading system, the Grades I - IV generally refer to mobilisation techniques with progressive increase in the velocity and a decrease in amplitude of thrusts that are applied within the normal physiological range of the joint. This results in Grade V being defined as a manipulation with the highest velocity and the lowest amplitude and usually applied such that the joint is taken past the elastic limit and into the para-physiological space. Thus, a Grade V classification is often associated with a gas bubble formation which results in an audible cavitation (Roston and Haines, 1947; Sandoz 1976; Meal and Scott, 1986). However, according to Mrozek and Vernon (2005), this cavitation may be associated with the breaking of adhesions, which may limit the motion of the patient's joint, therefore not allowing them to approximate the elastic barrier. In these instances, the high velocity low amplitude manipulation may be the only grade of manipulation that is able to break these adhesions and improve the range of motion over time (Mrozek and Vernon, 2005).

The applications of different grades of manipulation are usually associated with various forms of manual therapy: manipulation / adjustments (Grade V), joint mobilization (Grade I - IV), flexion distraction (Grade I - IV), manual traction /

distraction (Grade I - IV) and muscle energy techniques (Grade I - II) (Haldeman, 2005).

2.4 The chiropractic profession and joint manipulative techniques

Chiropractic (meaning "done by hand" from the Greek “kiros” and “praktikos”) (Chiropractic Association of South Africa, 2013; World Federation of Chiropractic, 2013), is a profession which is intimately associated with “spinal manipulation”, or as it is known in the chiropractic profession the “chiropractic adjustment” (Haldeman, 2005). The chiropractic profession’s underpinning philosophy was based on the belief that the nervous system controls the body (Keating, 1992; Plaugher, 1993; Leach, 2004). Thus, D.D.Palmer believed that by correcting the spinal joint by manual manipulative techniques, the nervous system would be affected which would facilitate in improving the neurological function, with the subsequent amelioration of dysfunction or disease (Leach, 2004; Bergmann and Peterson, 2011).

Palmer, a self-educated healer, studied spinal structure and manipulative techniques as a magnetic healer and through osteopathy (Keating, 1992). After having been exposed to these teachings and other varied teachings in health, philosophy, spirituality and physiology (Keating, 1992; Leach, 2004), he reportedly restored the hearing of a deaf man by applying a manipulative thrust to the fourth dorsal vertebra, resulting in restored motion and associated improvements in the patient’s hearing (Chapman-Smith, 2000; Redwood and Cleveland, 2003; World Federation of Chiropractic, 2013). As a result of this interaction, Palmer began to believe that most diseases resulted from abnormal nerve signals, caused by what was later termed a "vertebral subluxation" (a dysfunctional motion segment within the spine) (Chapman-Smith, 2000; Keating, 2003; Leach, 2004; World Federation of Chiropractic, 2013). The chiropractic vertebral subluxation has been theoretically explained as motion segment/s that show aberrant motion, alignment and / or physiological function (Gatterman, 1995; Leach, 2004), with the concomitant changes in the biochemistry of the region affecting muscles, nerves, ligaments / connective tissue and vessels. These changes are often associated with clinical symptomatology, which clinically defines a subluxation syndrome (which is not unlike a sprain of the joint with its attendant symptomatology) (Bergmann and Peterson, 2011). The subluxation

syndrome is, however, associated with spinal dysfunction and detected by palpation of the spine (Haldeman, 2005; Bergmann and Peterson, 2011), and is the target of chiropractic manipulative techniques.

2.4.1 Chiropractic joint manipulative techniques

Traditionally, the vertebral subluxation has been treated utilising short lever, high velocity, low amplitude thrust / manipulative techniques in order to restore the normal motion and alignment and thereby assisting with the restoration of normal physiology (Chapman-Smith, 2000; Leach, 2004; World Federation of Chiropractic, 2013). However, the chiropractic profession has developed many manipulative techniques (Keating, 1992; Cooperstein and Gleberzon, 2000), to aid the practitioner in delivering the most appropriate conservative care to his / her patients (Chapman-Smith, 2000; Cooperstein and Gleberzon, 2004).

The reasons for the development of these manipulative techniques include, but are not limited to: patient age and size, the presenting complaint and / or the presence of co-morbid pathologies (Davies, 2000; Gatterman, 2003). Furthermore, practitioners that have sustained an injury, may find it difficult to perform a HLVA, and would therefore require other techniques to treat the patient. Being able to offer a variety of treatment techniques is appealing to practitioners as it enables the practitioner to offer more to the patient thereby being able to gain a greater market share. In addition, the perceived level of clinical effectiveness of the manipulative techniques as well as patient preference also plays a role in the development of different manipulative techniques (Murray, 2007). Christensen and Kollasch (2005), Ndetan, *et al*., (2009) and Ailliet, Rubinstein and De Vet (2010) showed that Chiropractors use a variety of manipulative techniques such as, from most utilised to least utilised: Diversified technique, Activator technique, Thompson Derifield technique, Gonstead and FDCT to Adjustive instrument assisted techniques, whilst including other techniques such as: Sacro-occipital technique, Nimmo receptor-tonus technique, Applied kinesiology, or Cranial therapy, in the USA and Europe.

2.4.1.1 Flexion distraction chiropractic technique

While Hippocrates was described as one of the pioneers to apply the principles of traction and spinal manipulation, the implementation of specific traction and manipulation is a somewhat novel advance (Dagenais and Haldeman, 2012). The application of traction in a Chiropractic context can be drawn to a 1901 graduate of Palmer Chiropractic College, Solon Massey Langworthy, D.C. (Coleman, 2005). In 1908, Langworthy patented the “Ampilia Trill” traction table, which was duly able to perform cervical extension traction as well as lumbar extension traction (Troyanovich and Gibbons, 2003)

This technique was further developed by Cox (Cox, 1990; Bergmann and Peterson, 2011), and is described by Cooperstein and Gleberzon (2004) as a mechanically assisted chiropractic technique, whose aim is to restore normal physiological range of motion. More expansively, this manipulative technique, is a combination of osteopathic long axis distraction principles (as proposed by McManis) (Coleman, 2005) and the chiropractic high velocity low amplitude thrust manipulative technique (Cooperstein and Gleberzon, 2004). Flexion distraction although used by chiropractors is used by other manual therapists such as physiotherapists and osteopaths (Cooperstein and Gleberzon, 2000).

FDCT aims to (Cox, 1990; Hawkinson, Snyder and Sanders, 1992; Bergmann and Peterson, 2011; Dagenais and Haldeman, 2012):

- Increase the intervertebral disc height.
- Remove pressure on the intervertebral disc. This occurs through the separation of the vertebral bodies, as well as the production of a suction effect inside the disc.
- Centralise the nucleus of the intervertebral disc. This is thought to occur as a result of the centripetal forces that are exerted on the annulus fibrosis when muscles and the posterior longitudinal ligament are stretched along with increased posterior disc height.
- Restore normal range of motion to the facet joints.

- Decrease disc protrusion, increase intervertebral foramina widening and restore normal ligament flavum function to induce a subsequent reduction of stenosis.
- Improve posture through muscle activation.
- Increase nutrition into the disc due to “milking of the disc”.

The above may be based on the role of the nucleus pulposis in degenerative disc disease could ultimately represent the cornerstone of the degenerative cascade (Haefeli et al., 2006; Adams and Roughley, 2006; Zhao et al., 2007) while Kim *et al*., (2003) suggests that motility plays an important role in the development of cellular composition within the nucleus pulposis.

Thus, the effect of flexion distraction are achieved by utilising a specific adjusting table such as a Leander lumbar traction table (e.g. Zenith®-Cox®) or a traction table that is able to perform a similar function, such as the McManis or Chiro-Manis® table; where the patient is placed in the prone position (Cox, 1990; Troyanovich and Gibbons, 2003; Cambron *et al*., 2006; Gudavalli *et al*., 2006; Bergmann and Peterson, 2011). Additionally, mechanized mechanical decompression tables are also frequently used, as these are able to limit the intensity of distraction, the frequency of oscillations and the duration of each interval, depending on patient variables (i.e. size, weight, height) (Cox, 1996). In any application, the patient’s anterior superior iliac spines are usually placed such that they approach the thoracic section of the bed, so that once the ankle straps have been placed on the patient, the patient can be tractioned by moving the pelvis away (into a flexed and distracted position) from the lumbar spine, as illustrated in **Figure 2.4.**

Figure 2.4 The patient positioning and procedure for FDCT (Alliance Chiropractic Center, 2013)

Whilst the patient is placed into traction by the mechanical arm of the Leander traction, (Cox, 1996; Troyanovich and Gibbons, 2003; Cooperstein and Gleberzon, 2004), the practitioner uses their contact hand and applies pressure to the patient's spinous process. This structure is situated immediately above the disc of the aberrant motion segment and applies an inferior to superior and posterior to anterior pressure. The practitioner's caudad hand is usually placed on one of the patient's thighs to accentuate the traction or it is used to re-enforce the contact hand (Cox, 1990; Bergmann and Petersen, 2011).

Using the specialised treatment table, the practitioner pushes the table to induce gentle stretching and bending of the spine, in various directions, usually in a series of repetitive slow movements, while he / she adds gentle pressure to different parts of the spine (Cox, 1996; Bulbulian, 2002). The subsequent movements from the most extreme flexion and distracted position back to neutral with the process repeated, is referred to by Cox as "milking of the disc" (Cox, 1990; Cooperstein and Gleberzon, 2004) and is thought to be the fundamental reason why this manipulative technique affects disc syndromes or radicular pain syndromes in patients (Byfield, 2012). This is supported by Haldeman (2005), who suggested that the intradiscal pressure drops during the administering of traction and that it is especially evident in situations when patients present with intervertebral disc herniation (Haldeman, 2005).

Gatterman (1995) further explained that over time, Eckard, Markey and Cox, refined the flexion distraction manipulative techniques so that the effect was best achieved for both the intervertebral disc space and facet joints (**Figure 2.2**). However, a contradiction in the procedure occurs between Eckard (extension / distraction) and those of Markey and Cox (flexion / distraction) (Gatterman, 1995; Haldeman, 2005). It has been suggested that the differences in the application of the techniques may be responsible for the different outcomes reached for patients in the clinical context (Cooperstein and Gleberzon, 2004).

Based on the above literature on FDCT, various authors have suggested that the following conditions and anatomical variances may, or may not benefit from the clinical use of FDCT (Gatterman, 1995):

- Pain syndromes (radicular and low back syndromes). In terms of these conditions Dagenais and Haldeman (2012) indicate that there is contradictory evidence suggesting that traction (including FDCT) has significant evidence in support of its use in clinical practice. To this end, Kruse, Schliesser and DeBono, (2000) and Gudavalli *et al*., (2006) indicate that they achieved beneficial outcomes for participants. However, studies by Hawk, Long and Azad (1997) and Strunk and Hawk (2009) have shown limited or no benefit when this intervention was utilised in clinical practice.
- Degenerative disease (e.g. degenerative disc disease, lateral canal stenosis) (Haldeman, 2005; Colledge, Walker and Ralston, 2010; Bergmann and Peterson, 2011). Studies by Zylbergold and Piper (1985) and Manison (2011) suggest that the participants in their study – presenting with; foraminal stenosis, cervical disc disease and spondylosis, benefitted from the use of FDCT.
- Traumatic sequelae (e.g. spondylolisthesis, facetal hyperextension syndromes, retrolisthesis subluxation) (Haldeman, 2005; Bergmann and Peterson, 2011).
- Systemic disease (e.g. subluxation or related –listheses) (Haldeman, 2005; Bergmann and Peterson, 2011).

- Anatomical variances in segments making traditional manipulation difficult (e.g. transitional segments, facet tropism) (Haldeman, 2005; Colledge, Walker and Ralston, 2010; Bergmann and Peterson, 2011).

It must however be noted that the above discussion and its attendant recommendations were made primarily based on biomechanical (Gleberzon, 2001a; Leach, 2004; Bergman and Peterson, 2011; Byfield, 2012) and pathophysiological theories (Leach, 2004), the clinical experience of practitioners' (case studies) and a limited number of clinical trials (Cox, 2001; Gudavalli, *et al*., 2006; Hawk, 2007; Cox, 2009; Kruse and Cambron, 2011; Cox, 2012), thus indicating a deficit in evidence to conclusively supports or negates the use of FDCT.

This deficit poses a clinical conundrum as the Chiropractic profession has expanded over 117 years. In the USA, the profession has grown to more than 60,000 active chiropractic licenses (Christensen and Kollasch, 2005). In addition, Davis (2010) revealed that in the USA, adult chiropractic patients increased by 57% (7.7 million in 2000 to 12.1 million in 2003). This public acknowledgement within the USA mirrors the global changes that are occurring, which has led to international support for chiropractic care all over the world (Dagenais and Haldeman, 2012). The consequence of the above is that the FDCT, is utilised by between 54.8 and 57.2% of chiropractic practitioners, with approximately 27% of patients they treat receiving care through this manipulative modality in the USA alone (Christensen and Kollasch, 2005).

2.5 Evidence based medicine / practice

In the era of evidence based medicine/practice (EBM / P), a challenge occurs; due to an increased number of patients receiving care, and the limited research evidence to support the treatments of choice (Dagenais and Haldeman, 2012). In this context, Haldeman (2005) previously described a three pillar system that should underpin clinical practice. These considerations should include the clinical experience of practitioners, patient preference as well as scientific literature (evidence). While much clinical experience and anecdotal evidence has surfaced and been published over time (Cooperstein and Gleberzon, 2004; Dagenais and Haldeman, 2012),

controversy still exists due to the nature and significance of the literature available (Sackett *et al.,* 1996; Cambron *et al*., 2006; Dagenais and Haldeman, 2012). This significantly impacts on clinical practice as the move to evidence based care requires the following from practitioners (Waddell, 1992; Sackett *et al*, 1996; Andersson, 1999; Chapman-Smith, 2000; Manchikanti *et a*l., 2003; Redwood and Cleveland, 2003):

- Best clinical practice underpinning effective and affordable care,
- Best evidence availability to the patient underpinning patient safety,
- Informed consent from the patient and
- Patient centred care in a multi-disciplinary practice underpinning.

These principles indirectly and positively impact on patient improvement, patient satisfaction (Bergh and Theron, 1999), employee productivity, decreased health care costs (direct and indirect) to third party payers, employers and the economy at large (Dagenais *et al*., 2008; Martin *et al*., 2008).

Therefore, it is incumbent on all health care professionals to evaluate their practices to enable the appropriate application of evidence based principles within their health care practice. This would be particularly applicable to those practices which are commonly utilised (e.g. FDCT) but have limited evidence to support effective, efficient and appropriate use. This may be completed in a number of different ways, including, but not limited to clinical practice guidelines, systematic reviews, randomised controlled trials, non-randomised controlled trials, prospective / retrospective observational studies, case reports and / or expert opinions (Dagenais *et al*., 2008; Martin *et al*., 2008; Hemingway and Brereton*,* 2009; Dagenais and Haldeman, 2012). Each of these evidence sources contribute and play a role in evaluating a particular health care practice (**Figure 2.5**), typically the following relationships are outlined (Brink, 1996; Sackett *et al.,* 1996; Hemingway and Brereton*,* 2009; Dagenais and Haldeman, 2012):

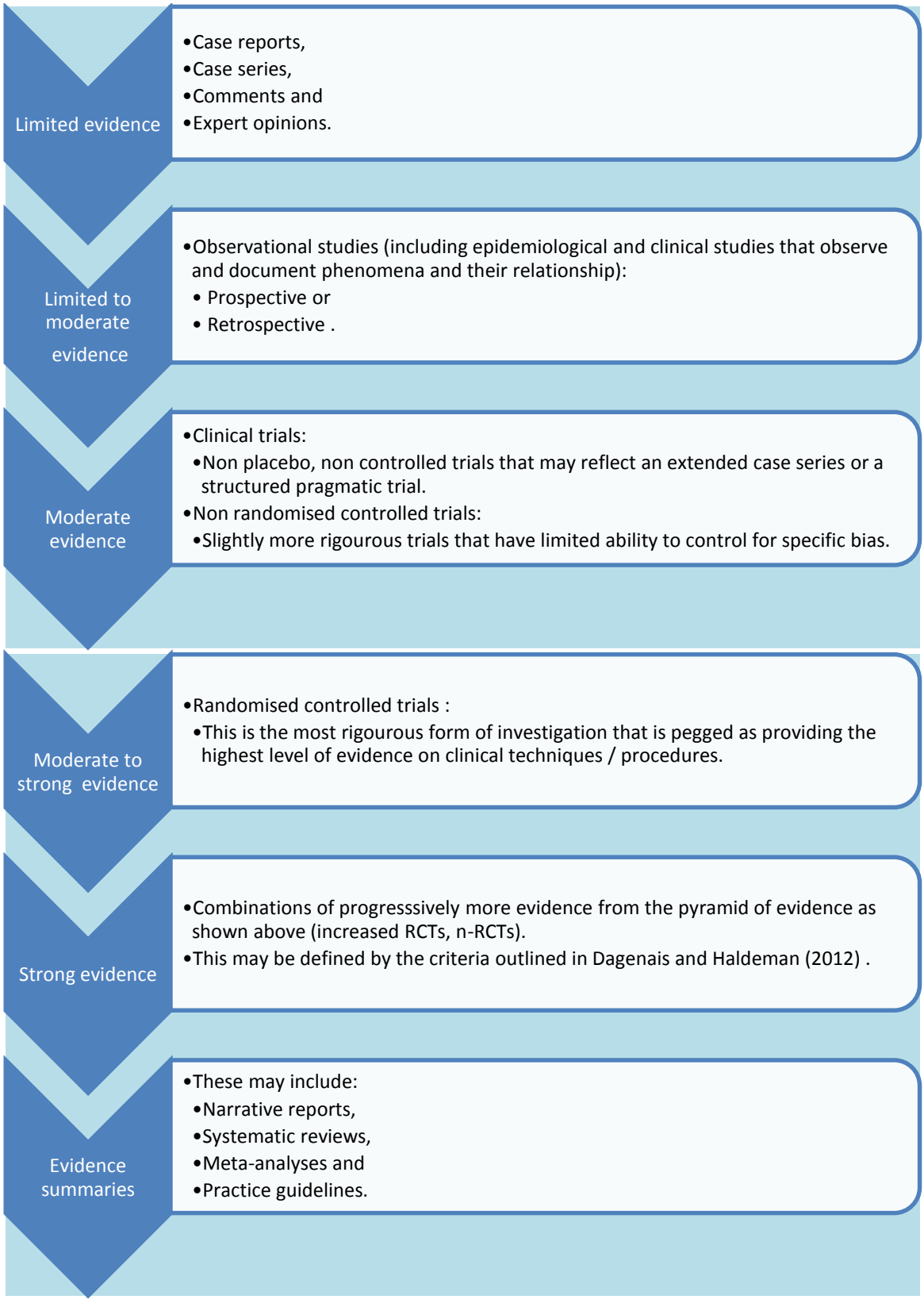

Figure 2.5 Evidence ranking

Gleberzon (2001a) identified only one article related to FDCT and it described the intra- and inter-examiner reliability of this procedure, rather than its effectiveness. Since then, several RCTs and n-RCTs have been published (Beyerman, *et al*., 2005; Cambron *et al*., 2006; Gudavalli, *et al*., 2006). Thus, an evaluation of what literature and the evidence that currently exists is required, to stimulate future research and to support the development of guidelines for clinical practice (Brink, 1996; Sackett *et al.,* 1996; Edzard, 2003; McHardy *et al*., 2008).

2.6 Systematic review

2.6.1 Introduction

While the importance of reviewing literature cannot be understated (Hemingway and Brereton*,* 2009), there are three types of reviews that exist; namely narrative, systematic and meta-analysis (Rhoades, 2011).

2.6.2 Review types

2.6.2.1 Narrative review:

This type of review offers practicality by critically summarizing the literature pertaining to specific topics. Although functional, they tend to be lacking in that they are often not peer-reviewed, and their results are often not reproducible and subject to personal bias and knowledge (Brink, 1996; Sackett *et al.,* 1996; Babbie and Mouton, 2001). Moreover, the ease at which these literature reviews can be prejudiced by authors for reasons of personal gain or beliefs, have often made this type of review rather controversial (Brink, 1996; Sackett *et al.,* 1996; Babbie and Mouton, 2001).

2.6.2.2 Systematic review:

As a result of the above, Hemingway and Brereton (2009), noted a trend favouring the replacement of narrative reviews by systematic reviews. This is possibly because systematic reviews principally review the extent and level of research evidence, as opposed to narrative reviews that resemble reports (Maher *et al.,* 2003). Moher *et al*.

(2009) defined a systematic review as an unambiguous technique to identify, select and critically analyse current and existing literature by means of clearly articulated questions.

Hemingway and Brereton (2009) acknowledged that for systematic reviews to offer unequivocal methodological quality (as opposed to a narrative review), an official scientific process would need to be adhered to. By providing a succinct summary of available evidence (Glazious *et al.*, 2004), systematic reviews can identify the methodological rigour of selected articles for the purpose of providing reproducible and consistent scientific findings against varying factors while reflecting on individual topics i.e. FDCT. In doing so, clinical practitioners are kept abreast of current literature (Mulrow, 1994; Oxman *et al.,* 1994; Green, 2005; Hemingway and Brereton, 2009), while offering a basis whereby practice guidelines can be developed (Moher *et al.,* 2009).

By using the evidence produced from reliable research, such as systematic reviews, best practice and regulation of health-care delivery can be offered (Green, 2005). This justifies systematic reviews as an important step in research, while promoting future studies of reinforced methodological quality, hence improved evidence-based outcomes (Mulrow, 1994).

2.6.2.3 Meta-analysis:

In statistics, a meta-analysis refers to methods focused on contrasting and combining results from different studies, in the hope of identifying patterns among study results, sources of disagreement among those results, or other interesting relationships that may come to light in the context of multiple studies (Rothman, Greenland and Lash, 2008). Meta-analyses are often, but not always, important components of a systematic review procedure (Liberati et al., 2009). For instance, a meta-analysis may be conducted on several clinical trials of a medical treatment, in an effort to obtain a better understanding of how well the treatment works (Liberati et al., 2009). Unlike systematic reviews, meta-analysis performs a statistical analysis which underpins the evaluation of the evidence, for or against whatever they are

investigating (Liberati et al., 2009). However, a systematic review has less need for similarity of outcomes data.

2.6.3 Conducting a systematic review:

A systematic review usually starts with a research question which is formulated from reading the literature around a particular topic (Lavis *et al*., 2005; Liberati *et al.,* 2009). Once this research question has been established, it forms the basis for aims and objectives of the study and frames the requirements for inclusion and / or exclusion of either particular study types or particular regions of studies and / or particular interventions (Cook *et al*., 1997; Lavis *et al*., 2005). These inclusion criteria are usually based on key words or key indexing terms, which are utilised for searching databases by means of search engines, such as: Summons, PubMed and Google (Creswall, 2009). It is important that the key indexing terms allow for maximal inclusion of the appropriate publications (Cook *et al*., 1997; Lavis *et al*., 2005). However, limitations in the combinations that the key indexing terms provide, as well as the limit on the number of key indexing terms may result in publications being inadvertently excluded. To this end, a factor that seems to have the most significant effect is that of language, as publications in different languages may be excluded by the typing in of one key word in English (Clarke, 2007; Higgins and Green, 2008). This needs to be carefully considered for each study and the domain in which the publications are to be found (Clarke, 2007; Higgins and Green, 2008).

The outcome of this process then leads the researcher to citations which are then screened for inclusion. Any ambiguity within the citations, usually result in the abstract and/or full article corresponding to that citation being sourced for screening with the inclusion criteria (Cook *et al*., 1997; Fox, 2005; Lavis *et al*., 2005). In addition to this process, searches through the reference lists and bibliographies of the publications found (secondary search), assists in identifying further publications that may not have been available electronically and thus excluded if only an electronic search was conducted (Vernon and Schneider, 2009). This secondary search assists in minimising publication bias and bias introduced by the manner in which the researcher finds and defines the publications utilised in the systematic review (Cook *et al*., 1997; Fox, 2005; Lavis *et al*., 2005).

Once all the publications have been found and screened for inclusion, the publications are then classified according to its study design (see Section 2.6.4 below). After this classification process has been completed, the publications are then reviewed by a number of appointed reviewers. The role of these reviewers are to rate the methodological quality of articles utilising standard grading scales, which are applicable to the particular classification of publications (e.g. using the PEDro scale for RCT classified studies). Then, in order to reduce the reviewer bias in systematic reviewers, the rankings from the various reviewers are collated and a consensus is reached (Ellis *et al*., 2007). This consensus may require further discussion between the reviewers once the data has been collated, particularly if there are significant differences between reviewer outcomes.

This reviewer based evaluation is then linked to the clinical outcomes obtained in each study. This allows for the methodological rigour to contextualise the clinical outcomes and to indicate the degree to which the clinical outcomes have been affected by the methodological flaws that have been identified. This, then allows for the reviewers to comment on the strength of the study's outcomes (refer to Figure 2.5) and collectively group studies within a particular domain (e.g. all studies that relate to a particular intervention in a particular region) and define the effectiveness of the intervention for that particular region or for that particular clinical condition.

2.6.4 Classification of publications, associated scales and its application

2.6.4.1. RCTs

The Centre for Reviews and Dissemination (Liberati et al., 2009) describes RCTs as group trials, whereby eligible participants are randomly assigned to two or more groups. They are treated according to designation, and comparisons between the groups are made regarding the outcomes of interest using the PEDro scale (PEDro, 1999). In an independent study, Maher *et al.,* (2011) reported that the PEDro scale is adequate for the screening and assessing of RCT's in terms of rigour and quality. With an overall Kappa score rating of 0.56 attained ("fair" to "good"), the PEDro Scale also managed an individual rating of "fair" to substantial". The PEDro Scale (1999) was utilised to review and assess randomised clinical trials.

2.6.4.2 Observational

- Cohort

Shaughnessy *et al*., (2005) describes an observational study as one in which a behaviour of the researched individuals are observed over time, without any influence from the researcher. The Liddle scale (Liddle *et al*., 1996) is used to evaluate observational studies of cohort design.

- Case / case series

By looking at small groups of individuals (case series) or a particular individual (case report), information can be gathered to present the evidence and thus make assumptions regarding the collected data. The focus of such research is usually a cause-effect relationship (Cassell and Symons, 2005). The Liddle scale (Liddle *et al*., 1996) is also used to evaluate case and case series.

2.6.4.3 Quasi experimental

- n-RCT

According to the Centre for Reviews and Dissemination (Liberati et al., 2009, and Moher et al., 2009), an n-RCT study is an experimental study in which participants are assigned to intervention groups using non-randomised methods. Deeks *et al.,* (2003) and Higgins and Green (2008) both recognised the ease of use and suitability of Newcastle-Ottawa Scale (NOS) for systematic reviews including n-RCT's. Recommendation was given for the inter-rater reliability as indicated by an interclass coefficient (ICC) of 0.94, as well as the continued refinement and review of the scale (Wells *et al.,* 2003; Hartling *et al.,* 2012). The NOS is used to review n-RCTs (Wells *et al*., 2003).

- Pre-post test experimental studies

Higgins and Green (2008) described pre-post studies as studies in which comparisons between outcomes of study participants, before and after treatment / interventions are made. Pre-post designs are evaluated using the NOS (Wells *et al*., 2003).

- Interrupted time series

These studies are designed to administer multiple interventions over a period of time that is “interrupted” generally by the treatment or the intervention that has been administered (Higgins and Green, 2008). Interrupted time series study designs are assessed using the NOS (Wells *et al*., 2003).

2.7 Choosing the most appropriate studies for a systematic review

The choice of publications for use in a systematic review varies and depends on the number of publications in that domain. As an example, the use of case studies, which are low on the research evidence scale (**Figure 2.5**), should only be considered when there are insufficient publications representing randomised clinical controlled trials or non-randomised clinical control trials (Liberati, 2009; Higgins and Green, 2008). Therefore, once the researcher has located all the relevant publications for the study a decision can be made on the types of studies to be included in the review.

In the context of this study, based on the citations, abstracts and publications available in the domain of FDCT, it was decided to utilise only those studies that represented the strongest forms of evidence in the form of RCTs and n-RCTs. This was decided upon in order to establish the rigour of the available evidence so to support or negate the use of FDCT in clinical practice.

Chapter Three
Research Methodology

3.1 Introduction

This chapter describes the methodology utilised in this study, and outlines the search for the literature. It also identifies the study selection, and defines the inclusion and exclusion criteria, as well as describes the data extraction method and evaluation, and the synthesis of the results.

3.2 Research design and approval

This study was designed as a systematic review without the completion of meta-analysis. A systematic review, as outlined in **Figure 3.1** and based on the PRISMA statement (Liberati *et al.,* 2009; Moher *et al.,* 2009), was approved by the Research and Higher Degree Committee (RHDC) of the Durban university of Technology (DUT) (**Appendix H**). Approval from the Institutional Research Ethics committee was not deemed necessary as the RHDC has been delegated the responsibility of level one studies i.e. those studies that do not involve human participants (**Appendix H**). Although this study required the assistance of reviewers they were not seen as research participants.

3.3 Characteristics of the articles to be included in the review:

Based on the aims and objectives of this study the following inclusion / exclusion criteria were developed:

3.3.1 Inclusion criteria

a) All citations had to be available in electronic format so they could be assessed.

b) All citations had to include the terms “Chiropractic” and “Flexion Distraction” as well as one or more of the following keywords:

   i) Technique

ii) Protocol

c) The articles had to include the following study design: Randomised controlled trials (RCTs) and non-randomised controlled trials (n-RCTs).

3.3.2 Exclusion criteria

a) Non-English articles,

b) Articles defined as a cohort study, case control / series, systematic review, a review of the literature or expert opinions (Creswall, 2009),

c) Book chapters were excluded from the review.

3.4 Preliminary search

3.4.1 Database search

A comprehensive search for articles relating to the topic of flexion distraction Chiropractic technique (FDCT) was performed (Creswall, 2009), using Summon. According to an interview on the 9th April 2013, Naidoo (DUT's subject librarian) indicated that Summon allowed for the navigating of multiple databases including:

- Ebscohost – (CINAHL Plus others, MEDLINE)
- Emerald
- Google scholar
- JSTOR
- Oxford English Dictionary
- Proquest
- SABINET
- SAePublications
- Science Direct
- SpringerLink
- Web of science

Summon does not search PubMed, therefore it was independently searched.

3.4.2 Search terms

The following key words were used to identify articles relevant to the research:

"Chiropractic" and "Flexion Distraction", and one or more of the following:

a) Technique

b) Protocol

The total number of articles identified is stated in **Table 3.1**.

Table 3.1 Number of articles yielded via database searches

Search Term:	Summon	PubMed
Chiropractic, flexion distraction, technique	259	10
Chiropractic, flexion distraction, protocol	148	4

Note: Database searches were limited to journal articles. Book chapters were not included, and duplicates were not removed.

The articles that met the inclusion criteria and which were represented in multiple databases were deemed duplicate articles. Therefore, a process of removing the duplicate articles was initiated, in addition to screening all articles, by means of the study selection criteria.

3.5 Study selection

3.5.1 Identification and screening of citations

Citation lists were generated from the above database search (**Table 3.1**) which was printed and further analysed by the researcher (**Appendix A**) so to identify articles which fell within the inclusion criteria. Full abstracts of the articles were obtained if the researcher was uncertain as to its suitability for inclusion into this review. Articles which were included could either have been in electronic or print form (**Table 3.2**).

Table 3.2 Number of articles for inclusion from each data source

Search Term:	Summon	PubMed
Chiropractic, flexion distraction, technique	10	3
Chiropractic, flexion distraction, protocol	9	2

Note: The number reflected includes duplicate articles that were found in each database.

All duplicate articles were removed whilst the articles were screened, resulting in the primary search representing 14 articles (**Table 3.3**).

3.5.2 Secondary search

The secondary search involved a reference and hand search. The reference search involved searching the references from the articles obtained from the primary search for additional citations. Whereas the hand search involved the researcher seeking all additional works by the authors identified in the primary search for additional citations relevant to the research (Vernon and Schneider, 2009). These were then considered for inclusion into this review. Through this secondary search method, the researcher identified four articles (**Table 3.3**).

Table 3.3 Total number of articles after the secondary search

Primary search	Secondary search	Total articles
14	4	18

Note: The number reflected excludes duplicate articles that were found in each database.

Thus, these articles were further sorted to produce a master list of articles (**Appendix B**), which included those articles that fell within the inclusion criteria, but excluded the duplicated articles. The articles reflected in the master list were then divided into study types (n-RCTs and RCTs) as per the inclusion criteria.

The remaining articles listed on the master list were then sourced in full text articles (if they had not already been sourced) to facilitate the designation of articles to individual reviewers. The abstracts listed on the master list were then sourced in full text articles, and resulted in the final screening of articles (**Table 3.4**).

Table 3.4 Total number of articles – Study type division

Study Types for Inclusion:	Total Number of Articles:
n-RCTs	4
RCTs	14
Total number of articles for inclusion	18

NOTE: All duplicate studies found within other databases have been excluded from the above representation.

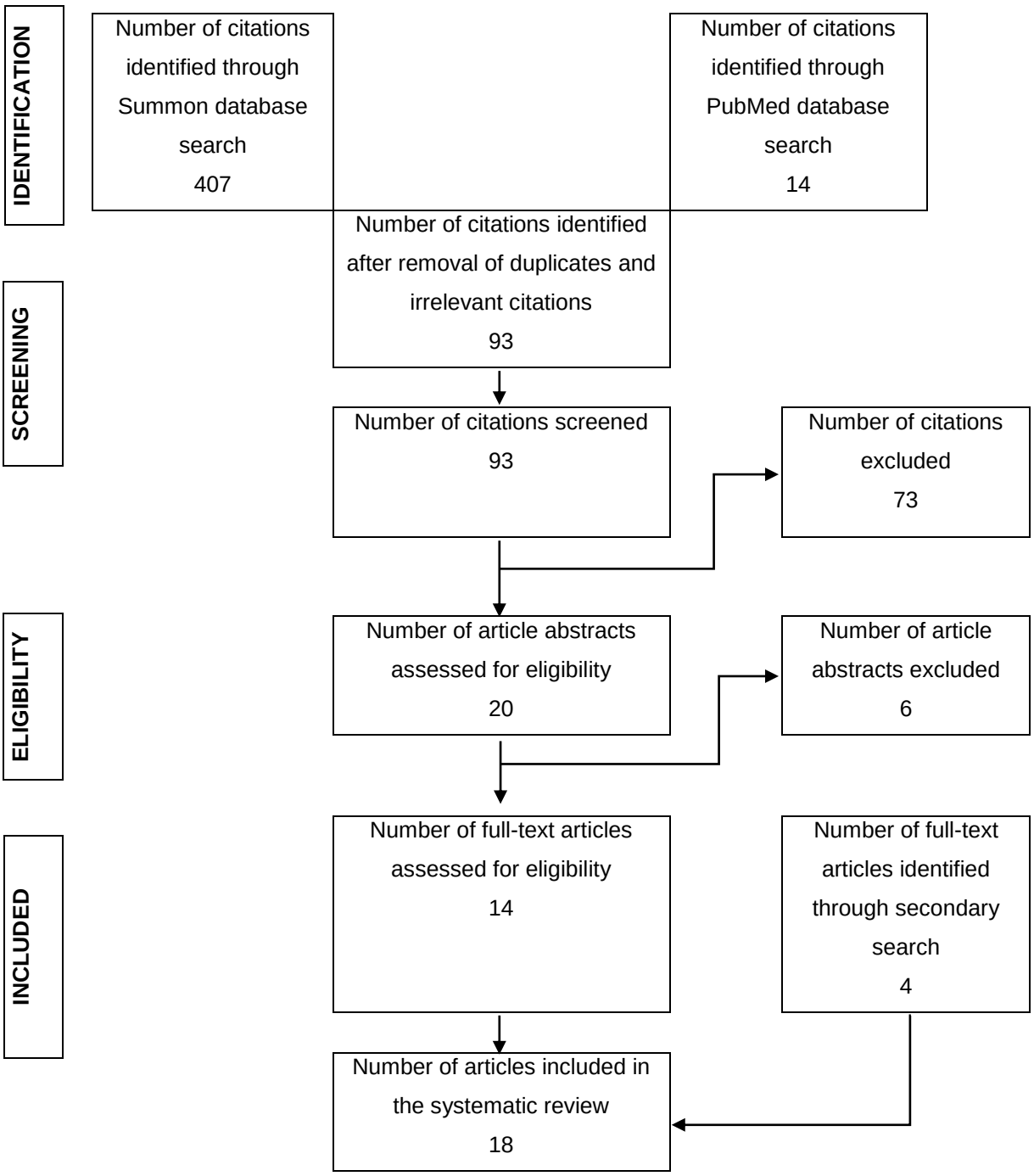

Figure 3.1 Flow Diagram illustrating search strategy based on the PRISMA statement

3.6 Quality assessment

3.6.1 Study types and measurement tools

Studies were allocated to study type divisions, for assessment purposes and according to:

a) n-RCTs – The Newcastle-Ottawa Scale (NOS) (**Appendix C**) was used to assess the n-RCTs in this study. A total of four n-RCTs were included in this study.

   The NOS contains 3 sub-sections: - selection, comparability and exposure. These sections contain 8 items/questions. Points are awarded for each item. Selection and exposure can each be awarded a maximum of one point per item, while comparability may be allotted a maximum of two points. A study may be allowed a maximum of nine points.

   By awarding a point for each fulfilled criterion, a mean score is calculated. This is achieved through calculating the end score for each of the three reviewers. The methodological rigour of the study is assessed by considering the mean score. Should a score of nine be attained, the highest level of methodological rigour can be assumed. Conversely, should a mean score of zero be achieved, an indication of the lowest level of methodological rigor can be assumed.

b) RCTs – The PEDro Scale was used in this study to assess RCT's (**Appendix D**).

   The PEDro Scale comprises of eleven specific criteria, with each criterion being used to establish the studies methodological strength. For each fulfilled criterion, one point may be awarded, with a maximum score of eleven and a minimum score of zero.

   By awarding a point for each fulfilled criterion, a mean score is calculated. This is achieved through calculating the end score for each of the three

reviewers. The methodological rigour of the study can be assessed by considering the mean score. Should a score of eleven be attained, the highest level of methodological rigour can be assumed. Conversely, should a mean score of zero be achieved, an indication of the lowest level of methodological rigor can be assumed.

3.6.2 Reviewers

Four external reviewers were asked to assist in the study, with the fifth reviewer being the researcher. For the purpose of confidentiality, the identities of the five reviewers will not be given. However, their qualifications are outlined below:

- Reviewer 1 (DC, MPH, PhD)
- Reviewer 2 (DC, PhD)
- Reviewer 3 (M.Tech: Chiropractic, CCFC)
- Reviewer 4 (BSc, MEd, HDE, M.Tech: Chiropractic, CCFC)
- Reviewer 5 (B.Tech: Chiropractic (researcher))

A Memorandum of Agreement (**Appendix E**) was signed by each reviewer. Reviewers were grouped in pairs and purposefully allocated to either Group 1 or Group 2 (**Table 3.5**). The researcher was assigned to both groups to ensure that three reviewers evaluated each study (Ellis *et al.,* 2007).

Table 3.5 Reviewer Groups

Group 1:	Group 2:
Reviewer 1 Reviewer 3 Reviewer 5	Reviewer 2 Reviewer 4 Reviewer 5

Allocation to a group ensured that each group contained one reviewer with a PhD qualification, and one reviewer had a background in education (**Table 3.6**). Reviewers were blinded in respect of who the other reviewers were, so to reduce any bias in the feedback of results.

Table 3.6 Reviewer – Individual characteristics

Reviewers:	PhD	Master's	Academic	Clinical	Research Experience	Group Allocation
Reviewer 1	X		X			1
Reviewer 2		X	X	X		2
Reviewer 3	X		X	X	X	1
Reviewer 4		X	X	X	X	2
Researcher						1,2

Table 3.7 Allocation of articles to the reviewing groups

	Group 1	**Group 2**
Study Type Allocation	1) n-RCTs 2) RCTs	1) n-RCTs 2) RCTs
Total number of articles allocated:	9	9

The allocation of articles was evenly distributed between the groups as illustrated in **Table 3.7**. Each group received two n-RCTs and seven RCTs. (**Appendix F** and **G)**. Copyright was obtained through the DUT copyright office to distribute the articles to the reviewers.

Each reviewer was provided with the appropriate scale and explanation sheet, for each article, which was then independently reviewed by each of the reviewers.

3.7 Data extraction

This occurred in three stages:

Stage one:
Reviewers were requested to submit the results of their individual reviews to the researcher to allow for the tabulation of the feedback data. Data tables were fashioned according to the criteria of the scales (viz. NOS and PEDro) to allow for the input of data from all three reviewers pertaining to each specific article. This allowed for the evaluation of similarity and discordance between individual reviewers feedback, as well as the opportunity to provide a total rank score. The total rank score was based on majority consensus, therefore it was considered unnecessary to perform statistical analysis for this study (Liberati *et al*., 2009; Moher *et al*., 2009).

Stage two:
The researcher extracted the following information from each of the articles (Harris, 2013):

- Form of measurement,
- Frequency of measurement,
- Duration of study,
- Number of participants,
- Assessors blinded,
- Control used and
- Randomisation of participants.

This was compiled in a table and each article was contextualised in terms of its clinical outcomes.

Stage three:
By assessing the ranking given by the reviewers and the strengths and weaknesses of each article as detailed in stage two, it allowed for the discussion of the clinical outcomes in the context of the methodological quality of the corresponding study.

3.8 Data synthesis

After the review process in Section 3.7 was performed, articles were then grouped into clinical categories (e.g. neck pain, low back pain, pelvic pain and physiological effects). Thereafter, FDCT for that particular category was discussed.

According to the levels of evidence as proposed by Foley *et al.,* (2003), the strength of evidence for the grouped articles can be ascertained. To this end, Foley *et al.,* (2003) and Dagenais and Haldeman, (2012) provide three levels of evidence. These three levels describe the degree or strength of evidence within a particular clinical category. Further to this, Foley *et al.*, (2003) indicated three successive categories which provide a mechanism to show whether the evidence presented, agrees or conflicts within the clinical category being discussed. Additionally, the third option allows for the researcher to indicate that no evidence is presented by the articles in the particular clinical category.

Furthermore, Chapter Five discusses the above results in order to assess the use of FDCT in terms of conditions (i.e. neck pain, physiological, low back pain and pelvic pain). Therefore, it provides a benchmark for practitioners to evaluate the use of FDCT in clinical practice.

Chapter Four

Results

4.1 Introduction

This chapter presents each individual study reviewed by the reviewers in a form of 'overall ranking' as well as 'percentage agreement between reviewers.' By looking at the following study characteristics: - form of measurement, frequency of measurement, duration of the study, number of participants, blinding of the assessors, the use of a control group and randomisation of participants (Harris, 2013); a ranking of the studies was obtained. Furthermore, limitations were identified by the authors of those specific studies, as well as by the reviewers of each article. These outcomes are discussed with considerations to the limitations of the study.

4.2. Data

4.2.1 Primary Data

Each article was assigned three reviewers, with the feedback data being represented in a table (e.g. Tabulated Feedback Data for Group 1 – n-RCTs – Article 1), as well as a majority ranking, representing the response that was reported as the ranking from the three reviewers. In order for a total score to be calculated, the scores in the ranking column were added. By analysing each criterion of the scale, a percentage agreement was established between reviewers. Should all three reviewers have agreed, a 100% percentage agreement was given.

By using the percentage agreement for each criterion, an overall percentage agreement was calculated for each study. The overall percentage agreement indicates the degree of consistency between reviewers, with a "good level" agreement being a percentage of 70% and above (Liberati *et al.,* 2009). This would show that identification and understanding of the articles' criteria, between reviewers were consistent.

4.2.2 Secondary Data

In order to facilitate a systematic analysis of every article considered for this study, information from multiple sources e.g. CONSORT, was required. Secondary data was acquired using multiple sources. Online articles were the primary source of information, including those articles accessed through the Durban University of Technology (DUT) library and its interlibrary loans (ILL) facility. Supplementary information was acquired through books and websites accessible at the DUT library.

4.3 Abbreviations

SM: Spinal manipulation
MCMC: Minimal Conservative Medical Care
LVVA-SM: Low velocity variable amplitude spinal manipulation
HVLA-SM: High velocity low amplitude spinal manipulation
>: Great than
<: Less than

4.4 Results

Two sections are presented in the results, each representing a study type. Each section provides an introduction, the reviewer agreements (which will be presented as a tabulated feedback per article) followed by an analysis of the article in terms of the properties of the study, its outcome and discussion and a conclusion. At the end of each section, a comparison of outcome and methodological strength of the studies per section will be presented.

4.4.1 Non-randomised Controlled Clinical Trials

4.4.1.1 Introduction

During the process of data capturing, each star on the Newcastle-Ottawa Scale (NOS) was represented with a “1” on the rating sheets, while a no star was recorded

as a “0”. A mean total score was aggregated by considering the total score of each reviewer. The percentage agreement considered each criterion and was calculated.

4.4.1.2 Examiner agreement and ranking of articles

The information stated in **Table 4.1** are the n-RCTs that are included in this study and a description of their table numbers which provides for reviewer feedback and analysis.

Table 4.1 List of table numbers for non-randomised controlled trial feedback and analysis

Tabulated feedback data:	Analysis of article:	Author(s):	Year:	Title:
Table 4.2	Table 4.3	Hawk *et al.*	1997	Chiropractic care for women with chronic pelvic pain: A prospective single-group intervention study.
Table 4.4	Table 4.5	Rowell and Polipnick	2008	A pilot mixed methods study of patient satisfaction with chiropractic care for back pain
Table 4.6	Table 4.7	Bulbulian *et al*.	2002	Spinal reflex excitability changes after lumbar spine passive flexion mobilization
Table 4.8	Table 4.9	Strunk and Hawk	2009	Effects of chiropractic care on dizziness, neck pain, and balance: a single-group, pre-experimental, feasibility study

Table 4.2 Tabulated Feedback Data for Group 1 – n-RCTs – Article 1

AUTHOR(S):	Hawk C, Long A and Azad A					
YEAR:	1997					
TITLE:	Chiropractic care for women with chronic pelvic pain: A prospective single-group intervention study.					
CRITERIA:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
Selection:	1. Is the case definition adequate?	1	0	0	0	66%
	2. Representativeness of the cases	1	0	0	0	66%
	3. Selection of controls	0	0	0	0	100%
	4. Definition of controls	0	0	0	0	100%
Comparability:	5. Comparability of cohorts on the basis of design or analysis	0	0	0	0	100%
Exposure:	6. Ascertainment of exposure	1	0	1	1	66%
	7. Same method of ascertainment for cases and controls	0	0	0	0	100%
	8. Non-response rate	0	0	0	0	100%
	TOTAL SCORE	**3**	**0**	**1**	**1**	
		OVERALL PERCENTAGE AGREEMENT:				**87.3**

Table 4.3 Properties of study, outcome and discussion – Group 1 – n-RCTs – Article 1

AUTHOR(S):	Hawk C, Long A and Azad A
YEAR:	1997
TITLE:	Chiropractic care for women with chronic pelvic pain: A prospective single-group intervention study.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
- Pain Disability Index (PDI) - Visual Analogue Scale (VAS) - RAND-36 Health Survey - Beck Depression Index (BDI).	Measurements were taken at week 0 and 6.	Six weeks.	19 completed of 21 included.	Not mentioned.	No control group.	Participants were not randomised into the flexion distraction Chiropractic technique (FDCT) and trigger point (TP) group.	1	87.3

LIMITATIONS:

According to the authors, the single-group, quasi-experimental design of this feasibility study did not:

- Fulfil the requirements of participant randomization.
- Allow the investigation of the effect of placebo or Hawthorne effects related to the treatment.

The latter of these two identified limitations may also have been influenced by the natural history of chronic pelvic pain (CPP), particularly when seen in the context of the length of the study (six weeks). The reasons given in the study for these limitations, was because of the lack of expected treatment effect sizes (as there were only case reports documenting treatment effects of chiropractic care in participants with CPP).

A further limitation of this particular study was the inclusion of only 19 participants with self-reported CPP. This self-reported chronic pelvic pain diagnosis is complicated by the fact that this condition is often a diagnosis by exclusion and has no definitive diagnostic criteria. This made it difficult for this study to achieve a sample that is both representatives of participants with chronic pelvic pain, but at the same time also homogenous (so as to allow a study of the intervention without undue influence from the variation in the CPP). These two limitations, therefore, do not allow either generalizability and / or the ability to conclusively state that a particular intervention has specific outcome

	possibilities for a specific subgroup of people who suffer from CPP. Another limitation of the study was the lack of follow-up beyond the six week mark, to determine whether the very strong treatment effects (potentially amplified as a result of the lack of a control or natural history group in this study) showed at the end of the study persisted. Further to the above, the lack of specific interventions in the treatment protocol and the use of multimodal combinations of a number of different techniques, could indicate that combination therapy may achieve particular clinical outcomes. However, this limits the ability of the study to ascribe the improvement in participants to one particular intervention.
OUTCOME:	Based on the study structure and notwithstanding its limitations, the following changes were noted for the participants from the baseline to the final readings : - PDI decreased significantly from 18.7 to 5.7, a mean difference of 13 (clinically significant). - VAS decreased significantly from 5.9 to 1.9, a mean difference of 4.0 (clinically significant). - The BDI of 9.0 decreased to 2.9 (clinically significant). - The mean scores of the West Haven-Yale Multidimensional Pain Inventory improved from baseline to week 6, with the greatest improvement seen in the pain severity (reflecting the PDI and the VAS) and interference with daily activities subscales. - RAND-36 profile was lower than that of the population norms, but at week 6 it was approximated the population norms.
DISCUSSION:	From the outcomes of the study it would seem evident that the multimodal therapy applied within the context of this feasibility study bore significant clinical outcomes for the participants. It would, however, be incorrect to assert that this response would be equally applicable to all people who suffer from CPP, due to the significant limitations noted above (particularly those related to the lack of a control / natural history group, the variance of low back pain stated by the group, the lack of randomisation into two equal groups with comparable interventions and the lack of controlling for the observer effect (the latter two noted specifically by the authors)). In the context of flexion distraction Chiropractic technique (FDCT), this study therefore provides limited / no-evidence in support of this intervention for participants that suffer with CPP and it is recommended future studies are structured to further investigate single and multimodal interventions for participants with CPP.

Conclusion:

This study, although preliminary in nature, found that multimodal chiropractic care (directed toward correcting the spine-related biomechanical dysfunction) has positive effects on symptoms of CPP (and potentially of attending complaints). However, the significant limitations of sample size, homogeneity, the lack of a control / natural history group and the inability to contextualise the results of this study based on these limitations, serve to significantly minimise the ability of this study to contribute to the literature in support of multimodal care for chronic pelvic pain.

This is further compounded when one considers the implications for FDCT and its application in the context of CPP in clinical practice. This outcome in the analysis of the above study is borne out by the results attained by the reviewers who ranked the study very low in terms of its compliance with the NOS requirements and its outcomes. It is significant to note that the reviewers showed a high percentage agreement, which indicates that the ranking of the study was attained with little disagreement between reviewers (agreement being highest for the description of the study parameters). Thus, limited / no evidence is presented by this study in favour of FDCT.
Therefore, the current documentation on the effects of chiropractic care (in particular FDCT) in chronic pelvic pain is limited and further studies could demonstrate a useful adjunct, potentially resulting in the inclusion of chiropractic into multidisciplinary approaches to CPP. This will, however, require further structured research in order to achieve this specific outcome.

Table 4.4 Tabulated Feedback Data for Group 1 – n-RCTs – Article 2

AUTHOR(S):	Rowell RM and Polipnick J					
YEAR:	2008					
TITLE:	A pilot mixed methods study of patient satisfaction with chiropractic care for back pain.					
CRITERIA:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
Selection:	1. Is the case definition adequate?	1	0	0	0	66%
	2. Representativeness of the cases	1	1	1	1	100%
	3. Selection of controls	0	0	0	0	100%
	4. Definition of controls	0	0	0	0	100%
Comparability:	5. Comparability of cohorts on the basis of design or analysis	0	0	0	0	100%
Exposure:	6. Ascertainment of exposure	1	0	1	1	66%
	7. Same method of ascertainment for cases and controls	0	0	0	0	100%
	8. Non-response rate	0	0	0	0	100%
	TOTAL SCORE	**3**	**1**	**2**	**2**	
		OVERALL PERCENTAGE AGREEMENT:				**91.5%**

Table 4.5 Properties of study, outcome and discussion – Group 1 – n-RCTs – Article 2

AUTHOR(S):	Rowell RM and Polipnick J
YEAR:	2008
TITLE:	A pilot mixed methods study of patient satisfaction with chiropractic care for back pain.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
- Roland Morris Back Pain Disability Questionnaire (RMQ) - VAS - Patient Satisfaction Scale (PSS)	Outcomes were assessed 1 working day after the last treatment of week 3 (week 3 outcomes) and again 3 to 5 days later at the beginning of week 4 (week 4 outcomes)	3 weeks	4 participants were enrolled but 2 dropped out soon after entering the study. Two additional participants were enrolled to replace the dropouts.	Not mentioned.	Not mentioned	Participants were not randomised into FDCT and diversified groups	2	91.5%

LIMITATIONS:	The sample size in this pilot study was small (n = 4), which does not allow for generalization to a larger population and limits the inferential statistics that could have been applied. The sample was further compromised by a 50% drop out rate. This dropout rate was, however, not attributed to the presenting condition, but rather variables beyond the scope of the study, which stand in favour of this pilot study. Another limitation of the study was the lack of training skills for the interviewers – this seemed more pertinent to the non-clinical staff that completed the first interview. The lack of training allows for questioning of the consistency with which the interviews were applied as well as the relative depth to which the interviews were driven. This inherent difference would have elicited differential results – as noted between the clinical and non-clinical staff. The wide age range of the participants – although potentially representative of patients with low back pain, may have resulted in

	differential improvement related to age (viz. healing time) and therefore a regression to the mean of the overall results. Therefore, it is a disadvantage for the study to have had such a wide age range in addition to such a small population size. Increased homogeneity may have allowed for better outcomes which are applicable to a more specific population. Although the treatments were performed within the window of natural history improvement, the study period approximated five weeks and therefore improvement attributable to the natural history of low back pain cannot effectively be excluded. The use of a natural history or a control group would have been important to exclude this consideration.
OUTCOME:	The outcomes of the study showed mild improvement at the very best, with no reported improvement to the point of a clinically important difference. Principle reasons for this include the regression to the mean and inability to show a difference from the natural history of low back pain.
DISCUSSION:	Although this study provided a basis for testing the feasibility of the study type and organisation, the outcomes of this study cannot be utilised to interpret the clinical outcomes attributable to the interventions for reasons noted in the limitations above. Therefore, this study provides no evidence in support of the intervention and thus does not contribute to the evidence in support of this intervention in clinical practice.

Conclusion:

In conclusion, it was found through the analysis of the publication (without the use of the appropriate rating scale) that the limitations outweigh the clinical outcomes and therefore limit the discussion on the effectiveness of the intervention in the treatment of low back pain. This implies that the study does not contribute to the development of the literature with regards to FDCT and does not assist clinicians in defining its usefulness. This outcome concurs with that of the reviewers, noted in **Table 4.4**, where it is noted that the most promising rating attained by this study was a 3 on the NOS and the lowest a 1. This indicates that the study did not fulfil the requirements of this scale to sufficiently allow for it to be a rigorous study and thus has a limited contribution to the body of literature with regards to FDCT. From this study the role of FDCT can therefore not be determined.

Table 4.6 Tabulated Feedback Data for Group 2 – n-RCTs – Article 1

AUTHOR(S):	Bulbulian R, Burke J and Dishman JD					
YEAR:	2002					
TITLE:	Spinal reflex excitability changes after lumbar spine passive flexion mobilization.					
CRITERIA:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
Selection:	1. Is the case definition adequate?	1	0	1	1	66%
	2. Representativeness of the cases	0	0	0	0	100%
	3. Selection of controls	0	0	0	0	100%
	4. Definition of controls	0	0	0	0	100%
Comparability:	5. Comparability of cohorts on the basis of design or analysis	0	0	0	0	100%
Exposure:	6. Ascertainment of exposure	1	0	0	0	66%
	7. Same method of ascertainment for cases and controls	0	0	0	0	100%
	8. Non-response rate	0	0	0	0	100%
	TOTAL SCORE	**2**	**0**	**1**	**1**	
		OVERALL PERCENTAGE AGREEMENT:				**91.5%**

Table 4.7 Properties of study, outcome and discussion – Group 2 – n-RCTs – Article 2

AUTHOR(S):	Bulbulian R, Burke J and Dishman JD
YEAR:	2002
TITLE:	Spinal reflex excitability changes after lumbar spine passive flexion mobilization.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
Maximally evoked muscle action potentials (M-waves) and maximal electrically stimulated reflex potentials (H-reflex) were recorded with bi-polar surface electromyographic techniques.	Once off in multiple positions	Pre – post one intervention	7 male 5 female (n=12)	Blinding of assessors was not mentioned.	No control group was used.	Participants were not randomised as there was only one group to assess of FDCT	1	91.5%

LIMITATIONS:	Firstly this study was not a clinical study as it required the participation of healthy persons to determine the physiological effect of an intervention (passive spinal flexion mobilisation or FDCT). As this study attempted to depict a physiological mechanism the participants became their own controls. This would negate the need for a control group. Secondly, this study structure would however not allow for the extrapolation of the data obtained in this study to be used in populations with different characteristics or those that are compromised by a physiological phenomenon due to a clinical condition. In addition, the sample size utilised in the study was small (12 participants) and therefore cannot be extrapolated to the general population. It is, however, acknowledged that the small and very homogenous sample (students from within a college setting) is better suited for a performance study which hopes to elicit the same response from similar people. Clinical studies can then take this physiological phenomenon into the clinical and pathological sphere with particular population groups. The acknowledged and noted limitations that the authors presented in the study were: - Participant positioning and size resulted in varied subject motion in the three tested planes. The full effect of this could not be

	discussed within the scope of the study and requires further study. - The data that was recorded was a static data recording of dynamic reflex activity and the use of multiple measures or more dynamic measures to more accurately document the reflex was suggested.
OUTCOME:	The study reported that in response to FDCT, there was an attenuation of spinal reflex response.
DISCUSSION:	Based on the outcomes of this study, there seems to be support for the attenuation of the spinal reflexes measured in the study with the use of FDCT. As a result of the limitations however, the conversion of this result into clinical practice remains limited as these reflex responses require further testing in pathological populations to determine whether the effect remains consistent and may be associated with improved clinical outcomes for patients with clinical signs and symptoms. Therefore, this study requires more than just the two case studies done by Cox and Aspergen, (1987) and Cox, Hazen and Mungovan, (1993) in order to validate its physiological outcomes and their clinical applicability.

Conclusion:

As a result of the above discussion, it is now possible to understand the reason why the reviewers rated this n-RCT very low on the NOS. This scale determines set criteria that allow for the outcomes of a study to be translated into the context of clinical practice. As a result of the limited ability to which this study addresses clinical practice, it is only natural that the rating obtained by the reviewers would be low. This low rating therefore suggests that although positive physiological outcomes were obtained in the use of FDCT in this study, it is necessary for this phenomenon to be tested in clinical practice and on patients that present with pathologies before a decision can be made in respect of the level of evidence that this physiological phenomenon of FDCT may contribute to the clinical improvement of patients with low back pain.

Table 4.8 Tabulated Feedback Data for Group 2 – n-RCTs – Article 2

AUTHOR(S):	Strunk RG and Hawk C					
YEAR:	2009					
TITLE:	Effects of chiropractic care on dizziness, neck pain, and balance: a single-group, pre-experimental, feasibility study.					
CRITERIA:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
Selection:	1. Is the case definition adequate?	1	0	1	1	66%
	2. Representativeness of the cases	1	1	1	1	100%
	3. Selection of controls	0	1	1	1	66%
	4. Definition of controls	0	1	1	1	66%
Comparability:	5. Comparability of cohorts on the basis of design or analysis	0	0	0	0	100%
Exposure:	6. Ascertainment of exposure	0	1	0	0	66%
	7. Same method of ascertainment for cases and controls	0	0	0	0	100%
	8. Non-response rate	0	0	0	0	100%
	TOTAL SCORE	**2**	**4**	**4**	**4**	
			OVERALL PERCENTAGE AGREEMENT:			**83%**

Table 4.9 Properties of study, outcome and discussion – Group 2 – n-RCTs – Article 2

AUTHOR(S):	Strunk RG and Hawk C
YEAR:	2009
TITLE:	Effects of chiropractic care on dizziness, neck pain, and balance: a single-group, pre-experimental, feasibility study.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
- Dizziness Handicap Inventory (DHI), - Short Form Berg Balance Scale (SF-BBS), - Neck Disability Index (NDI)	A baseline measurement was taken and after after the 8 week intervention period.	Thirteen months	19 completers of 21 included	Blinding of assessors was not mentioned.	No control group was used.	Participants were not randomised into groups consisting of: Spinal manipulative therapy (SMT): Diversified, Instrument assisted, Drop table SMT and flexion distraction (FD) Soft tissue: Myofascial release, Post isometric relaxation with heat and cold	4	83%

LIMITATIONS:	One of the biggest limitations of this study was its inability to associate improvement with any one intervention modality. This is as a result of the fact that this study was a pragmatic trial that incorporated several different intervention strategies that were aimed at a predominantly geriatric populace. To further compound this, the lack of a control group and the close approximation of the study period with the natural history of mechanical neck pain make it difficult for the study to differentiate the outcomes obtained from the effects of the natural history.

	A small study sample (n=21) as well as the inclusion of either / or mechanical neck pain and dizziness further compounds the homogeneity of the sample and thus the generalizability of the results. This second limitation (dizziness) may further be affected in terms of participant characteristics such a stress levels, medication use and co-morbid diseases, some of which were not recorded (but are more likely in the age of the population in this study). Further, it is unclear whether this information was utilised in the analysis of the outcomes (i.e. as confounding variables). In addition, a clinical criterion / criteria to test for cervicogenic dizziness does not exist. Therefore, making a diagnosis is not always conclusive, as it is based on the compilation of a history, the physical findings and the clinical experience of the practitioner. These limitations collectively and individually may have an affect on the clinical outcome measure of the study. With regards to the specific interventions utilised in the study, it is: - Unclear as to how the combination of therapies was determined or whether this was left at the discretion of the treating principle investigator and the consulting intern and determined by the participant's clinical context and the participant's preference. - Unclear whether the interns we consistently proficient (although minimum criteria of their inclusion were given) and whether this would have been different had a more qualified practitioner been responsible for the participants care. To the credit of the researchers, it was noted that the interns did undergo a training programme prior to the study. However, there was no feedback concerning the programme, nor was it tracked over time. - Also noted that some participants were treated by interns and others by the principle investigator / clinicians, it is unclear as to whether the subjective clinical experience differed between these two and whether this would have resulted in any measureable effect in terms of the outcome measures. Therefore, differing levels of proficiency between the doctors and the interns providing care may have prejudiced the outcomes. To the authors credit, the analysis of the drop out participants revealed that the participants that did not complete the study were similar in terms of their demographic characteristics and baseline outcome scores. Therefore, the assertion that these participants may have dropped out because of increasing clinical signs and symptoms are negated and the study sample could be identified as representing the clinical picture accurately.
OUTCOME:	In this feasibility study, most participants had a clinically significant improvement in balance (DHI but not the SF-BBS) regardless of whether dizziness was present or the known status of their neck pain. By contrast, the participants with neck pain, either with or without dizziness, showed no or very little improvement on the NDI. Additionally, twelve minor adverse reactions (headaches, dizziness, and neck and back

	soreness) to treatment were reported by 8 of the participants, with 3 of these reactions lasting longer than 24 hours. I cant link 12 to your bracketed information, This outcome seems to suggest that balance is independent of the dizziness reported by the participants and has limited association with the presence or absence of neck pain.
DISCUSSION:	The purpose of this study was a feasibility study to collect preliminary information on the effects of chiropractic care on cervicogenic dizziness, balance, and mechanical neck pain. As a result, it is apparent that the study outcomes had an effect on the inherent testing structures within this feasibility study. As a result of these limitations, the study was unable to draw conclusions about the differential response to treatment among participants and was only able to extrapolate the outcomes of participants of a similar description (within the constraints of a lack of a control group). Although the results suggested possible promising outcomes, the authors need to be given credit for noting the small sample and the lack of a comparison group, which were significant negative determinants in the generalizability of this study. In addition, the lack of a comparison group decreased the possibility of contextualising the transient adverse reactions during the treatment period. Although the frequency of the recorded adverse reactions were similar among patients treated by interns or clinician-treated patients, it would have been more beneficial to be able to compare to a similar group within the same study period to exclude extraneous factors that may have had an affect on the current study.

Conclusion:

When compared to the other non-RCT studies in this systematic review, it is evident that the structure of this feasibility study was significantly more stringent. This was because it allowed for a greater number of participants and delineated protocol and procedure more explicitly than the study outlined in **Table 4.7.** Notwithstanding this however, the study had some significant flaws in participant selection (homogeneity), lack of a control group and lack of clarity around the exact treatment procedures employed (other than to state that the treatment was multimodal). These flaws highlighted in the previous sentence, are also the areas that the reviewers found to be lacking in their consensus. This lack of consensus indicates that the manner in which the study was written could be interpreted in different ways,

thus leading to ambiguity and therefore an overall reduction in the strength of the ranking ascribed by the reviewers. This outcome suggests that although the use of FDCT within the context of a multimodal intervention series may be of benefit, ascribing the improvements seen to FDCT would be inappropriate. Therefore, the level of evidence that this study brings to the clinical application of FDCT for mechanical neck pain and / or dizziness and balance is at best limited. This outcome suggests that further studies should be performed to elucidate the possibility that FDCT may have a greater role to play in these conditions.

4.4.1.2 Discussion

Table 4.10 Comparison of Outcome and Methodological Strength of n-RCTs

Study Type:	**Non-randomised Clinical Trials**			
Author(s)	**Year:**	**Title:**	**Ranking:**	**Outcome as determined by reviewers:**
Hawk *et al.*	1997	Chiropractic care for women with chronic pelvic pain: a prospective single-group intervention study.	1	Limited
Rowell and Polipnick	2008	A pilot mixed methods study of patient satisfaction with chiropractic care for back pain.	2	Limited
Bulbulian *et al*.	2002	Spinal reflex excitability changes after lumbar spine passive flexion mobilization.	1	Limited
Strunk and Hawk	2009	Effects of chiropractic care on dizziness, neck pain, and balance: a single-group, pre-experimental, feasibility study.	4	Limited

4.4.2 Randomised controlled trials

4.4.2.1. Introduction

The PEDro Scale (PEDro, 1999) was employed for the review of all Randomised controlled trials (RCTs). The scale comprised of 11 criteria and therefore a maximum rating of 11 could be achieved.

4.4.2.2 Examiner agreement and ranking of articles

All the RCTs in **Table 4.11** are included in this study. Similarly, the table number to which feedback is given in respect of these studies is also stated under Tabulated feedback data.

Table 4.11 List of table numbers for randomised controlled trial feedback and analysis

Tabulated feedback data:	Analysis of article:	Author(s):	Year:	Title:
Table 4.12	Table 4.13	Hawk *et al.*	2007	Feasibility study of short-term effects of chiropractic manipulation on older adults with impaired balance.
Table 4.14	Table 4.15	Hawk and Long	2000	Use of a pilot to refine the design of a study to develop a manual placebo treatment.
Table 4.16	Table 4.17	Hawk *et al.*	1999	Preliminary study of the effects of a placebo chiropractic treatment with sham adjustments.
Table 4.18	Table 4.19	Hondras *et al*.	2009	A randomized controlled trial comparing 2 types of spinal manipulation and minimal conservative medical care for adults 55 years and older with subacute or chronic low back pain.
Table 4.20	Table 4.21	Schulz *et al.*	2011	Chiropractic and self-care for back-related leg pain: design of a randomized clinical trial
Table 4.22	Table 4.23	Wilder *et al.*	2011	Effect of spinal manipulation on sensorimotor function in back pain patients: study protocol for a randomised controlled trial
Table 4.24	Table 4.25	Zylbergold and Piper	2002	Cervical spine disorders: a comparison of three types of traction.

Table 4.11 List of table numbers for randomised controlled trial feedback and analysis continued…				
Tabulated feedback data:	**Analysis of article:**	**Author(s):**	**Year:**	**Title:**
Table 4.26	Table 4.27	Beyerman *et al*.	2005	Efficacy of treating low back pain and dysfunction secondary to osteoarthritis: chiropractic care compared with moist heat alone.
Table 4.28	Table 4.29	Bronfort *et al.*	2004	Spinal manipulation, epidural injections, and self-care for sciatica: A pilot study for a randomized clinical trial.
Table 4.30	Table 4.31	Gudavalli *et al.*	2006	A randomized clinical trial and subgroup analysis to compare flexion-distraction with active exercise for chronic low back pain.
Table 4.32	Table 4.33	Cambron *et al.*	2006	Amount of health care and self-care following a randomized clinical trial comparing flexion-distraction with exercise program for chronic low back pain.
Table 4.34	Table 4.35	Cambron *et al.*	2006	One-year follow-up of a randomized clinical trial comparing flexion-distraction with an exercise program for chronic low-back pain.
Table 4.36	Table 4.37	Hawk *et al.*	2002	Issues in planning a placebo-controlled trial of manual methods: results of a pilot study.
Table 4.38	Table 4.39	Hawk *et al.*	2005	A randomized trial investigating a chiropractic manual placebo: a novel design using standardized forces in the delivery of active and control treatments.

Table 4.12 Tabulated Feedback Data for Group 1 – RCT- Article 1

AUTHOR(S):	Hawk *et al.*					
YEAR:	2007					
TITLE:	Feasibility study of short-term effects of chiropractic manipulation on older adults with impaired balance.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	Y	Y	Y	100%
3	Allocation was concealed	Y	N	N	N	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	Y	Y	Y	Y	100%
5	There was blinding of all subjects	N	N	N	N	100%
6	There was blinding of all therapists who administered the therapy	N	N	N	N	100%
7	There was blinding of all assessors who measured at least one key outcome	Y	N	N	N	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	N	N	N	N	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 analysed by “intention to treat”	Y	N	Y	Y	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	N	N	N	N	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Y	N	N	N	66%
	TOTAL SCORE	**7**	**3**	**4**	**4**	
		OVERALL PERCENTAGE AGREEMENT:				**87.6%**

Table 4.13 Properties of study, outcome and discussion – Group 1 – RCT – Article 1

AUTHOR(S):	Hawk *et al.*
YEAR:	2007
TITLE:	Feasibility study of short-term effects of chiropractic manipulation on older adults with impaired balance.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
Berg Balance Scale (BBS), One leg stalk standing (OLSS), PDI, DHI, fall calendar.	Baseline, visit eight, visit 16.	Eight weeks.	11 initially started project, but eight remained to the end.	No.	A control group (exercise group with three participants).	Yes – however, there was stratification to ensure baseline comparability (by age and BBS score). Groups consisted of: - Chiropractic care: Diversified and modified (lower force) adjustive procedures, myofascial release, hot / cold therapy. - Supervised exercise: balance exercises.	4	87.6%

LIMITATIONS:	The authors of the study noted that inferences to the outcomes of the study could not be made with regards to treatment effect, due to the small sample size (n=11 at entry and n=8 at terminal readings). This small sample size was attributed to the limitation of time for assessments and participant reported transport issues which resulted in eligible participants declining participation. Further inferences with regards to the outcomes of this study may also only be limited only to Caucasian participants reflecting the same demographics as those included in the study.

	Further, although a reduction in bias with regard two baseline readings was achieved with a minimization algorithm, bias was not excluded with regards to the blinding of participants and / or assessors. In addition, the effects of medication did not seem to have been controlled for, as there were difficulties with deciphering the participants written records (11 participants' records being "indecipherable"). An explicit explanation of medications would have allowed for a greater understanding and analysis of the effect of medication on participant reported dizziness. An additional limitation with regards to the assessors was, as noted in the publication, that of different assessors, assessing participants at different time points. Even though training was provided to the assessors, the gold standard would have been to have one blinded assessor for all participants, at all the time points, to ensure that assessor bias did not influence the outcomes. In terms of the subjective findings, only one participant completed and returned their "fall calendars", so no data on falls frequency during the study was available. To overcome the lack of calendar submission and provide for fall information, clinicians asked participants about falls at each visit. This data however, contradicted data collected at the exit interview. As an example, one of the participants who had reported a fall to the clinician did not report it at the exit interview, which took place at the end of the 8-week study period. Additionally, a participant who reported four falls to the clinician during the study, reported seven falls at the exit interview, over the same period. This latter intervention, although supportive of the "fall calendars" relied on participant memory, which with time is subject to memory decay (Mouton, 1996; Mouton, 2001). As this memory decay is also more prevalent in older patients. Therefore, the reliability of the data recorded in this study is questioned. Furthermore, the combination of therapies within this study, with a delineated and specific protocol makes this study a pragmatic trial which has limited ability to define the contribution of any one intervention strategy.
OUTCOME:	At baseline, 83% of the participants in the chiropractic treatment group and 75% in the exercise group had a BBS score of >45. By visit sixteen, 33% in the chiropractic treatment group and 33% in the exercise group had BBS scores <45. This shows that the BBS in this context was responsive and shows variability reflecting clinical reality. By contrast, the OLST scores did not show a consistent trend, with both groups appearing to change only slightly from baseline to visit sixteen. This shows that the OLST in this context was not responsive to

	the clinical reality of the participants. In terms of the PDI scores, only those participants that reported a high PDI at the outset, showed substantial improvements at visit sixteen. Similarly, the DHI scores also varied a great deal; however by contrast to the PDI, even the participants that reported considerable impairment due to dizziness, showed no clinically meaningful change between baseline to visit sixteen. This lack of clinically meaningful change may be due to the use of medication to control dizziness in at least two of the participants. According to the authors, it was suggested that to draw and extrapolate firm conclusions from this small study was not possible (Hawk *et al*., 2007); since no consistent pattern was observed with respect to clinical improvements (no inferential statistics were utilised). The authors suggest the need to collect more in-depth data on participant experience and the interrelationship between balance, dizziness, and chronic pain in the context of fall frequency and its amelioration. This assertion is consistent with the outcome of this feasibility study; however, it does also speak to outcomes that may be attainable through a larger sample size.
DISCUSSION:	When comparing the structure and size of the study presented in this publication, it becomes apparent that the strength of the statistics and analysis reflecting the outcomes becomes limited and is weak. This is further compounded by the limited ability to be able to extrapolate the findings to a wider audience (because of the limited group of participants that the study sample reflects). This is additionally hampered by the significant limitations noted in the above limitations section. Therefore, from the perceived lack of rigour, it is not possible to conclusively determine from this study whether there is a clinical effect with regards to the chiropractic intervention and / or the exercise intervention for the treatment of balance, dizziness, and chronic pain in the context of fall frequency and its amelioration. Thus, the level of evidence that this study provides is limited at best and at worst inconclusive. Therefore, when one considers that only the BBS improved significantly in both groups, there seems to be a suggestion that the two interventions employed in this study are only and equally effective for this outcome measure in the participants studied. However, the applicability of this outcome and those of the other measures are limited in interpretation based on the limitations discussed above.

Conclusion:

When comparing the outcomes of the review in **Table 4.12**, it can be seen that the majority rating was given as a 4 by the reviewers. This ranking is indicative of the fact that this study has significant methodological flaws and therefore has limited ability to contribute to evidence for or against FDCT. This assertion presented here is supported by the limitations of the study presented in **Table 4.13**, which indicates that the following had a negative impact on the study:

- Small sample size.
- Limited generalizability.
- Limited sample homogeneity.
- Baseline reading inconsistency between groups.
- Limited control of confounding variables e.g. medication.
- Multiple practitioners providing varied interventions.
- Inconsistent and contradictory feedback, particularly the subjective outcomes.

Table 4.14 Tabulated Feedback Data for Group 1 – RCT - Article 2

AUTHOR(S):	Hawk C and Long CR					
YEAR:	2000					
TITLE:	Use of a pilot to refine the design of a study to develop a manual placebo treatment.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	Y	Y	Y	100%
3	Allocation was concealed	Y	Y	Y	Y	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	Y	N	N	N	66%
5	There was blinding of all subjects	Y	N	Y	Y	66%
6	There was blinding of all therapists who administered the therapy	N	N	Y	N	66%
7	There was blinding of all assessors who measured at least one key outcome	N	Y	Y	Y	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Y	Y	Y	Y	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 analysed by “intention to treat”	Y	N	Y	Y	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	N	N	Y	N	66%
11	The study provides both point measures and measures of variability for at least one key outcome	Y	Y	Y	Y	100%
	TOTAL SCORE	**7**	**6**	**8**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**78.4%**

Table 4.15 Properties of study, outcome and discussion – Group 1 – RCT – Article 2

AUTHOR(S):	Hawk C and Long CR
YEAR:	2000
TITLE:	Use of a pilot to refine the design of a study to develop a manual placebo treatment.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
PDI RMQ SF-36 BDI VAS	At baseline, after the pre-treatment week. Some additional information was gathered at week three. At the last offices visit of week six. Conclusion of the study.	seven weeks	32 initially started the project but 29 remained to the end.	Yes	Yes	Randomisation of participants into groups consisting of: - FDCT and TP - Sham and effleurage - FDCT and effleurage - Sham and TP	8	78.4%

LIMITATIONS:	The authors noted limitations with respect to sample size (n=32, with only 29 completing the study). As a result, this study did not have adequate statistical power to allow for statistical inferences to hold significant weight. In addition, the groups within this study were not similar at baseline for the most prognostic indicators. This may have been as a result of the consecutive sampling of participants into the study before their randomisation into the groups even though there was concealed allocation. Notwithstanding the reason for the differences, the implications for the outcomes of the study imply that the groups may not be comparable and that the outcomes may be differentially affected. Therefore, the likelihood of achieving significant differences was less possible.

	In addition to the above, the age ranges of the participants (29-84 years) resulted in a lack of homogeneity of the study sample, within and between the groups. This lack of homogeneity stems, not only from the possible causes of low back pain, but also the age related changes and the age related ability to heal from injury and respond to care. Further to the above, one objective of the study was to develop a placebo. The development of a placebo intervention, is based and reliant on the differences observed between the placebo and active care groups, which would be compromised by the above limitations as well as the fact that the researchers noted the majority of participants had previous exposure to chiropractic care (28/32). This large number of participants who previously received chiropractic care would have made the placebo less easy to conceal. Additionally, the use of the pre-treatment week and the six week treatment period did not preclude the effect of the natural history of low back pain, and therefore, this factor confounds the outcomes. In terms of the interventions, the use of the dual interventions (combinations of more than one intervention), decreases the ability of this study to determine the effect of any one treatment and therefore it is uncertain to what extent the placebo intervention actually did / did not have an effect. This assertion is equally applicable to the active intervention. To counteract the effects of the above however, the study did provide for concealed allocation and blinding of the participants, practitioners and assessors.
OUTCOME:	The RMQ median score changes were similar across groups (with no significant difference or clinically significant difference between the groups). The median change from baseline to week 3 in the PDI was greatest in Group A (FDCT and trigger point therapy), less in Groups C and D, and least in Group B (sham adjustment and effleurage). At week 6, Group A had less change than was shown at week 3, Groups C and D had similar changes to those at week 3 and group B showed the least change. The PDI scores at week 3, show a decrease in PDI scores (indicating improvement in pain-related disability) which was shown by most participants in Group A (5 of 8), B (7 of 8), and C (6 of 7), while participants in Group B (full placebo) showed some increase in the score (5 of 7). Again, this was not clinically or statistically significant.
DISCUSSION:	Although the study enabled the comparison of manual therapy versus placebo, it has significant limitations in being able to discern the effects of the interventions from each other. Therefore, it is uncertain whether the drawn comparisons are truly reflective of the possible clinical outcomes when this trial is compared to a significantly larger sample size.

Conclusion:

This study, as it was presented had significant rigour when assessed through the PEDro scale – as indicated by the outcomes of the reviews noted in **Table 4.14**. These factors included the randomisation, the blinding of assessing personnel and participants as well as the structure and repeated measures design that allowed for the majority of participants to complete the research process. However, there are significant limitations with the combination of the dual interventions and the difficulty in determining the effect of any one intervention (against the skewed baseline). In addition, the inability to be able to account for natural history detracts from the study. As a result, the ability of the study to contribute to the evidence in favour of or not in favour of FDCT is at best limited. Therefore, it is suggested that the contribution of this publication is equivalent to no evidence.

Table 4.16 Tabulated Feedback Data for Group 1 – RCT - Article 3

AUTHOR(S):	Hawk *et al.*					
YEAR:	1999					
TITLE:	Preliminary study of the effects of a placebo chiropractic treatment with sham adjustments.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	Y	Y	Y	100%
3	Allocation was concealed	Y	Y	Y	Y	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	Y	N	N	N	66%
5	There was blinding of all subjects	N	N	N	N	100%
6	There was blinding of all therapists who administered the therapy	N	N	N	N	100%
7	There was blinding of all assessors who measured at least one key outcome	N	N	N	N	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Y	Y	Y	Y	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 analysed by “intention to treat”	Y	Y	Y	Y	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	N	N	N	Y	66%
11	The study provides both point measures and measures of variability for at least one key outcome	Y	N	N	N	66%
	TOTAL SCORE	**7**	**5**	**5**	**6**	
		OVERALL PERCENTAGE AGREEMENT:				**90.7%**

Table 4.17 Properties of study, outcome and discussion – Group 1 – RCT – Article 3

AUTHOR(S):	Hawk *et al.*
YEAR:	1999
TITLE:	Preliminary study of the effects of a placebo chiropractic treatment with sham adjustments.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
VAS GWBS.	Before and after all four visits.	Two weeks.	18 participants.	Assessors were not blinded.	A control group of nine participants was used.	Randomization to either FDCT or Sham adjustment (activator).	6	90.7

LIMITATIONS:	The authors noted three identified limitations. These included that the outcomes of this study should only be compared to studies using similar procedures and similar design due to the multitude of limitations and criteria involved in the sample population. Secondly, it was noted that the sample population was limited to students and administrators of the college (very specific population limiting generalizability), and a small sample size which, due to limited power, did not permit significance testing. For this reason, data was not aggregated and statistical analysis was not performed. Additionally, although there was a randomization procedure for participants into this study, the application of concealed allocation was not delineated. These processes or lack thereof lead to the groups being significantly different in terms of the VAS at the baseline reading prior to entering the study. Although not significantly different, the GWBS follows a similar trend to the VAS. With a small sample, the effect of a large difference at the outset would be difficult to control, which in addition to the limited power and lack of parametric comparisons between the groups, may amplify the results obtained such that the conclusion results in no significant difference between the groups from baseline to crossover and from cross over to the final readings. The results may also have been confounded by the crossover design, where there may have been a carryover of effects from the

	treatments. Furthermore, it must be considered that students and college members may be in a better position to identify the placebo versus the active treatment based on their knowledge of chiropractic interventions. In addition to which, they may also have been able to bias the results in terms of their understanding of research process and procedure within the study and therefore presenting data that may not have been reflective of their clinical reality. The above is compounded by the lack of blinding: - Participants were aware of which treatments was placebo and which was not. - It was not stated whether those treating the participants were also the same researchers that were responsible for taking the outcome measures, which may have biased the outcome.
OUTCOME:	Although VAS and GWBS scores improved with both treatments, a somewhat greater improvement occurred in most cases with the active treatment. Eight of 14 participants interviewed believed that the placebo had a treatment effect.
DISCUSSION:	With regards to the specific aims of the study, the information obtained related to the participants perceptions of a symptomatic response to the active and placebo treatments. The outcomes suggested that the placebo treatment utilised, may have had some degree of success in blinding participants to group status. However, with the participants being students and staff at a Chiropractic college, full blinding of participants may not have been possible. Therefore, it would seem that the assertion of the participants affecting the outcome may have been negated as the placebo seemed to be seen as an active treatment. The structure of the study (viz. a 2-period cross over design) may, however, have amplified the conclusion artificially as the authors note that an interpretation for the findings may be based on the fact that the participants who received the active treatment first and made the greatest improvements when subsequently receiving the placebo. This assertion may hold true as the study period (close to natural history) may also have influenced the outcomes as participants naturally got better after treatment followed by the reduction in symptoms within the natural history period of low back pain. Thus, the improvements would not have been related to the placebo / intervention at all.

Conclusion:

The study therefore does not have any ability to contribute to a discussion on the effects of the interventions directly, thus limiting the ability to talk specifically about the placebo or the active (FDCT) interventions and the effective difference between them. The analysis of the study concurs with the outcome attained by the reviewers in **Table 4.16** (reviewer's singular outcome) in terms of the structure of the study and its rigour. The reviewer singular outcome suggests that although the study had some limited rigour, the outcomes of the study are definitively affected by the limitations noted. Therefore, this study has only a very limited ability to contribute to the literature on FDCT.

Table 4.18 Tabulated Feedback Data for Group 1 – RCT - Article 4

AUTHOR(S):	Hondras *et al*.					
YEAR:	2009					
TITLE:	A randomized controlled trial comparing 2 types of spinal manipulation and minimal conservative medical care for adults 55 years and older with subacute or chronic low back pain.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	Y	Y	Y	100%
3	Allocation was concealed	Y	Y	Y	Y	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	Y	Y	Y	Y	100%
5	There was blinding of all subjects	N	N	N	N	100%
6	There was blinding of all therapists who administered the therapy	N	N	N	N	100%
7	There was blinding of all assessors who measured at least one key outcome	Y	Y	Y	Y	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Y	Y	Y	Y	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 analysed by “intention to treat”	N	N	N	N	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Y	Y	Y	Y	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Y	Y	Y	Y	100%
	TOTAL SCORE	**8**	**8**	**8**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**100%**

Table 4.19 Properties of study, outcome and discussion – Group 1 – RCT – Article 4

AUTHOR(S):	Hondras *et al*.
YEAR:	2009
TITLE:	A randomized controlled trial comparing 2 types of spinal manipulation and minimal conservative medical care for adults 55 years and older with subacute or chronic low back pain.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
RMQ VAS BDI SF-36.	Baseline at assessment, followed by baseline before treatment commenced, followed by week three, six, 12, 24.	24 weeks.	A total of 240 participants were included in the study.	Yes.	No placebo, no natural history group.	Participants randomized into three groups: - HVLA-SM (n=96) - LVVA-SM (n=95) - MCMC (n=49).	8	100%

LIMITATIONS:	Randomised sampling technique was noted, although the concealment of allocation of participants was not outlined. The lack of concealment of participant allocation does raise concerns about the quality of the randomisation (selection bias as noted by the authors). Although the analyses of the imputed data did not differ from the analyses that included only the observed data, the analyses cannot account for the possibility of selection bias. Although the eligibility criteria were well defined, 40% of participants were obese, and the eligibility criteria only excluded participants with significant co-morbidities (those that provide contra-indication to manipulative therapies). Therefore, the effects of the increased body mass index, with lesser co-morbidities or those without direct contra-indications may also pose a threat to the outcomes of the study, as these co-morbidities have an effect on healing rates and pain reduction. In addition, this older populace with potentially multiple co-morbidities limits the generalizability of study results. This is particularly true in that this population is an older population with a lesser ability to heal more rapidly / has more likelihood of being on medication (affecting outcome).

	While a disproportionate drop-out rate in the MCMC group occurred in contrast to the HVLA-SM and LVVA-SM groups, data for 82% of the MCMC participants was analysed for at least one end point. It must be understood that while 82% of the MCMC participants were analysed for at least one end point, the drop-out rate had the potential to skew results showing greater improvement in the MCMC group than the participants actually attained (as the drop-outs had more severe presentation of their condition). This significant drop-out was attributed to dissatisfaction of the participants in the MCMC group. The flow diagram (CONSORT) for screening, enrolment and follow up throughout the 24 weeks may accurately depict the follow up of participants. However, it does make it difficult for the reader to determine how different data points were compared (when the composite groups comprised different numbers of participants), and it is not clear whether the groups actually had the same participants at follow up time points to enable an accurate comparison. Similarly, as in typical practice, participants receiving SM obtained a greater amount of time and attention with a clinician compared to the participants in MCMC. Although attempts were made to provide some control for the greater time and attention spent with participants assigned to the SM treatment arms by adding the home exercise instruction for all participants, there was no systematic monitoring or collecting of compliance data for the home exercise instruction duration by the doctors. Therefore, it is not known whether the attention, SM loads (visit number), exercise compliance, or other factors could have provided the explanation for any clinical benefit. These latter factors also hinder the ability of allocating improvement to any one intervention and the lack of a placebo hinders the ability to determine whether there was improvement beyond that of natural history.
OUTCOME:	Although there were no significant differences between LVVA-SM and HVLA-SM at any of the end points, the LVVA-SM group showed improvements in adjusted mean RMD scores ranging from 1.3 to 2.2 points over the MCMC group that were statistically significant at all end points. Adjusted mean RMD scores were significantly better in HVLA-SM than MCMC at week three but not at other end points. Although the adjusted mean SF-36 Physical Function subscale was statistically significantly improved in LVVA-SM than MCMC, it probably did not represent an important clinical difference. Adjusted mean perception of global improvement at week 12 and 24 follow-up end points was significantly better in both the SM groups than in the MCMC group (week 12: 4.2; week 24: 3.9). There were no significant differences between the SM groups for any of the secondary outcome variables. Further, the authors suggest that biomechanically different interventions may attain the same outcomes for the participants. This may not be true as the effect of the exercise and education is negated as negligible – the effect of which are unknown in this clinical trial.

	In terms of the outcomes, it may be possible to consider from an evidence-based care perspective, and assessing participant's preference and clinical experience that SM procedures seem to be beneficial for this participant's population.
DISCUSSION:	These outcomes suggest that both the SM groups fared better than the MCMC group. This implies that there is a favourable treatment effect that is produced with the application of SM for participants similar to those in the study. The only factors that detract from this outcome are the extraneous variables discussed under the limitations above – in particular the seemingly high dissatisfaction with the MCMC group (resulting in significant drop outs). The impact of this factor further seems to question the value placed on the exercise / education programme that was structured in this study for the purpose of negating the effects of the large difference between the MCMC and SM groups. The inability of the MCMC group to benefit from this intervention also places questions around its impact on the SM groups – if the impact provided a positive re-enforcement in the MCMC group, the outcomes of the study would be artificially amplified. These limitations curtail the ability of the authors in determining the effect of one intervention alone and it is perhaps more accurate to delineate that the SM groups, in addition to exercises / education, fared better than the MCMC groups with similar exercises and education. Thus, it would be wise to consider a study with single interventions in the future - if the aim is to determine the exact effects of these interventions. This suggestion would, however, be less pragmatic and isolated to determining efficacy and effects of the specific intervention only.

Conclusion:

When comparing the outcomes of **Table 4.18** (reviewer's outcomes) versus **Table 4.19** (an assessment of the study), it can be seen that although the study structure was highly ranked and there was unanimous agreement between the reviewers, there were some structural deficiencies present in the current study. These structural limitations however do not detract sufficiently from the outcomes of the study, and therefore, it is suggested that this study does provide moderate to strong evidence in favour of the SM interventions (viz. HVLA-SM and LVVA-SM). This infers that there is moderate to strong evidence for the use of FDCT in the treatment of older adults with low back pain.

Table 4.20 Tabulated Feedback Data for Group 1 – RCT - Article 5

AUTHOR(S):	Schulz *et al.*					
YEAR:	2011					
TITLE:	Chiropractic and self-care for back related leg pain: design of a randomized clinical trial.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	-	Y	Y	Y	66%
3	Allocation was concealed	-	Y	Y	Y	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	-	Y	Y	Y	66%
5	There was blinding of all subjects	-	Y	Y	Y	66%
6	There was blinding of all therapists who administered the therapy	-	Y	Y	Y	66%
7	There was blinding of all assessors who measured at least one key outcome	-	Y	Y	Y	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	-	N	N	N	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 analysed by “intention to treat”	-	Y	Y	Y	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	-	N	N	N	66%
11	The study provides both point measures and measures of variability for at least one key outcome	-	N	N	N	66%
	TOTAL SCORE	**1**	**8**	**8**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**69.09%**

Table 4.21 Properties of study, outcome and discussion – Group 1 – RCT – Article 5

AUTHOR(S):	Schulz *et al.*
YEAR:	2011
TITLE:	Chiropractic and self-care for back related leg pain: design of a randomized clinical trial.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
- VAS - Bothersome of symptoms - Frequency of symptoms - Modified Roland Morris Scale - SF-36v2 - FABQ - Patient satisfaction - Improvement - Medication use - Self-efficacy - Standing postural sway - EMG - Straight leg raise - Patient expectation of care - Side effects - Pain Self-Efficacy Questionnaire	Self-reported outcome measures are made at baseline, week 3, 12, 26, and 52. Objective biomechanical measurements are done at baseline and week 12. Qualitative measurements are done at 12 weeks.	52 weeks.	192.	Yes.	Yes Home Exercise Programme (n=96).	Yes Two groups: - Home Exercise Programme and Chiropractic programme (n=96). - Home Exercise Programme (n=96).	8	69.09%

LIMITATIONS:	The significant limitation to this study was that no data was collected or it was in the process of being collected at the time of the publication, therefore, the authors were unable to report on outcomes, hence key measures and intra /inter-group statistical comparisons could not be made. The participants' inability to read or verbally comprehend English was reported as a limitation of this study. This implies that a population

	similar to that presented in the study, would be the only mechanism to attain similar results to this study. As a result, repeatability of the study would be positively affected if only English speaking participants were utilized, as the subjective outcomes may produce different results in groups that have another language as their principle language (Baynham, 1995; Scollen and Scollen, 1995).
OUTCOME:	No outcome data was reported
DISCUSSION:	This study was a unique study in that it represented a full scale randomized clinical trial to evaluate spinal manipulative therapy (SMT) for back related leg pan (BRLP). By using a two site design, the approach enhanced the generalizability of study. In addition, the increased sample size further allowed for greater generalizability, although some limitations may have curtailed this. In addition, with the study combining SMT and participant's education versus participant's education alone (although pragmatic) would have minimised the ability of the researchers to be able to define the effect of any one outcome on BRLP. The study did note that there was a standardizing of the participants education which may have enhanced the study's ability to investigate SMT's unique contribution to treatment outcome. However, the study did not suggest that there was training in this regard across the two sites. The latter may have differentially affected the non-specific effects associated with participant's education (Richardson, 2007). However, as participants expect to receive information and advice about their condition, the effect of the lack of training across sites may have been ameliorated, by any information received whether it was standardised or not. The study also indicated that there would be biomechanical outcome measures, which on completion would provide clinically useful information regarding the intervention. However, as there was no active intervention on participants in this protocol publication, no comment can be made on these outcomes and their measurement of BRLP.

Conclusion:

When looking at the analysis of Schulz' *et al.,* (2001) study, it can be seen that although the study provided for a rigorous methodology, the authors did not report any findings. As a result, two of the reviewers ranked the study highly, with one reviewer not providing any comments. These responses characterise the dichotomy of the impact that these two standpoints and have on

the level of evidence provided by this study, where the rigorous structure provides for the potential for a high level / strong evidence in support of a clinical outcome. The lack of the same clinical outcomes renders null and void the well-developed structure of the trial. With this in mind, it can be concluded that this study provides no evidence with regard to FDCT.

Table 4.22 Tabulated Feedback Data for Group 1 – RCT - Article 6

AUTHOR(S):	Wilder *et al.*					
YEAR:	2011					
TITLE:	Effect of spinal manipulation on sensorimotor function in back pain patients: study protocol for a randomised controlled trial.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	-	Y	Y	Y	66%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	-	Y	Y	Y	66%
3	Allocation was concealed	-	Y	Y	Y	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	-	Y	Y	Y	66%
5	There was blinding of all subjects	-	Y	Y	Y	66%
6	There was blinding of all therapists who administered the therapy	-	Y	Y	Y	66%
7	There was blinding of all assessors who measured at least one key outcome	-	Y	Y	Y	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	-	N	N	N	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 analysed by “intention to treat”	-	N	N	N	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	-	N	N	N	66%
11	The study provides both point measures and measures of variability for at least one key outcome	-	N	N	N	66%
	TOTAL SCORE	**-**	**7**	**7**	**7**	
		OVERALL PERCENTAGE AGREEMENT:				**66%**

Table 4.23 Properties of study, outcome and discussion – Group 1 – RCT – Article 6

AUTHOR(S):	Wilder *et al.*
YEAR:	2011
TITLE:	Effect of spinal manipulation on sensorimotor function in back pain patients: study protocol for a randomised controlled trial.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
Postural sway, RMQ, Numerical Rating Scale (NRS), SF-36v2.	Outcome measurements are assessed at baseline, visit 2, week 2 and week 6.	Six weeks.	A total of 219 participants were included into the study.	Yes.	A control group (n=73).	Randomization of participants into groups consisting of: - Sham treatment, - HVLA-SM - LVVA-SM.	7	66%

LIMITATIONS:	A significant limitation to this study was that no data was collected (as it was in the process of being collected at the time of this study being reviewed). Therefore, the authors were unable to report on outcomes with the result that key measures and intra/inter-group statistical comparisons could not be made. Furthermore, the reported lack of blinding (multiple meetings of all personnel) has the ability to obscure the "blinding process" that was adopted / not adopted in this study (not clearly articulated). Another limitation of the study was that of the three groups, two groups had highly structured interventions over a period of six weeks. By contrast, the third group received a sham intervention for two weeks followed by a "doctors choice" treatment, which would have resulted in the following potential downfalls (for Group Three) : - Decreased time exposure with the practitioners,

	- Decreased interventions and - Differing combinations of interventions (pragmatic as it was the “doctor’s choice”). Further limitations could not be identified as this publication was incomplete.
OUTCOME:	Although highly structured with a good structural context to support outcomes that are reliable and valid, no data had yet been collected due to the authors being unable to report on outcomes (incomplete trial).
DISCUSSION:	This study was a unique study in that it represented a full scale RCTs to evaluate the sensorimotor functions in participants with back pain. The approach enhanced the generalizability of the study. The study also indicated that there would be biomechanical and clinical outcome measures, which on completion would provide clinically useful information regarding the intervention. However, as there was no active intervention involving participants in this protocol publication, no comment can be made on these outcomes and their measurement of sensorimotor functions.

Conclusion:

Similarly to the analysis of Schulz *et al*., (2011), the analysis of Wilder *et al*., (2011) provides the reader with a study of high methodological rigour, but lacking in outcomes / findings. This study can therefore provide no evidence with regard to FDCT.

Table 4.24 Tabulated Feedback Data for Group 1 – RCT - Article 7

AUTHOR(S):	Zylbergold RS and Piper MC					
YEAR:	1985					
TITLE:	Cervical spine disorders: a comparison of three types of traction.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	N	Y	Y	66%
3	Allocation was concealed	N	N	N	N	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	Y	Y	Y	Y	100%
5	There was blinding of all subjects	N	N	N	N	100%
6	There was blinding of all therapists who administered the therapy	N	N	N	N	100%
7	There was blinding of all assessors who measured at least one key outcome	Y	N	N	N	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	N	Y	Y	Y	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 analysed by “intention to treat”	Y	N	N	N	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Y	Y	Y	Y	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Y	Y	Y	Y	100%
	TOTAL SCORE	**7**	**5**	**6**	**6**	
		OVERALL PERCENTAGE AGREEMENT:				**87.6%**

Table 4.25 Properties of study, outcome and discussion – Group 1 – RCT – Article 7

AUTHOR(S):	Zylbergold RS and Piper MC
YEAR:	1985
TITLE:	Cervical spine disorders: a comparison of three types of traction.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
The McGill Pain Questionnaire, Flexometer, subjective use of medication and neck collar usage were noted.	Pre, post and change scores were attained for all four measures.	Six weeks.	One hundred and twenty nine initially started the project but one hundred remained to the end.	No.	Yes - A placebo control group.	Randomization into groups of: - Static traction - Intermittent traction - Manual traction - Neck care.	6	87.6%

LIMITATIONS:

Although the study was structured as a RCT, the following limitations were acknowledged by the author:

- There was a lack of homogenisation of the participants of the study with particular reference to the cervical spine conditions with which the participants were diagnosed (cervical disc disease, osteoarthritis and spondylosis); in addition some participants had radiculopathy (20%). This latter inclusion, would in some studies, have been considered a more severe condition than a diagnosis without Radiculopathy (Dagenais and Haldeman, 2012).
- The participants were not stratified by age and included those from the age of 18 through 70 years of age. This age range would influence the healing rate which may affect the clinical outcomes in this study. It is, however, noted that average age per group was similar (and therefore not statistically different). This may additionally have been ameliorated by the fact that participants were stratified by the level of chronicity of their cervical spine pain.
- Allocation concealment was not noted although randomisation was indicated.
- The study did not indicate whether there was any blinding with regards to the participants, therapists and / or the persons measuring the outcomes over time. This deficiency introduces “researcher bias” into the study.

	- There were 29 drop out participants (29/129), which is a large proportion of the initial participants that were accepted onto the study. Although the analysis of these participants determined that they were similar in terms of the demographic and baseline measures when compared to the participants that remained in the study, it was not reported as to which group lost the most participants and why. This bias may introduce (to one or more groups) the likelihood that they were able to achieve an artificially better outcome than they would have, as the exclusion of the more severe drop out participants in that / those groups would have altered the groups outcome measures. In contrast to the limitations noted above, the authors did make an effort to assess whether the groups were equivalent at baseline for all measures, in order to determine the effect of the randomisation and stratification processes.
OUTCOME:	The outcome measures used to determine the efficacy of the different treatment regimens were pain, range of motion, usage of medication, and/or the use of a neck collar. Of the three traction groups, only the intermittent traction was significantly different in terms of these outcomes when compared to the placebo group. When the three traction groups were combined, it was found that overall the participants receiving traction did significantly better with forward flexion and rotation and the no traction group / neck care group had a significantly higher need for post-trial interventions as well as an increased significant use of medication. It was noted overall by the authors that all groups improved over the six week period. This may, however, be attributed to the natural history of the condition and not the intervention utilised in the study. Therefore, the results obtained need to be interpreted with caution in this respect.
DISCUSSION:	Although all study subjects regardless of treatment group improved significantly on all the outcome variables over the six week period, the use of traction did, in fact, enhance participant's outcomes in terms of mobility in forward flexion and right rotation. Moreover, traction participants, as a group, were less likely to require further treatment and used less medication following the trial period when compared to their no-traction counterparts. Further, when pre-existing differences between the treatment groups were accounted for with the analyses of covariance, participants receiving intermittent traction experienced less pain and greater mobility in terms of forward flexion, right and left rotation than those participants who only received neck care instruction. No significant differences were found between the three individual traction groups.

	However, the traction groups collectively when compared with the no-traction group and the intermittent traction versus the no traction group showed significantly greater improvements. This suggests that intermittent traction is superior.

Conclusion:

Based on the analysis of this study, it would seem that the rigour was strong, but unable to counteract the impact of the limitations of the study noted above. Therefore, the limitations would restrict the study from achieving a high ranking when assessed with the PEDro. This outcome agrees with the outcomes of the reviewers where the majority ranking achieved was a 6/11. This outcome suggests that although this study supports traction (FDCT) it needs to be considered within the restrictive context of this study and its significant limitations. Therefore, the level of evidence that this study provides is at best limited and thus a suggestion for follow up studies need to be considered to refute or support the outcomes of this study. These future studies need to pay heed to the limitations noted and address these systematically in order to improve the level of evidence in support of traction in participants with chronic neck pain.

Table 4.26 Tabulated Feedback Data for Group 2 – RCT - Article 1

AUTHOR(S):	Beyerman *et al*.					
YEAR:	2005					
TITLE:	Efficacy of treating low back pain and dysfunction secondary to osteoarthritis: chiropractic care compared with moist heat alone.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	Y	Y	Y	100%
3	Allocation was concealed	N	N	N	N	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	Y	Y	Y	Y	100%
5	There was blinding of all subjects	N	N	N	N	100%
6	There was blinding of all therapists who administered the therapy	N	N	N	N	100%
7	There was blinding of all assessors who measured at least one key outcome	N	N	N	N	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Y	Y	Y	Y	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 analysed by “intention to treat”	Y	Y	Y	Y	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	N	Y	N	N	66%
11	The study provides both point measures and measures of variability for at least one key outcome	N	Y	N	N	66%
	TOTAL SCORE	**5**	**7**	**5**	**5**	
		OVERALL PERCENTAGE AGREEMENT:				**93.8%**

Table 4.27 Properties of study, outcome and discussion – Group 2 – RCT – Article 1

AUTHOR(S):	Beyerman *et al*.
YEAR:	2005
TITLE:	Efficacy of treating low back pain and dysfunction secondary to osteoarthritis: chiropractic care compared with moist heat alone.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
Oswestry VAS Range of movement (ROM)	First visit and at visits five, ten, 15, and 20	Between January 2001 and January 2005.	225 originally started but 217 completed the study	No	Yes	Randomization into groups of FDCT and hot pack and hot pack alone	5	93.8%

LIMITATIONS:

This study indicated no form of age limitation. This decreases the homogeneity of the participants, particularly with response to the treatment (as the responses to treatment / healing times are different at different ages (Gleberzon, 2001b). This decreases the ability to compare improvements between the groups unless this variable is controlled for in the statistical analysis (not noted in the publication). This clinical picture is further complicated by the reference to several different forms of osteoarthritis which were included in this study.

It is acknowledged that the sample homogeneity and reliability of the outcome measures were improved in this study by virtue of the inclusion of only English speaking participants, but it could also be argued that the use of only English speakers may have limited the severity of the low back pain that presented in the study (viz. English speakers are more likely to be able to access care when necessary than non-English speakers and therefore their presentation is usually less severe (Mbutho, 2012). This concurs with the noted pain levels in this study. This would have limited the possibility for improvement and therefore may have negated the possibility of attaining significance in terms of improvement.

To further compound the outcomes of the study, it was noted that there was no accounting for the effects of medication (particularly chronic medications) in the population that participated in the study. The use of combinations of medication have the tendency to increase with age (Gleberzon, 2001b) and are more likely in participants that present with the conditions defined as forming part of the osteoarthritis inclusion

	into the study (Deyle *et al*., 2005). Additionally, the study was completed over a period that is commensurate with the natural history of low back pain and therefore it is difficult to ascertain whether the low back pain improved by itself or whether the improvements are attributable to the interventions utilised. This is compounded by the combination of treatment therapies, where the outcomes of the study can only be limited to the combination of the therapies (chiropractic care) with very little ability of the study to be able to identify the specific active modality that was linked with the improvement in the participants recorded outcomes.
OUTCOME:	In the outcomes of the study, it was noted that chiropractic care was more effective than heat treatment alone for pain reduction. It was specifically noted that chiropractic care and moist heat were more effective than moist heat alone for improving range of motion especially flexion scores. It is, however, noted that all ranges of motion improved significantly in both groups (except lateral flexion). For the Oswestry Low Back Pain Questionnaire significant results were obtained for personal care, walking, sitting, and social life for both groups with the chiropractic care group improving to a greater extent. Marginally significant findings included lifting and travelling. Three factors were not significant: standing, sleeping and sexual activity. These improvements were limited to the chiropractic care group only with the moist heat only group reaching significance with the total Oswestry score. This latter improvement was, however, predominantly driven by the Oswestry pain score, which is noted to have been significant for the moist heat only group. It is, therefore, suggested that the chiropractic care group received a superior outcome when compared to the moist heat only group. Therefore the study did not offer much evidence for FDCT.
DISCUSSION:	Although this study had a good RCT based structure, there were several flaws with the participant selection procedures and the overall intervention strategy (in terms of time and the combination of therapies). It could be argued that the moist heat within each of the groups served as a control and served to standardise the groups and therefore the outcome of the study may be attributed to the FDCT. The latter suggestion would be ignoring the effects of natural history and the impact of the differences in the pathological processes underlying the two groups (as it is not noted in the study how the different pathologies were allocated to the two groups in order to ensure homogeneity).

Conclusion:

From the discussion of the study in **Table 4.27**, it is evident that the outcomes of the study although tenuous seem to suggest a favourable outcome for participants that received the chiropractic care (combination therapy). This outcome, however, requires further testing and validation through the use of more rigorous RCTs in order to exclude the extraneous factors that have had an impact on this study. Therefore, the outcome at best suggests that the evidence in favour of FDCT for the clinical treatment of low back pain is at best limited. This outcome concurs with and reflects the ranking obtained through the independent review of this study, where it is noted in **Table 4.26**, that there was a high level of agreement for an average ranking of the study.

Table 4.28 Tabulated Feedback Data for Group 2 – RCT - Article 2

AUTHOR(S):	Bronfort *et al*.					
YEAR:	2004					
TITLE:	Spinal manipulation, epidural injections, and self-care for sciatica: a pilot study for a randomized clinical trial.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	Y	Y	Y	100%
3	Allocation was concealed	Y	Y	Y	Y	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	N	Y	N	N	100%
5	There was blinding of all subjects	N	N	N	N	100%
6	There was blinding of all therapists who administered the therapy	N	N	N	N	100%
7	There was blinding of all assessors who measured at least one key outcome	Y	N	Y	Y	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Y	Y	Y	Y	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 analysed by “intention to treat”	N	Y	N	N	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	N	N	N	N	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Y	Y	Y	Y	100%
	TOTAL SCORE	**6**	**7**	**6**	**6**	
		OVERALL PERCENTAGE AGREEMENT:				**93.8%**

Table 4.29 Properties of study, outcome and discussion – Group 2 – RCT – Article 2

AUTHOR(S):	Bronfort *et al*.
YEAR:	2004
TITLE:	Spinal manipulation, epidural injections, and self-care for sciatica: a pilot study for a randomized clinical trial.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
Self-report questionnaires, straight leg raise, and lumbar spinal motion. Modified Roland Morris Disability Scale and Oswestry Disability Questionnaire. Leg pain / Low-back pain. Bothersome symptoms Frequency of symptoms Cut back on activities (no. of days). Stayed in bed (no. of days). Missed work or school (no. of days) (NHIS).	Self-report, SLR and lumbar spinal motion assessed twice at baseline, three weeks and 12 weeks and 52 weeks.	52 weeks.	32 initially assigned with one participant refusing treatment and four failing to complete week 52 follow-up.	Yes.	Yes.	Randomization into groups: - Chiropractic treatment (FD, mobilisation, soft tissue, heat / cold) - Epidural injection.	6	93.8%

LIMITATIONS:	From the limitations noted by the authors and an analysis of the study, it became apparent that this study suffered with flaws related to : - Small sample size.

	- Lack of participant's homogeneity, with regards to their clinical presentation (viz. low back pain, with leg pain (distal or proximal; with or without neurological signs). - The study sample was drawn from a previous study from which they had been excluded. It is not noted why they were excluded from the previous study and why the status for their inclusion had changed for this particular study. - Being a pragmatic study for participants with pain, the participants had continued access to their medication, epidural steroid injection as well as "prescription strength rescue medications", allowing differences between the participants and participants groups. - The use of combination treatments – although pragmatic – reduces the ability of the study to be able to identify the active intervention, and therefore, to also account for synergistic or antagonistic effects that the interventions may have on one another. Further to the above and in line with the pragmatic nature of the study, it was noted that there was no "set amount" of treatments and the periodicity / interval for these treatments may have varied for the three different treatment groups. This variance between the groups may have allowed the study to be influenced by amongst others: natural history, the Hawthorne effect, participant's expectation discordance and contact with the research team may have varied.
OUTCOME:	The data suggested that for all participants, the most improved outcomes were recorded at the 12 week evaluation (or the terminal point of the treatment). At this point, the outcome measures indicated that the greatest change with regards to the Oswestry Questionnaire for leg pain severity and how bothersome the symptoms were, occurred at 12-weeks. This was coupled with 24 of the participants reporting to be "very satisfied" or "completely satisfied" with the care they received in the study and on average, suggesting a 75% to 100% improvement for each participant, with only two participants reporting regression of symptoms. After 52 weeks, the greatest changes ascribed to the intervention were changes in the leg pain severity, followed by the Oswestry questionnaire and how bothersome the participant's symptoms were. The number of satisfied participants reduced to 18, with only 15 participants reporting a 75% or 100% improvement. The remainder of the participants reported a regression of their symptoms.

DISCUSSION:	Although the outcomes of this study seem to suggest that there was global improvement in the measured outcomes of the participants over time, no group comparisons were completed and thus no comment could be directed at the ranking of the interventions employed in the study (viz. self-care, chiropractic care and injections). Thus, the study at best presented a feasibility study (as it was set out) and contributes little to the overall knowledge of the interventions employed.

Conclusion:

When analysing **Table 4.28**, it becomes evident that the structure of this study starts to approximate to that of a rigorous clinical trial, with a PEDro ranking of 6 (majority ranking). It is, however, noted that there are several flaws that do not allow this study to attain a higher score and these are related to the lack of baseline comparability, the lack of blinding of all persons involved in the study and the lack of completion of statistical comparisons between the groups. In essence these are also the flaws that were found when the study was critically analysed by the reviewers (**Table 4.29)**. As a result of this, the study has no ability to present any evidence in support of the chiropractic care (in particular FDCT) and thus does not contribute to the current knowledge base for this intervention strategy.

Table 4.30 Tabulated Feedback Data for Group 2 – RCT - Article 3

AUTHOR(S):	Gudavalli *et al.*					
YEAR:	2006					
TITLE:	A randomized clinical trial and subgroup analysis to compare flexion-distraction with active exercise for chronic low back pain.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	Y	Y	Y	100%
3	Allocation was concealed	Y	Y	Y	Y	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	Y	Y	Y	Y	100%
5	There was blinding of all subjects	N	Y	N	N	66%
6	There was blinding of all therapists who administered the therapy	N	N	N	N	100%
7	There was blinding of all assessors who measured at least one key outcome	Y	Y	Y	Y	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Y	N	Y	Y	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 analysed by “intention to treat”	Y	Y	Y	Y	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Y	Y	Y	Y	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Y	Y	Y	Y	100%
	TOTAL SCORE	**9**	**8**	**9**	**9**	
		OVERALL PERCENTAGE AGREEMENT:				**93.81%**

Table 4.31 Properties of study, outcome and discussion – Group 2 – RCT – Article 3

AUTHOR(S):	Gudavalli *et al.*
YEAR:	2006
TITLE:	A randomized clinical trial and subgroup analysis to compare flexion-distraction with active exercise for chronic low back pain.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
VAS RMQ SF-36 Strength test ROM test.	At baseline, four weeks, 13 weeks, 26 weeks and 52 weeks.	52 weeks.	235 initially assigned to groups. 197 completed intervention phase (4 weeks).	Yes.	Yes.	Randomization into groups: - FDCT - active trunk exercise protocols.	9	93.81%

LIMITATIONS:

From the analysis of the above study, it was noted that there were limitations with regards to the :

- introduction of bias, as a result of the lack of blinding of therapists and participants.
- lack of homogeneity introduced into the study as a result of the sample selection process. It is noted that there were a variety of techniques utilised to recruit participants from a variety of sources. It is also noted in the study that it was hoped that a broad range of participants responded so as to eliminate expectation bias. Thus, there was a trade-off between the two.

Fewer, but still confounding variables within the context of this study include :

- Participants that had low back pain for more than three months. It is unclear as to whether the participants presenting with low back pain had an acute episode, with a history of low back pain; an aggravation of low back pain that is consistently there or the first period of low back pain ever experienced that happened to be present for more than three months. These individual possible

	presentations would have an effect on the overall outcomes of the presented study, as it affects both the symptom severity and its healing time or response to treatment as the underlying causes and confounders (e.g. depression) may be different. - It was noted that although there was a large range for certain population parameters, the only significant difference was related to income. It is possible that those with higher incomes and accessibility to care generally would present with fewer low back pain symptoms than those with lower incomes (Dyer, 2012). The association between income and medical boarding, disability and mental health may also carry influences into a clinical trial if groups are significantly disparate (Dagenais and Haldeman, 2012). To the credit of the authors, these factors were statistically controlled for in data analysis for this trial. Also, to the authors' credit, it was noted that the study duration was within the natural history of resolution of low back pain.
OUTCOME:	Significant differences were observed in the pre to post measures for all primary outcomes at four weeks, regardless of treatment group (FDCT versus active exercise). There was, however, a statistically significant difference in the VAS between the two treatment groups - which favoured FDCT. Further, initial gains made (both groups) appear to remain stable through the completion of the follow-up period. Although attrition occurred, data was obtained from 78% of subjects in the FDCT group and 70% of subjects in the active exercise group after 12 months. In addition to the outcomes above the study also determined that : - A trend toward greater improvement in perceived pain occurred for subjects with radiculopathy in the FDCT groups. - Subjects with moderate to severe continual chronic pain seem to have benefited most from FDCT. - Subjects with recurrent pain seemed to have benefitted more from active exercise.
DISCUSSION:	As a result of the analysis of this study, it is apparent that the study was rigorously structured with due concern being paid to baseline differences which were accounted for in the statistical analysis of the data. In addition, the use of subgroup analysis was able to allay concerns to the possible variations of back pain presentation that may have been included in the study. Although the latter was not fully addressed, its potential for bias was reduced and contextualised in the discussion of the results. Thus, from the above analysis it would appear that FDCT is able to assist with the reduction of low back pain, particularly subgroups with

	continuous pain that is moderate to severe and also for the participants who present with associated leg pain. By contrast, participants with recurrent and intermittent back pain seem to benefit more from the active exercise. Therefore, this study seems to suggest that future research should focus on trying to develop clinical prediction rules to outline specific clinical benefit for specific subgroups , for example, participant with low back pain

Conclusion:

From **Table 4.31** it seems evident that this study provides moderate to strong evidence in support of the use of FDCT for the use in patients with low back pain – particularly those with associated leg pain, continuous pain and / or pain that is moderate to severe in nature. This assertion is underpinned by the high review ranking (**Table 4.30**) that was attained by this study, where there was a high level of agreement between the examiners. Therefore, this publication provides strong evidence in support of the clinical use of FDCT for treating low back pain over the short term.

Table 4.32 Tabulated Feedback Data for Group 2 – RCT - Article 4

AUTHOR(S):	Cambron *et al.*					
YEAR:	2006					
TITLE:	Amount of health care and self-care following a randomized clinical trial comparing flexion-distraction with exercise program for chronic low back pain.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	Y	Y	Y	100%
3	Allocation was concealed	Y	Y	Y	Y	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	N	N	N	N	100%
5	There was blinding of all subjects	N	N	N	N	100%
6	There was blinding of all therapists who administered the therapy	N	N	N	N	100%
7	There was blinding of all assessors who measured at least one key outcome	N	Y	Y	Y	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Y	Y	Y	Y	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 analysed by “intention to treat”	Y	Y	Y	Y	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Y	Y	Y	Y	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Y	Y	Y	Y	100%
	TOTAL SCORE	**7**	**8**	**8**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**96.9%**

Table 4.33 Properties of study, outcome and discussion – Group 2 – RCT – Article 4

AUTHOR(S):	Cambron *et al.*
YEAR:	2006
TITLE:	Amount of health care and self-care following a randomized clinical trial comparing flexion-distraction with exercise program for chronic low back pain.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
VAS RMQ.	Base line week 0, upon completion of the 4 week intervention period (week 5), and at weeks 13, 25 and 53.	One year.	235 participants were initially randomised, 197 completed interventions and 191 completed follow up calls.	Yes.	Yes.	Randomization into groups: -FDCT -exercise programme.	8	96.9%

LIMITATIONS:	This study is a follow on publication, which presented the long term (annual) health care seeking results of the participants in the study that was reviewed in **Tables 4.30** and **4.31**. Therefore, the initial limitations noted in the previous analysis are still applicable to this study. In addition, the following areas of bias may be applicable: - Following participants over a long term period has its limitations in that the subjects may be removed from the location of study, may elect not to continue and may for valid reasons not be able to fully participate in all of the required data collection points over a long term period. In order to minimise the effect of this attrition, the authors provided for a process of annualization of the data. However, an increasing lack of subject participation may have results in biased / skewed results, as annualization does not reflect reality and is based on best guess estimates.

	- Further to the above, the authors noted that due to the number of statistical tests that were performed, there was an increased chance of a Type 1 error. - Many of the visits reported to the researchers, seem to have been steered by insurance, which may be cast back to the significant difference found at the baseline reported in the initial study, were there were differences between the groups at outset. These differences may have steered the participants in being driven be open access to medical care provision. - The effect of drop outs should perhaps have been reported more thoroughly, with reporting on reasons for self-exclusion or withdrawal from the study.
OUTCOME:	It was noted that the FDCT group seemed to have fared better than the active exercise group in terms of : - The numbers of visits to the general practitioner as well as practitioners in general (FDCT participants had fewer visits / care seeking reported on both counts). - Although both groups sought over the counter medication, the FDCT group sought less medication and the exercise group had a higher utilization rate. Both groups reflected a similar percentage of prescription medication use. - In terms of work sick leave, the FDCT group reported less than the active exercise group. - All participants completed home / self-care – the extent to which was unknown.
DISCUSSION:	From the results obtained in this study it seems evident over the longer term, that the FDCT provides better outcomes even with a four week trial intervention followed by participant management of their care.

Conclusion:

The above study, notwithstanding its limitations in terms of the flaws noted in **Table 4.33**, has attempted to present the 12 month sequelae of FDCT intervention versus active exercise intervention (which constituted a one month intervention period). The results, which have also been analysed by the controlling of specifically identified variables, has shown that the FDCT intervention has a better prognosis over the long term (however, not statistically significant) for patients with low back pain. The study as reviewed by the reviewers indicate that they had a high level of agreement indicating that the study was well structured and highly ranked

according to the PEDro parameters of rigour. Therefore, the outcomes of this study provide for moderate outcomes in favour of health seeking care after an interval of FDCT intervention with long term follow up.

Table 4.34 Tabulated Feedback Data for Group 2 – RCT - Article 5

AUTHOR(S):	Cambron *et al.*					
YEAR:	2006					
TITLE:	One-year follow-up of a randomized clinical trial comparing flexion-distraction with an exercise program for chronic low-back pain.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	N	Y	Y	66%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	Y	Y	Y	100%
3	Allocation was concealed	N	N	N	N	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	Y	N	Y	Y	66%
5	There was blinding of all subjects	N	N	N	N	100%
6	There was blinding of all therapists who administered the therapy	N	N	N	N	100%
7	There was blinding of all assessors who measured at least one key outcome	N	N	N	N	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Y	N	Y	Y	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 analysed by “intention to treat”	Y	Y	Y	Y	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Y	Y	Y	Y	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Y	Y	Y	Y	100%
	TOTAL SCORE	**7**	**4**	**7**	**7**	
		OVERALL PERCENTAGE AGREEMENT:				**90.72%**

Table 4.35 Properties of study, outcome and discussion – Group 2 – RCT – Article 5

AUTHOR(S):	Cambron *et al.*
YEAR:	2006
TITLE:	One-year follow-up of a randomized clinical trial comparing flexion-distraction with an exercise program for chronic low-back pain.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
VAS RMQ.	Base line week 0, upon completion of the 4 week intervention period (week 5), and at weeks 13, 25 and 53.	4 weeks.	235 participants. 38 withdrew during the intervention period and a further 23 in the follow-up phase.	Yes.	Yes, an exercise group.	Randomization into groups: - FDCT - exercise programme.	7	90.72%

LIMITATIONS:

This study is a follow on publication, which presented the long term (annual) clinical results of the study that was reviewed in **Tables 4.32** and **4.33.** In the reading and analysis of this particular study, it was noted by the authors that:

- The term "chronic low-back pain" had various definitions, making the results difficult to generalize. As a result the study attempted to assess differences in back pain presentation using recurrence of pain and radiculopathy as covariates in their analysis. It was suggested that neither treatment group was differentially affected. This does not, however, rule out the possibility that a variety of diagnoses may have led to differential outcomes (as one form of treatment may benefit from a particular intervention as compared to another).
- A second limitation noted that the subjects had relatively moderate baseline scores for pain and disability compared to previous studies. As a result, the ability of the subjects to improve over time and record significant changes with regards to their clinical measures were limited (known as the "floor effect").
- Similarly, missing data resulted in a significant problem. When tested, it was found that the missing data were significantly associated with pain but not disability, leading the authors to believe that subjects with more pain were less likely to return their questionnaire (the influence of this on the study is unknown).
- Baseline differences for some of the measures included existed. This was accounted for by the authors of the study during controlled

	statistical analysis, which diminished the impact of this limitation.
OUTCOME:	Even though there were baseline differences for some of the outcome measures, no other statistically significant group differences were found. This analysis also included participant gender, age, presence of radiculopathy (pain in leg), and presence of recurrent pattern of back pain as covariates in the analysis and as potential prognostic factors. It was found that the SF36 mental health scores were different between the subjects that withdrew and those that did not withdraw from the study. The subjects that withdrew had a significantly lower score on this data outcome. Generally, the response rates were higher in the FDCT group than in the active exercise group. The average pain scores initially (after the four week intervention phase) decreased, followed by a gradual increase over the subsequent 48 weeks to about half of the original scores. This is similar to the disability scores, which dropped up to week 13 and then remained relatively consistent. In totality, the outcomes demonstrated a significant pre–post change in pain and disability in both treatment groups individually. When assessing the outcomes between the groups (in terms of pain and disability outcomes), during the follow-up period, it was found to be significant. This indicated that the FDCT group had significantly lower pain scores during the follow-up portion of the study as compared to the active exercise group.
DISCUSSION:	As a result of the analysis of the study, it can be seen that the FDCT employed in this study resulted in a significant decrease in pain in the long term (52 weeks) over the active exercise period, after controlling for possible confounding variables. All other clinical measures, even though producing significant results were not different between the groups. It is however noted that this may have been as a result of the “floor effect” noted by the authors.

Conclusion:

The above study, notwithstanding its limitations in terms of the flaws noted in **Table 4.35**, has attempted to present the 12 month clinical sequelae of FDCT intervention versus active exercise intervention (which constituted a one month intervention period at the beginning of the year). The results, which were analysed by the controlling for specifically identified variables, provide limited evidence in support of FDCT intervention with particular reference to pain scores for which FDCT has a better prognosis over the

long term (for patients with low back pain). The study, as reviewed by the reviewers, indicated that they had a high level of agreement (85%) indicating that the study was well structured and highly ranked (7/11) according to the PEDro parameters of rigour. Therefore, the outcomes of this study provide for moderate outcomes in favour of clinical outcomes for FDCT over the long term.

Table 4.36 Tabulated Feedback Data for Group 2 – RCT - Article 6

AUTHOR(S):	Hawk *et al.*					
YEAR:	2002					
TITLE:	Issues in planning a placebo-controlled trial of manual methods: results of a pilot study.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	Y	Y	Y	100%
3	Allocation was concealed	Y	Y	Y	Y	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	Y	Y	Y	Y	100%
5	There was blinding of all subjects	Y	N	Y	Y	66%
6	There was blinding of all therapists who administered the therapy	N	N	N	N	100%
7	There was blinding of all assessors who measured at least one key outcome	Y	Y	Y	Y	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Y	Y	Y	Y	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 analysed by “intention to treat”	Y	N	N	N	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Y	N	N	N	66%
11	The study provides both point measures and measures of variability for at least one key outcome	Y	N	N	N	66%
	TOTAL SCORE	**10**	**6**	**7**	**7**	
		OVERALL PERCENTAGE AGREEMENT:				**87.63%**

Table 4.37 Properties of study, outcome and discussion – Group 2 – RCT – Article 6

AUTHOR(S):	Hawk *et al.*
YEAR:	2002
TITLE:	Issues in planning a placebo-controlled trial of manual methods: results of a pilot study.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
PDI McGill pain questionnaire VAS SF-36 BDI	Base line week three, week 6, week 12 and week 24	24 weeks	39 started treatment phase but only 36 completed	Yes	Placebo control group	Randomization into groups: - FDCT and TP - instrument assisted adjusting and effleurage	7	87.63%

LIMITATIONS:

Limitations associated with this study included:

- This was a pilot study structured principally to test the efficacy of a study design. This study was however included in the review process as it included FDCT as part of the treatment intervention.
- Based on this pilot study structure, the study has some inherent flaws in its design, which include but may not be limited to:
  - Sample size.
  - Concealed allocation.
  - Lack of blinding of therapists, which questions the bias to which the repeated measures were exposed.
  - The combination of interventions within each of the intervention groups, therefore negating the possibility of identifying the effect of the active intervention.
  - The intervention period was just inside of the natural history of CPP.

	▪ Use of multiple clinicians for interventions between and within sites, with the application of the inventions unique to the clinicians. This clinician bias was noted (by the authors) to have potentially influenced the results. ▪ The participants also started other interventions for their conditions during the study period. There was no formal analysis of the interventions.
OUTCOME:	There were no differences between the groups at baseline, collectively there seemed to be no difference between the groups at the conclusion (although the discussion suggested that the placebo group improved to a greater extent).
DISCUSSION:	Although the attempt at the standardization of protocols among sites and intervention procedures can be commended, it seems that this influenced the outcomes directly. As this was a pilot study; it was not designed to investigate the efficacy of chiropractic care for symptoms of CPP. It was designed to provide the investigators with information on whether it is feasible to move forward with plans for a RCT on that topic. Nevertheless, the inclusion of particular interventions can at times provide for direct / indirect evidence in favour of an intervention. As a result, of these two principle points, along with the other limitations noted in this study, it is suggested that this study does not provide any evidence to support FDCT as an intervention technique.

Conclusion:

Based on the analysis in **Table 4.37**, it is evident that the study had several structural flaws that limit its ability to extrapolate the findings without first addressing these concerns. This falls within the aim of the study – a pilot to determine feasibility. As a result, this study provides no evidence in support of FDCT for use in patients with chronic pelvic pain. The ambiguity of the study is evident in the reviewer's review of the study in **Table 4.36**, where the reviews ranged from 10 to 6, and 7 between the reviewers. The areas in which the reviewers disagreed were directly related to the analysis of the results for this study – implying that these

posed significant faults within this study. However, within the context of the limited sample size, this is expected. Therefore, the outcome of the reviewer's ranking indicates that the "no evidence" this study brings to the clinical use of FDCT is indeed valid.

Table 4.38 Tabulated Feedback Data for Group 2 – RCT - Article 7

AUTHOR(S):	Hawk *et al*.					
YEAR:	2005					
TITLE:	A randomized trial investigating a chiropractic manual placebo: a novel design using standardized forces in the delivery of active and control treatments.					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Ranking**	**Percentage Agreement**
1	Eligibility criteria were specified	Y	Y	Y	Y	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Y	Y	Y	Y	100%
3	Allocation was concealed	Y	N	Y	Y	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	Y	Y	Y	Y	100%
5	There was blinding of all subjects	Y	N	Y	Y	66%
6	There was blinding of all therapists who administered the therapy	N	N	N	N	100%
7	There was blinding of all assessors who measured at least one key outcome	Y	Y	Y	Y	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Y	Y	Y	Y	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 analysed by “intention to treat”	Y	Y	Y	Y	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Y	Y	Y	Y	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Y	Y	Y	Y	100%
	TOTAL SCORE	**10**	**8**	**10**	**10**	
		OVERALL PERCENTAGE AGREEMENT:				**90.72%**

Table 4.39 Properties of study, outcome and discussion – Group 2 – RCT– Article 7

AUTHOR(S):	Hawk *et al*.
YEAR:	2005
TITLE:	A randomized trial investigating a chiropractic manual placebo: a novel design using standardized forces in the delivery of active and control treatments.

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
PDI, VAS, RMQ, BDI and SF-36	PDI - visit 4, VAS, RMQ, BDI and SF-36 - baseline and visit 9	Three weeks.	A total of 111 participants were included into the study.	Yes	Yes	Randomization of participants into groups: - FDCT and TP - sham adjusting and effleurage	10	90.72%

LIMITATIONS:	Limitations of this study were related to the large variation between participants in terms of their low back pain presentation, and age. Further it would seem that the consumption of medication (over the counter or chronic medications) were not seen as confounders and excluded. These three inclusion / exclusion criteria compromise the integrity of the results as they are potentially responsible for differences between the groups. It was, however, noted (to the author's credit) that these factors did not cause a difference in the outcomes of the two groups when these factors were controlled for in the statistical analysis. To compound the above, the participants were exposed to more than one form of intervention, leading to the conclusion that no comment could be made about any one form of care and the identification of the active care intervention was not possible.

	The blinding of the person responsible for measurements was not noted. The authors also noted that the length of time that the study ran for may have been too short for commenting on the effectiveness of the interventions, particularly due to the chronicity of the participant's complaint.
OUTCOME:	There were no noted differences between the two groups with the exception of duration of low-back pain, which was greater in the control group. The proportion of participants who had experienced either FDT or Activator technique showed that more participants in the active than the control group had experienced FDT (28% versus 16%, respectively). As noted in the study, the control group participants were more likely than active group participants to accurately perceive their treatment. Participants in both treatment groups improved on the PDI and the RMQ, but there were no differences in improvement between groups.
DISCUSSION:	The outcome of this study suggests that there is no difference between the control group (sham manipulation and effleurage) and the FDCT group (FDCT with trigger point therapy) in terms of the outcomes of the study, even controlling for the factors that may have influenced this. This may be attributed, as the authors suggest, to the brevity of the study and the converse length of time that the participants noted as the duration of their complaint. As a result, within the short term, this study suggests that there is no evidence to support FDCT intervention with trigger point therapy to be any better than the sham manipulation and effleurage.

Conclusion:

This rigorous study (rated as a 10 by the reviewers) (**Table 4.38**) suggests strong support in favour of no evidence in support of a combination of FDCT and trigger point therapy for patients with low back pain.

4.4.2.1 Discussion

Table 4.40 Comparison of Outcome and Methodological Strength of RCTs

Study Type:	**Randomised Clinical Trials**			
Author(s)	**Year:**	**Reported Outcome:**	**Ranking:**	**Outcome in favour of FDCT:**
Hawk *et al.*	2007	Feasibility study of short-term effects of chiropractic manipulation on older adults with impaired balance.	4	Limited
Hawk and Long	2000	Use of a pilot to refine the design of a study to develop a manual placebo treatment.	8	Limited
Hawk *et al.*	1999	Preliminary study of the effects of a placebo chiropractic treatment with sham adjustments.	6	Limited
Hondras *et al*.	2009	A randomized controlled trial comparing 2 types of spinal manipulation and minimal conservative medical care for adults 55 years and older with subacute or chronic low back pain.	8	Moderate to strong
Schulz *et al.*	2011	Chiropractic and self-care for back-related leg pain: design of a randomized clinical trial.	7	No evidence
Wilder *et al.*	2011	Effect of spinal manipulation on sensorimotor function in back pain patients: study protocol for a randomised controlled trial.	8	No evidence
Zylbergold and Piper	1985	Cervical spine disorders: a comparison of three types of traction.	6	Limited
Beyerman *et al*.	2005	Efficacy of treating low back pain and dysfunction secondary to osteoarthritis: chiropractic care compared with moist heat alone.	5	Limited
Bronfort *et al*.	2004	Spinal manipulation, epidural injections, and self-care for sciatica: a pilot study for a randomized clinical trial.	6	Limited
Gudavalli *et al*.	2006	A randomized clinical trial and subgroup analysis to compare flexion-distraction with active exercise for chronic low back pain.	9	Strong
Cambron *et al*.	2006	Amount of health care and self-care following a randomized clinical trial comparing flexion-distraction with exercise program for chronic low back pain.	8	Moderate
Cambron *et al*.	2006	One-year follow-up of a randomized clinical trial comparing flexion-distraction with an exercise program for chronic low-back pain.	7	Moderate
Hawk *et al*.	2002	Issues in planning a placebo-controlled trial of manual methods: results of a pilot study.	7	Limited
Hawk *et al*.	2005	A randomized trial investigating a chiropractic manual placebo: a novel design using standardized forces in the delivery of active and control treatments.	10	No evidence

4.5 Overall discussion and conclusions

4.5.1 Limitations of NOS

It was reported by the reviewers, that the NOS was difficult to interpret. This was based on some incongruence between the NOS and the articles reviewed. However, as the NOS is the preferred scale for n-RCTs (Wells *et al.,* 2003; Dagenais and Haldeman, 2012, and Hartling *et al.,* 2012), it is inappropriate to steer away from the accepted norm applied within the research setting as the norms are validated, responsive and appropriate scales for particular contexts (Higgins and Green, 2008; Liberati *et al.,* 2009, and Moher *et al*., 2009). Another possible reason for reviewer difficulty was not being familiar with the NOS and its application (although this was controlled for in this study – see end of Section 3.6.2).

Updating of criteria on scales and the renewal of scales is also a consideration in terms of their contextual applicability (Wells *et al*., 2012), as well as the possibility that some publications may be hybrid in the manner in which they present research – viz. not falling into the appropriate category of research with explicit ease.

4.5.2 Conclusions of n-RCTs:

Hawk *et al.,* (1997)

This study suggests that multimodal chiropractic has positive effects on symptoms of CPP, however the significant limitations serve to significantly minimise the ability of this study to contribute to the literature in support of multimodal care for chronic pelvic pain.

Therefore, the current documentation around the effects of chiropractic care (in particular FDCT) in CPP is *limited.* Further studies could demonstrate a useful adjunct and result in the inclusion of chiropractic into multidisciplinary approaches to CPP.

Rowell and Polipnick, (2008)

Through the analysis of the publication, the limitations outweigh the clinical outcomes and therefore limit the discussion on the effectiveness of the intervention in the treatment of low back pain. This indicates that the study did not fulfil the requirements of this scale to sufficiently allow for it to be a rigorous study and thus *limits* the ability to contribute to the body of literature with regards to FDCT. From this study, the role of FDCT can therefore not be determined.

Bulbulian *et al.,* (2002)

The NOS determines set criteria that allow for the outcomes of a study to be translated into the context of clinical practice. As a result of the *limited* ability to which this study addresses clinical practice, it is only natural that the rating obtained by the reviewers would be low. This low rating therefore suggests that although positive physiological outcomes where obtained in the use of FDCT, it is necessary for this phenomenon to be tested in clinical practice and on patients that present with pathologies before a decision can be made in respect of the level of evidence that this physiological phenomenon of FDCT may contribute to the clinical improvement of patients with low back pain.

Strunk and Hawk (2009)

This outcome suggests that although the use of FDCT within the context of a multimodal intervention series may be of benefit, ascribing the improvements seen to FDCT would be inappropriate and therefore the level of evidence that this study brings to the clinical application of FDCT for mechanical neck pain and / or dizziness and balance is at best *limited*. This outcome suggests that further studies should be performed to elucidate the possibility that FDCT may have a greater role to play in these conditions.

4.5.3 Conclusions of RCTs

One reviewer commented that any computer generated randomization (or stratified randomization) was scored as “allocation was concealed”. This may be a problem with interviewer agreement for that criterion as randomizations can occur independent of concealment.

Hawk *et al.,* (2007)

This study has significant methodological flaws and therefore has *limited* ability to contribute to evidence in favour or not in favour of FDCT.

Hawk and Long (2000)

Significant limitations have severely hampered the outcomes of the reviews and as a result the ability of the study to contribute to the evidence in favour of or not in favour of FDCT is at best limited, therefore it is suggested that the contribution of this publication is equivalent to *limited evidence*.

Hawk *et al*., (1999)

With the outcomes of the study being definitively affected by the limitations noted, this reviewer outcome suggests that although the study has some limited rigour. Therefore, this study has only a *very limited* ability to contribute to the literature on FDCT.

Hondras *et al.,* (2009)

While some structural deficiencies exist, the study ranked highly amongst reviewers. These limitations however do not *detract sufficiently from the outcomes of the study and therefore infers that there is moderate to strong evidence* for the use of FDCT in the treatment of older adults with low back pain.

Schulz *et al.,* (2011)

While providing a methodology of high rigour, a lack of outcomes, results in this study offering *no evidence* in support of the use of FDCT.

Wilder *et al.,* (2011)

Similarly to Schulz *et al*., (2011), a lack of outcomes does not allow for the high methodological rigour to have any effect on the evidence; hence *no evidence* in support of the use of FDCT can be afforded.

Zylbergold and Piper,(1985)

With an indication of strong rigour, but high impact of limitations, the level of evidence that this study provides is at best *limited* in its support of traction (FDCT), and thus a suggestion for follow up studies need to be considered to refute or support the outcomes of this study.

Beyerman *et al*., (2005)

The outcome suggests that the evidence in favour of FDCT for the clinical treatment of low back pain is at best, *limited*, with the feeling that this outcome requires further testing and validation through the use of more rigorous RCTs in order to exclude the extraneous factors that have had an impact on this study.

Bronfort *et al*., (2004)

While being structured to that of a rigorous CT, several limitations exist that severely reduces score rating. As a result of these limitations, the study *has no ability to present any evidence* in support of the chiropractic care (in particular FDCT) and thus does not contribute to the current knowledge base for this intervention strategy.

Gudavalli *et al*., (2006)

This study provides moderately strong evidence in support of the use of FDCT for the use in patients with low back pain. This assertion is underpinned by the high review ranking that was attained by this study, where there was a high level of agreement between the examiners. Therefore, this publication provides *strong evidence* in support of the clinical use of FDCT for treating low back pain over the short term.

Cambron *et al*., (2006)

The results have shown that the FDCT intervention has a better prognosis over the long term (however not statistically significant) for patients with low back pain. Taking into account the limitations, level of agreement and structure of this study, the outcomes of this study provide for *moderate outcomes* in favour of health seeking care after an interval of FDCT intervention with long term follow up.

Cambron *et al*., (2006)

The outcomes of this study provide for *moderate outcomes* in favour of clinical outcomes, in particular in reference to pain scores; for which FDCT has a better prognosis over the long term (for patients with low back pain).

Hawk *et al*., (2002)

While the aim of the study was a pilot to determine feasibility, it is evident that the study had several structural flaws that limit its ability to extrapolate the findings. As a result, this study provides *no evidence* in support of FDCT for use in patients with CPP.

Hawk *et al*., (2005)

This rigorous study (rated as a 10 by the reviewers) suggests strong support in favour *of no evidence* in support of a combination of FDCT and trigger point therapy for patients with low back pain.

4.5.4 Conclusion

Based on the above, it would seem that there is limited to moderate evidence in support of FDCT generally. However, as the above studies have different contexts (e.g. neck pain and low back pain); the next Chapter (Chapter Five) will present a breakdown of evidence per anatomical region / clinical complaint, in order to determine the levels of evidence for these specific regions / complaints.

Chapter Five

Discussion of Results

5.1 Introduction

Based on the results of Chapter Four, Chapter Five determines the level of evidence to support the use of FDCT in various clinical categories.

5.2 Review of interventions per condition for flexion distraction Chiropractic technique

Post review process, the following patient conditions were noted as being treated using FDCT:

Table 5.1 Interventions per condition

NECK PAIN		
Zylbergold and Piper 1985	• Spondylosis • Cervical disc disease • Osteoarthritis	• Static traction • Intermittent traction • Manual traction • Neck care
Strunk and Hawk 2009	• Dizziness • Mechanical neck pain	• Spinal manipulative therapy (SMT): Diversified, Instrument assisted, Drop table SMT and flexion distraction (FD) • Soft tissue: Myofascial release, Post isometric relaxation with heat and cold
PHYSIOLOGICAL MECHANISMS		
Hawk *et al.,* 2007	• Dizziness	• Chiropractic care: Diversified and modified (lower force) adjustive procedures, myofascial release, hot / cold therapy. • Supervised exercise: balance exercises
Bulbulian 2002	• Muscle reflex	• FDCT
LOW BACK PAIN		
Wilder *et al.,* 2011	• Low back pain	• Sham treatment • High velocity low amplitude spinal manipulation (HVLA-SM) • Low velocity variable amplitude spinal manipulation (LVVA-SM)
Schulz *et al.,* 2011	• Back related leg pain	• Home Exercise Programme (HEP) • SMT + HEP
Bronfort *et al.,* 2003	• Back related leg pain	• Chiropractic treatment, FD, Mobilisation, Soft tissue, heat and cold, Epidural injection
Hondras *et al.,*	• Low back pain	• High velocity low amplitude spinal manipulation (HVLA-SM)

		• Low velocity variable amplitude spinal manipulation (LVVA-SM) • HVLA-SM • LVVA-SM • minimal conservative medical care (MCMC)
Hawk *et al.,* 1999	• Low back pain	• Flexion distraction Chiropractic technique (FDCT) • Sham adjustment (activator)
Hawk and Long 2000	• Low back pain	• FDCT and trigger point therapy (TP) • Sham and effleurage • FDCT and effleurage • Sham and TP
Rowell and Polipnick 2008	• Low back pain	• FDCT • Diversified
Hawk *et al.,* 2005	• Low back pain	• FDCT and TP • Sham and effleurage
Cambron *et al.,* 2006	• Low back pain	• FDCT • Exercise programme
Cambron *et al.,* 2006	• Low back pain	• FDCT • Exercise programme
Gudavalli *et al.,* 2006	• Low back pain	• FDCT • Active trunk exercise protocol
Beyerman *et al.,* 2005	• Low back pain	• FDCT and hot pack • Hot pack
PELVIC PAIN		
Hawk, Long and Azad 1997	• Chronic pelvic pain	• FDCT and TP
Hawk *et al.,* 2002	• Chronic pelvic pain	• FDCT and TP • Instrument assisted adjusting and effleurage (light)

5.3 Discussion of the criteria for ranking evidence

Based on the studies reviewed in the previous chapter, each of the interventions / combinations of interventions noted in Table 5.1 were ranked according to the level of evidence which they produced in the context of FDCT.

Using the criteria as delineated by Foley *et al.,* (2003), it is now possible to collectively consider the level of evidence that is available for each of the conditions that FDCT was applied in – viz. cervical spine pathology, lumbar spine pathology, chronic pelvic pain and lastly in normal subjects in which physiological reflexes were elicited.

The levels of evidence are outlined as follows:

Strong: This is when the findings of studies within one area (e.g. neck pain) are supported by the results of two or more randomised controlled trials (RCTs) of at least “fair / moderate” quality.

Moderate: This is when the findings of studies within one area (e.g. neck pain) are supported by the results of one RCT of at least “fair / moderate” quality.

Limited: This is when the findings of studies within one area (e.g. neck pain) are supported by the results of at least one non-experimental study (e.g. non-randomised controlled trials (n-RCT)).

Consensus: In this context either:

a. In the absence of evidence, consensus or agreement can be reached by a group of experts on the appropriate treatment course for a condition (e.g. neck pain). This is the lowest form of evidence.

b. This is when the data between the studies agree that the outcome for a particular intervention is consistent – i.e. the outcomes are always strong evidence in favour of or against a particular intervention for a particular condition. This latter has been utilised in this study.

Conflicting: By contrast to the consensus, here there is disagreement between the findings of at least two RCTs. When there are multiple RCTs and the results of only one is conflicting, the conclusion is usually based on the results of the majority of the studies, unless the study with the conflicting results is of higher quality.

No evidence: This is self-evident, particularly when there are low grade studies showing limited or no evidence or conversely high grade studies that show that the tested intervention is no better than a placebo group.

5.4 Ranking of evidence for each of the interventions

5.4.1 Neck pain

Table 5.2 Condition: Neck Pain

Author(s) / Year:	Study Type:	Ranking:	Level of Evidence					
			Strong	Moderate	Limited	Consensus	Conflicting	No Evidence
Zylbergold and Piper 1985	RCT	6			X		X	
Strunk, R.G., and Hawk 2009	n-RCT	4						

The analysis of the Zylbergold and Piper (1985) study indicated a moderate ranking of methodological rigour for this study. Within this context, the outcomes of the study showed that intermittent traction (FDCT) significantly improved the clinical outcomes of the patients in comparison to the no traction group. This resulted in a *moderate level of evidence* provided by this study for patients with neck pain.

Conversely, Strunk and Hawk (2009), while having a moderate to low ranking of methodological rigour, produced an inability to determine the effects of chiropractic care on dizziness due to lack of a comparison group. This provided *no evidence* in the treatment of neck pain.

By considering the level of evidence for neck pain based on the above two studies, it is the opinion of the researcher that limited evidence for the use of FDCT for neck pain exists which is conflicting.

5.4.2 Physiological Mechanisms

Table 5.3 Physiological Mechanisms

Author(s) / Year:	Study Type:	Ranking:	Level of Evidence					
			Strong	Moderate	Limited	Consensus	Conflicting	No Evidence
Bulbulian *et al*., 2002	n-RCT	1			X	X		X
Hawk *et al*., 2007	RCT	4						

Bulbulian *et al*., (2002) reported that in response to FDCT, there was an attenuation of spinal reflex response. However, this systematic review showed poor methodological rigour with limited outcomes due to high levels of methodological limitations. It would be difficult to infer a result, therefore further testing would be necessary to demonstrate the efficacy of FDCT on spinal reflex response; resulting in *limited evidence*.

Hawk *et al*., (2007) looked to collect information to determine the effect of an adjustment on older adults with diminished balance in order to reduce falls. An analysis of this study by Hawk *et al*., (2007) pointed to limited methodological rigour within the study. Furthermore, due to the significant limitations, the authors noted that the results for balance, dizziness and chronic pain, would be difficult to ascertain and a conclusion with regard to its efficacy impossible to extrapolate. Therefore, the evidence at best is *very limited to no evidence*.

By considering the level of evidence for physiological mechanisms based on the above two studies, it is the researcher's opinion that the evidence indicates consensus and limited evidence to no evidence for the use of FDCT.

5.4.2 Low Back Pain

Table 5.4 Condition: Low Back Pain

Author(s) / Year:	Study Type:	Ranking:	Level of Evidence					
			Strong	Moderate	Limited	Consensus	Conflicting	No Evidence
Single Intervention								
Hawk *et al.,* 1999	RCT	6		X			X	
Bronfort *et al.,* 2004	RCT	6						
Cambron *et al.,* 2006	RCT	7						
Cambron *et al.,* 2006	RCT	8						
Gudavalli *et al.,* 2006	RCT	9						
Rowell and Polipnick 2008	n-RCT	2						
Hondras *et al.,* 2009	RCT	8						
Wilder *et al.,* 2011	RCT	8						
Multimodal								
Hawk and Long, 2000	RCT	8		X			X	
Beyerman *et al.,* 2005	RCT	5						
Hawk *et al.,* 2005	RCT	10						
Schulz *et al.,* 2011	RCT	7						

Due to the discordance between the limitations and outcomes in the study by Hawk *et al*., (1999), it could be concluded that there is a *lack of evidence* afforded to the use of FDCT on patients with low back pain.

The methodological ranking (6/11) of Bronfort *et al.,* (2004) suggests that of a fairly rigorous clinical trial, but also a number limiting flaws, resulting in a study which reflects *limited to no evidence* to support FDCT.

While analysing Cambron *et al.,* (2006) and Table 4.32 and Table 4.33, it is suggested that the strong methodological ranking provides for a *moderate level of evidence* in the support of FDCT for the treatment of low back pain within the context of the outcomes of the study.

Cambron *et al.,* (2006) provides strong methodological rigour to their study and along with the high level of reviewer agreement, the support for the use of FDCT treatment can be considered as being strong, resulting in a *strong level of evidence*.

A study by Gudavalli *et al*., (2006) compared FDCT to active exercise. With a strong methodological rigour, a *strong level of evidence* exists to support the use of FDCT for low back pain over a short term period.

An analysis of Rowell and Polipnick's (2008) n-RCT indicates that insufficient rigour and structure to the study as well as a limited ranking showed that the role of FDCT could not be determined in its use for patients' satisfaction with low back pain (*limited to no evidence*).

By contrast, the study by Hondras *et al.,* (2009) assessing the use of two types of spinal manipulation (including FDCT) and minimal conservative medical care for the treatment of low back pain in older patients; provides for a *moderate to strong level of evidence* based on the review of the study and its high methodological ranking. Thus, it could be suggested that there is moderate to strong evidence to support the use of FDCT on older patients with low back pain.

By contrast, the study by Hondras *et al.,* (2009) assessing the use of two types of spinal manipulation (including FDCT) and minimal conservative medical care for the treatment of low back pain in older patients; provides for a *moderate to strong level of evidence* based on the review of the study and its high methodological ranking. Thus, it could be suggested that there is moderate to strong evidence to support the use of FDCT on older patients with low back pain.

Hawk and Long (2000) considered the design of a placebo treatment protocol for the treatment of low back pain. While the structure of this article was ranked very strongly by the reviewers, several significant limitations resulted in the level of evidence provided by this study to be *limited* at best.

Beyerman *et al.,* (2005) considered the use of chiropractic care (including FDCT) in comparison to moist heat alone for the treatment of low back pain secondary to

osteoarthritis. While the study achieved a moderate ranking, in terms of methodological rigour, limited evidence was achieved due to several limitations as noted in Table 4.27. Thus, it was suggested that FDCT (with moist heat) may provide some favourable outcome in the treatment of low back pain secondary to osteoarthritis. Therefore, the level of evidence for FDCT alone is *limited*.

A very high ranking and high reviewer agreement, indicates that the study by Hawk *et al.,* (2005) suggested strong support of a *lack of evidence* in regard to the combination of FDCT with trigger point therapy for patients with low back pain.

With regards to Schulz *et al*., (2011) and Wilder *et al.,* (2011), there is an inability to categorise the outcomes effectively as the ranking provided by the reviewers could not be linked to the outcomes for the FDCT utilised in their study. This was as a result of the lack of published results that were attached to the publication. Thus, without the final clinical outcomes, *no level of evidence* could be attached to these two studies and they have been excluded from contributing to the overall outcomes of the level of evidence in support / not in support of the FDCT.

Therefore, by considering the level of evidence for low back pain based on the above ten studies (excluding Schulz *et al*., (2011) and Wilder *et al.,* (2011)), it is suggested, based on the criteria of Foley *et al.,* (2003), that the research outcomes for FDCT are contradictory. Notwithstanding this, the level of evidence for and against this technique is moderate.

5.4.2 Pelvic Pain

Table 5.5 Condition: Pelvic Pain

Author(s) / Year:	Study Type:	Ranking:	Level of Evidence					
			Strong	Moderate	Limited	Consensus	Conflicting	No Evidence
Hawk, Long and Azad, 1997	n-RCT	1			X	X		X
Hawk *et al*., 2002	RCT	7						

While Hawk, Long and Azad, (1997) showed positive effects on chronic pelvic pain, the level of evidence while using multimodal chiropractic care can only be ranked as limited due to the significant limitations. Therefore, the evidence is at best ***limited.***

While the study by Hawk *et al*., (2002) was a pilot study to determine feasibility, no to limited evidence was attained from the study due to structural flaws. Based on the reviewer ranking, it is suggested that the methodological rigour is of a moderate level and in the context of the outcomes; *no evidence* can be offered by FDCT for pelvic pain.

Therefore, by considering the level of evidence for chronic pelvic pain based on the above two studies, it is suggested, based on the criteria of Foley *et al.,* (2003), that the research outcomes for FDCT results in *limited* to *no evidence* for chronic pelvic pain.

5.5 Conclusion of Chapter Five

Table 5.6 Level of evidence for conditions

Conditions:	Level of Evidence					
	Strong	Moderate	Limited	Consensus	Conflicting	No Evidence
Neck pain			X		X	
Physiological Mechanisms			X	X		
Low back pain – single intervention		X			X	
Low back pain – multimodal intervention		X			X	
Pelvic Pain			X	X		X

In terms of Table 5.6 above, the strongest level of evidence favoured the use of FDCT for the use in treating patients for low back pain (either as a single intervention or as part of a multimodal intervention strategy). However, this evidence did have some contradictory / conflicting studies which suggested that FDCT was either better than placebo or, at times, significantly better than placebo. Therefore, it is evident that future studies are required to validate the use of this technique in practice. It is hoped that the studies of Schulz *et al.,* (2011) and Wilder *et al.,* (2011) would be able to contribute to this debate and allow for more definitive decision making based on the available evidence.

In a similar manner, the use of FDCT is also conflicting for neck pain, however conflicts exist between studies that are of a limited level of evidence and therefore this study suggests that there is a need for increased research in this domain to assist with categorically defining the level of evidence for the use of FDCT in the treatment of neck pain. Thus, there if currently limited evidence to support the use of FDCT in clinical practice.

By contrast the use of the FDCT for patients with chronic pelvic pain seems to be consistent, however because of the poor studies or the limited ability to comment on FDCT specifically (as a result of multimodal care), the evidence is limited. This

requires future studies with larger sample sizes in order to validate the small studies that provide the current limited evidence. Therefore, it is suggested that the use of FDCT be limited to patients with similar clinical presentations as those seen in the reviewed studies in order to avoid the use of this technique in patients that potentially would not benefit from its use.

Similarly, it has been shown that FDCT is able to elicit physiological responses consistently, although the evidence is limited by small sample sizes and methodological flaws within the current published literature. In a similar manner to chronic pelvic pain, this area requires further, larger studies in order to validate these initial outcomes. In addition, the impact of these physiological reflexes on assisting with the amelioration of clinical pain syndromes needs to be investigated further before more specific recommendations can be made for the use of FDCT in clinical practice, based on these principles.

When reviewing the above results, it would suggest that with fewer studies (that are of a good methodological rigour), there is an increased likelihood for a consensus in the available evidence, which collectively would result in higher levels of evidence in support of or against a particular intervention. In terms of the low back pain studies reviewed in this systematic review, it can be seen that an increase in the numbers of studies (as compared to the other clinical categories) seems to result in increased conflict in the outcomes of the clinical results attained, which may hinder the ability of the collective evidence to achieve higher evidence levels through a consensus. By contrast, two of the smaller groups (pelvic pain and physiological mechanisms categories) achieved consensus with fewer studies. However, the impact of the methodological rigour of the studies hampered the ability of the studies to collectively attain a high level of evidence.

Based on the above, it is therefore suggested that further high quality and rigorous studies are completed and published according to the CONSORT (Berkman *et al*., 2013), or other appropriate guidelines. This is required in order to reduce the likelihood of poor study quality and / or reporting resulting in a compromised picture of evidence that does not allow for conclusive or definitive guidelines to be established. The lack of these guidelines means that field practitioners have limited

guidance as to the clinical utility of particular interventions (in this instance FDCT) and thus they are not able to provide appropriate information to patients from which these patients can make informed decisions about their care (Sackett *et al*., 1997).

Chapter Six
Conclusion and Recommendations

6.1 Introduction

This chapter will conclude this dissertation and present recommendations for future studies.

6.2 Conclusions

The aim of this study was to conduct a systematic review to determine the evidence to support the use of flexion distraction Chiropractic technique (FDCT) in clinical practice. By systematically searching for articles according to inclusion and exclusion criteria, a total of 18 articles were found and reviewed. These were subsequently ranked according to specified scales and criteria. This chapter summarises the current strengths in FDCT, in addition to guide future research.

Based on Chapter Four, the articles were reviewed and given an overall methodological ranking by considering the limitations and outcomes of each of the included study. Studies were ranked in terms of “no evidence”, “limited evidence”, “moderate evidence” and “strong evidence”. Two articles presented no evidence due to their results not being published, 12 articles were limited in their strength of evidence, two showed moderate levels of evidence, one for moderate to strong, and one for strong evidence to support the use of FDCT in clinical practice.

Chapter Five however, commented and discussed the aggregated articles in terms of the conditions treated (e.g. neck pain and low back pain), in order to determine the levels of evidence for these specific regions / conditions. The majority provided no to limited evidence with the exception of 3 articles (low back pain – moderate to strong evidence for the use of FDTC in clinical practice).

Therefore, in the context of the aims and objectives of this study, it was determined that the use of FDCT in the investigated conditions was rated as limited.

6.3 Recommendations

6.3.1 Recommendations to improve this study

- Increase the budget funds available to the researcher, to enable the inclusion of English articles,
- Provide the reviewer with a mock review so they are familiar with the scales and
- Include those results of Wilder *et al.,* (2011) and Schulz *et al*., (2011).

6.3.2 Recommendations for future studies

- In reviewing the articles for inclusion into this study, a wealth of case series and reports were found. Although these were not evaluated in this study, they provide a valuable resource for investigating the use of FDCT in a variety of conditions. However, the only mechanism to validate and provide further evidence for FDCT would be to use these case series and reports as a basis for future RCTs.
- Setting a minimum number of participants per included study would further strengthen the evidence thereby eliminating non-RCTs and RCTs with very small sample sizes.
- Well-designed RCTs to investigate efficacy of FDCT for the various conditions FDCT purported to treat.

6.3.3 Recommendations for practitioners

In conclusion, evidence for the use of FDCT can be found in its application to low back pain conditions, with a moderate level of evidence provided through this study. While limited evidence exists in the use of FDCT for neck pain, physiological effects and pelvic pain, it is up to the practitioner to alert the patient to the fact that limited evidence exist in its treatment efficacy.

References

Activator Methods®, 2012. *Activator Methods* (online). Available: www.activator.com (Accessed 05 November 2013).

Adams, M.A., and Roughley, P.J. 2006. What is intervertebral disc degeneration and what causes it? *The Spine Journal*, 31:2151-2161.

Ailliet, L., Rubinstein, S. M., and De Vet, H. C. W. 2010. Characteristics of Chiropractors and their Patients in Belgium. *Journal of Manipulative and Physiological Therapeutics,* 33(8): 618.

Alliance Chiropractic Center. 2013. The patient positioning and procedure for FDCT (image). Available: http://alliancechiropracticcenter.com/contact-us.html (Accessed 10 December 2013).

Anderson, R.T. 1983. On doctors and bonesetters in the 16th and 17th centuries. *Chiropractic History*, 3(1): 13-14.

Anderson, R.T. 1992. Spinal manipulation before chiropractic. In: Haldeman, S. *Principles and practice of chiropractic*. Norwalk, Connecticut, USA: Appleton and Lange.

Andersson, G.B.J., Lucente, T., Davis, A.M., Kappler, R.E., Lipton, J.A., and Leurgans, S. 1999. A comparison of osteopathic spinal manipulation with standard care for patients with low back pain. *New England Journal of Medicine*, 341(19):1426-1431.

Babbie, E.R., and Mouton, J. 2001. *The Practice of Social Research.* South African Edition. Cape Town. Oxford University Press Southern Africa.

Barral, J-P. 2005. *Visceral Manipulation*. Vista, California: Eastland Press.

Basmajian, J.V., and Nyberg, R. (eds). 1993. Rational *manual therapies*. Baltimore: Williams and Wilkins.

Baynham, M. 1995. *Literacy Practices: Investigating Literacy in Social Contexts.* London: Longman.

Bergh, Z.C., and Theron, A.L. 1999. Psychology in the Work Context. 1st Ed. South Africa: International Thompson Publishing.

Bergmann, T.F. and Peterson, D.H. 2011. *Chiropractic Technique: Principles and Procedures.* 3rd ed. Mosby.

Bergmann, T.F., Peterson, D.H. and Lawrence, D.J. 1993. *Chiropractic Technique.* 7th ed. London, United Kingdom, Churchill Livingstone.

Berkman, N.D., Lohr, K.N., Morgan, L.C., Kuo, T-M., and Morton, S.C. 2013. Interrater reliability of grading strength of evidence varies with the complexity of the evidence in systematic reviews. *Journal of Clinical Epidemiology*, 66:1105-1117.

Beyerman, K.L., Palmerino, M.B., Zohn, L.E., Kane, G.M., Foster, K.A. 2005. Efficacy of treating low back pain and dysfunction secondary to osteoarthritis: chiropractic care compared with moist heat alone. *Journal of Manipulative and Physiological Therapeutics*, 29(2): 107-114.

Brink, H. 1996. *Fundamentals of research methodology for health care professionals.* Cape Town. Juta.

Bronfort, G., Evans, R.L., Maiers, M., and Anderson, A.V. 2004. Spinal Manipulation, Epidural Injections, and Self-Care for Sciatica: A Pilot Study for a Randomized Clinical Trial. *Journal of Manipulative and Physiological Therapeutics,* 27(8):503-508.

Bulbulian, R., Burke, J., and Dishman, J.D. 2002. Spinal reflex excitability changes after lumbar spine passive flexion mobilization. *Journal of Manipulative and Physiological Therapeutics,* 25(8): 526-532.

Byfield, D. 2012. *Technique skills in chiropractic*. Churchill Livingstone/Elsevier,

Cambron, J.A., Gudavalli, M.R., McGregor, M., Jedlicka, J., Keenum, M., Ghanayem, A.J., Patwardhan, A.G., and Furner, S.E. 2006. Amount of health care and self-care following a randomized clinical trial comparing flexion-distraction with exercise program for chronic low back pain. *Chiropractic and Osteopathy*, 14:19.

Cambron, KJ.A., Gudavalli, M.R., Hedeker, D., McGregor, M., Jedlicka, J., Keenum, M., Ghanaym, A.J., Patwardhan, A.G., and Furner, S.E. 2006. One-Year Follow-Up of a Randomized Clinical Trial Comparing Flexion-Distraction with an Exercise Program for Chronic Low-Back Pain. *The journal of Alternative and Complementary Medicine*, 12(7): 659- 668.

Cassell C and Symon G, 2005. *Essential guide to qualitative methods in organizational research*. London. Sage Publications Ltd.

Chaitow, L. 2006. *Muscle energy techniques.* 2nd ed. Edinburgh: Churchill Livingstone; 2006

Chaitow, L., DeLany, J. 2000. *Clinical Application of Neuromuscular Techniques: The upper body*. London, United Kingdom, Churchill Livingstone.

Chapman-Smith, D. 2000. *The Chiropractic Profession*. Canada: Harmony Printing Limited

Chiropractic Association of South Africa, 2013. *Chiropractic Association of South Africa* (online). Available: www.chiropractic.co.za (accessed 05 November 2013).

Christensen, M.G., and Kollasch, M.W. 2005. *Professional functions and treatment procedures* (online). Available: http://nbce.org/pdfs/job-analysis/chapter_10.pdf (Accessed 24 August 2008).

Clarke, M. 2007. The Cochrane collaboration and systematic reviews. *British Journal of Surgery,* 94(4): 391-2.

Coleman, R.R., and Troyanovich, S.J. 2005. *A Brief History of Lumbar Traction in Chiropractic Rehabilitation* (online). Available: http://www.theamericanchiropractor.com/articles-rehabilitation/5569-a-brief-history-of-lumbar-traction-in-chiropractic-rehabilitation.html (Accessed 20 October 2013).

Colledge, N.R. (ed.), Walker, B.R. (ed.) and Ralston, S.H. (ed.) 2010.*Davidsons Principles and Practice of Medicine*. 21st ed. Churchill Livingstone.

Cook, D.J., Mulrow, C.D., and Haynes, B.R. 1997. Systematic Reviews: Synthesis of Best Evidence for Clinical Decisions. *Annals of Internal Medicine*, 126(5): 376-380.

Cooperstein, R., and Gleberzon, B.J. 2004. *Technique Systems in Chiropractic*. Churchill Livingstone.

Cox, J.M., and Aspegren, D.D. 1987. A hypothesis introducing a new calculation for discal reduction: emphasis on stenotic factors and manipulative treatment. *Journal of Manipulative and Physiological Therapeutics*, 10(6): 287-294.

Cox, J.M. 1990. *Low back pain. Mechanism, diagnosis and treatment*. 5th ed. Philadelphia. Williams and Wilkins.

Cox, J.M., Hazen, L.J., and Mungovan, M. 1993. Distraction manipulation reduction of an L5-S1 disc herniation. *Journal of Manipulative and Physiological Therapeutics*, 16(5): 342-346.

Cox, J.M., Feller, J., and Cox-Cid, J. 1996. Distraction chiropractic adjusting: clinical application and outcomes of 1000 cases. *Topic in Clinical Chiropractic*, 3(3):45-57.

Cox, J.M., and Alter, M. 2001. Schwanoma: Challenging Diagnosis. *Journal of Manipulative and Physiological Therapeutics*, 24(8):526-528.

Cox, J.M. 2006. Distraction manipulation: a review of the literature. *Journal of Manipulative and Physiological Therapeutics*, 29(1): 89-90.

Cox, J.M. 2012. Chiropractic management of a patient with lumbar spine pain due to synovial cyst: a case report. *Journal of Chiropractic Medicine*, 11: 7-15.

Cox® Technic, 2012. *Cox Technic* (online). Available: www.coxtechnic.com (Accessed 05 November 2013).

Creswall, J.W. 2009. *Qualitative, quantitate and mixed methods approaches*. 2nd Edition. Sage Publications Ltd.

Dada, M., and McQuoid-Mason, P. 2011. A-Z of medical law. 1st ed. Capetown: JUTA.

Dagenais, S., Caro, J., and Haldeman, S. 2008. A systemic review of low back pain cost of illness studies in the United States and internationally. *The Spine Journal*, 8:8-20.

Dagenais, S. and Haldeman, S. 2012. *Evidence-Based Management of Low Back Pain*. 1st ed. Los Angeles, California, USA, Mosby

Davies, N.J. 2000. *Chiropractic Pediatrics: A Clinical Handbook*. 1st ed. Saunders Ltd.

Davis, M.A., Sirovich, B.E., and Weeks, W.B. 2010. Utilization and expenditures on chiropractic care in the United States from 1997 to 2006. Health Services Research, 45(3): 748-61.

Deeks, J.J., Dinnes, J., D'Amico, R., Sowden, A.J., Sakarovitch, C., Song, F., Petticrew, M., and Altman, D., 2003. Evaluating non-randomised intervention studies (online). *Health Technology Assessment*, 7(27). Available at: http://www.hta.ac.uk/fullmono/mon727.pdf (Accessed 15 July 2013).

Deyle, G.D., Allison, S.C., Matekel, R. L., Ryder, M.G., Stang, J.M., Gohdes, D.D., Hutton, J.P., Henderson, N.E., and Garber, M.B. 2005. Physical therapy treatment effectiveness for arthritis of the knee: A randomised comparison of supervised clinical exercise and manual therapy procedures versus a home exercise program. *Physical Therapy*, 85(12):1301-1317.

Durban University of Technology. 2013. *Handbook for 2013* (online). Available at: http://www.dut.ac.za/sites/default/files/handbooks/HEALTH%20CHIRO%20AND%20SOMA.pdf (Accessed 05 December 2013)

Dyer, B. 2013. An epidemiological investigation of low back pain in the white Caucasian population in the greater eThekwini Metropolitan Area. MTech Chiropractic Dissertation, Durban University of Technology, South Africa.

Eckard, L. n.d. Literature packet and training manual for use with the Leander table. Leander Research,Washington.

Ellis, R., Hing, W., and Reid, D. 2007. Iliotibial band friction syndrome: A systematic review. *Manual Therapy*, 12(3): 200–208.

Edzard, E. 2003. Chiropractic manipulation for non-spinal pain--a systematic review. New Zealand medical journal, 116(1179): 539.

Ferguson, L.W., and Gerwin, R. 2005. *Clinical Mastery in the Treatment of Myofascial Pain*. Lippincott Williams and Wilkins.

Foley, N.C., Teasell, R.W., Bhogal, S.K., and Speechley, M.R. 2003. Stroke rehabilitation evidence based review: methodology. *Topics in Stroke Rehabilitation*, 10(1): 1-7

Fox, D.M. 2005. Evidemce of Evidence –Based Policy: the Politics of Systematic Reviews in Coverage Decisions. *Health Affairs*, 24(1): 114-122.

Fuhr, A. 2009. *The activator method*. 2nd ed. Los Angeles, California, USA,Mosby Elsevier.

Gatterman, M.I. 1995. *Foundations of Chiropractic – Subluxation*. 1st ed. Mosby.

Gatterman, M.I. 2003. *Chiropractic Management of Spine Related Disorders*. 2nd Edition. Philadelphia, Pennsylvania, USA. Lippincott Williams & Wilkins.

Glazious, P., Vandenbroucke, J., and Chalmers, I. 2004. Assessing the quality of research. *British Journal of Medicine,* 328(7430): 39-41.

Gleberzon, B.J. 2001a. Chiropractic "Name Techniques": A review of the literature. *Journal of Canadian Chiropractic Association,* 45(2): 86–99.

Gleberzon, B.J. 2001b. *Chiropractic care of the older patient*. Kent: Butterworth-Heinemann.

Goodridge, J.P. 1981. Muscle energy techniques: definition, explanation, methods of procedure. *Journal of the American Osteopathic Association*, 81(4):249-254.

Green, S. 2005. Systematic reviews and meta-analysis. *Singapore Medical Journal,* 46(6): 270-274.

Guadagnino, 1997. Flexion / distraction manipulation of a patient with a proven disc herniation. *Journal of the Neuromusculoskeletal System*, 5: 70-73.

Gudavalli, M.R., Cambron, J.A., McGregor, M., Jedlicka, J., Keenum, M., Ghanayem, A.J., and Patwardhan, A.G. 2006. A randomized clinical trial and subgroup analysis to compare flexion–distraction with active exercise for chronic low back pain. *European Spine Journal*, 15:1070-1082.

Haefeli, M., Kalberer, F., Saeesser, D., Nerlich, A.G., Boos, N., and Paesold, G. 2006. The course of macroscopic degeneration in the human lumbar intervertebral disc. *The Spine Journal*, 31:1522-1531.

Haldeman, S. ed. 2005*. Principles and Practice of Chiropractic*. 3rd ed. Baltimore, Maryland, USA, McGraw-Hill.

Hammer, W.I. 2007. Functional soft-tissue examination and treatment by manual methods. 3rd ed. Ontario, Canada: Jones and Bartlett Publishers Incorporated.

Haneline, M.T. 2007. *Evidence - Based Chiropractic Practice*. 1st ed. United Sates of America: Jones and Bartlett Publishers, Inc.

Harris, K. 2013. Conservative management of iliotibial band friction syndrome: A literature synthesis. MTech Chiropractic Dissertation, Durban University of Technology, South Africa.

Hartling, L., Hamm, M., Milne, A., Vandermeer, B., Santaguida, P.L., Ansari, M., Tsertvadze, A., Hempel, S., Shekelle, P., and Dryden, D.M. 2012. *Validity and inter-rater reliability testing of quality assessment instrument* (online)*.* Available at: http://www.ncbi.nlm.nih.gov/books/NBK92293/pdf/TOC.pdf (Accessed 25 July 2013).

Hawk, C., Long, C., and Azad, A. 1997. Chiropractic care for women with chronic pelvic pain: a prospective single-group intervention study. *Journal of Manipulative and Physiological Therapeutics*, 20(2): 73 – 79.

Hawk, C., Azad, A., Phongphua, c., Long, C.R. 1999. Preliminary study of the effects of a placebo chiropractic treatment with sham adjustments. *Journal of Manipulative and Physiological Therapeutics, 22(7): 436 – 443.*

Hawk, C., and Long, C.R. 2000. Use of a pilot to refine the design of a study to develop a manual placebo treatment. *Journal of the Neuromusculoskeletal System*, 8(2): 39 – 48.

Hawk, C., Long, C.R., Reiter, R., Davis, C.S., Cambron, J.A., and Evans, R. 2002. Issues in Planning a Placebo-Controlled Trial of Manual Methods: Results of a Pilot Study. *The Journal of Alternative and Complementary Medicine*, 8(1): 21-32.

Hawk, C., Long, C.R., Rowell, R.M., Gudavalli, M.R., and Jedlicka, J. 2005. A Randomized Trial Investigating a Chiropractic Manual Placebo: A Novel Design Using Standardized Forces in the Delivery of Active and Control Treatments. The *Journal of Alternative and Complementary Medicine*, 11(1): 109-117.

Hawk, C., Pfefer, M.T. Strunk, R., Ramchara, M., and Uhl, N. 2007. Feasibility study of short-term effects of chiropractic manipulation on older adults with impaired balance. *Journal of Chiropractic Medicine*, 6:121-131.

Hawkinson, E.J., Snyder, B.J., and Sanders, G.E. 1992. Evaluation of the Toftness system of chiropractic adjusting for the relief of acute pain of musculoskeletal origin. *Chiropractic Techniques*, 4(2):57-60.

Hemingway, P., and Brereton, N. 2009. *What is a systematic review?* (online). Available: http://www.whatisseries.co.uk/whatis/pdfs/What_is_syst_rev.pdf (Accessed 22 November 2011).

Higgins, J.P.T., and Green, S. ed. 2008. *Cochrane Handbook for Systematic Reviews of Interventions* (online). Available: www.cochrane-handbook.org. (Accessed 14 March 2013).

Hondras, M.A., Long, C.R., Cao, Y., Rowell, R.M., Meeker, W.C. 2009. A Randomized Controlled Trial Comparing 2 Types of Spinal Manipulation and Minimal Conservative Medical Care for Adults 55 Years and Older With Subacute or Chronic Low Back Pain. *Journal of Manipulative and Physiological Therapeutics*, 32(5): 330 – 343.

Howard, G. 1997. Cox Flexion Distraction Manipulation and Literature Review.

Hurwitz, E.L., Morgenstern, H., Philip, H., *et al*. 2002. A randomized trial of medical care with and without physical therapy and chiropractic care with and without physical modalities for patients with low back pain: six month follow-up outcomes from the UCLA low back pain study. *Spine,* 27:2193–2204.

Isaacs, E.R., and Bookhout, M.R.. 2002. *Bourdillons spinal manipulation*. 6th ed. United States of America. Butterworth-Heinemann.

Keating, J.C. 1992. *Toward a Philosophy of the Science of Chiropractic: A Primer for Clinicians.* Stockton Foundation for Chiropractic Research.

Keating, J.C. 2003. Several pathways in the evolution of chiropractic manipulation. *Journal of Manipulative and Physiological Therapeutics*, 26(5): 300-321.

Khorsan, R., Smith. M., Hawk, C., and Haas, M. 2009. A public health immunization resource website for chiropractors: Discussion of current issues and future challenges for evidence-based initiatives for the chiropractic profession. *Journal of Manipulative and Physiological Therapeutics*, 32(6): 500-504.

Koes, B.W., Bouter, L.M., van Mameren H., *et al*. 1993. A randomized clinical trial of manual therapy and physiotherapy for persistent back and neck complaints: subgroup analysis and relationship between outcome measures. *Journal of Manipulative Physiology and Therapeutics,* 16:211–219.

Kim, K-W., Lim, T-H., Kim, J.G., Jeong, S-T., Masuda, K., and An, H.S. 2003. The origin of chondrocytes in the nucleus pulposis and histological findings associated with the transition of a notochordal nucleus pulposis to a fibrocartilaginous nucleus pulposis in intact rabbit intervertebral discs. *The Spine Journal*, 28: 982-990.

Kruse, R.A., and Cambron, J.A. 2011. Chiropractic management of postsurgical lumbar spine pain: a retrospective study of 32 cases. *Journal of Manipulative and Physiological Therapeutics,* 34(6): 408-412.

Kruse, R.A., Schliesser, J., and DeBono, V.F. 2000. Klippel-Feil Syndrome with radiculopathy. Chiropractic management utilizing flexion-distraction technique: A case report. *Journal of the Neuromusculoskeletal System*, 8: 124-131.

Lavis, J., Davies, H., Oxman, A., Denis, J.L., Golden-Biddle, K., and Ferlie, E. 2005. Towards systematic reviews that inform health care management and policy-making. *Journal of Health Services Research and Policy*, 10(1): 35-48.

Leach, R.A. 2004. *The Chiropractic Theories: A Textbook of Scientific Research.* 4th ed. Philadelphia, Pennsylvania. Lippincott Williams & Wilkins.

Lennard, T.A., Vivian, D.G., Walkowski, S., and Singla, A.K. 2011. *Pain Procedures in Clinical Practice*. 3rd ed. Philadelphia. Elsevier

Liberati, A., Moher, D., Tetzlaff, J., and Altman, D.G. 2009. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *British Medical Journal*, 339: b2535.

Liddle, J., Williamson, M., and Irwig, I. 1996. *Method for evaluating research and guideline evidence (MERGE*). Sydney: New south Wales Department of Health.

Ligeros, K.A. 1937. *How ancient healing governs modern therapeutics*. New York: Putnam.

Lomax, E. 1975. Manipulative therapy: A historical perspective from ancient times to the modern era. In: the research status of spinal manipulative therapy: A workshop held at the National Institute of Health. DHEW.

Maher, C., Sherrington, C., Herbert, R., Moseley, A., and Elkins, M. 2003. Reliability of the PEDro Scale for rating quality of randomized controlled trials. *Physical Therapy*, 83(8): 713-721.

Maher, A.R., Maglione, M., Bagley, S., Suttorp, M., Hu, J-H., Ewing, B., Wang, Z., Timmer, M., Sultzer, D., and Shekelle, P.G. 2011. Efficacy and Comparative Effectiveness of Atypical Antipsychotic Medications for Off-Label Uses in Adults. A Systematic Review and Meta-analysis. *Journal of American Medical Association*, 306(12):1359-1369.

Maitland, G.D. 1986. *Vertebral Manipulation*. 5th ed. Butterworth Heinemann.

Manchikanti, L., Heavner, J.E., Racz. G.B. *et al*. 2003. Methods for evidence synthesis in interventional pain management. *Pain Physician*, 6:89-111.

Manison, A.M. 2011 Chiropractic management using Cox cervical flexion - distraction technique for a disk herniation with left foraminal narrowing in a 64 - year-old man. *Journal of Chiropractic Medicine*, 10(4): 316 - 321.

Markey, L.P. 1985. Markey distraction technique: new protocol for doctor's and patient's safety: A pragmatic approach, part 1. *Digest of Chiropractic Economics*, 66-69.

Martin, B.I., Deyo, R.A., Mirza, S.K., *et al.* 2008. Expenditures and health status among adults with back and neck problems. *Journal of American Medical Association*, 299:656-664.

Masarsky, C.S., and Todres-Masarsky, M (eds). 2008. *Somatovisceral aspects of chiropractic. An evidence-based approach*. Churchill Livinstone.

Mbutho, N. 2012. Health care workers in the HIV unit's knowledge, attitudes and practices towards the use of Complementary Alternative Therapy in Durban hospitals. MTech Somatology Dissertation, Durban University of Technology, South Africa.

McHardy, A., Hoskins, W., Pollard, H., Onley, R., Windsham, R. 2008. Chiropractic treatment of upper extremity conditions: A systematic review. Journal of Manipulative and Physiological Therapeutics, 31(2): 146-159.

Meal, G.M., and Scott, R.S. 1986. Analysis of the joint crack by simulataneous recording of sound and tension. *Journal of manipulative and physiological therapy*, 9(3):189-195.

Moher, D., Liberati, A., Tetzlaff, J., Altman, D.G., and the PRISMA Group. 2009. *Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement* (online). Available at: http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000097 (Accessed 12 January 2012).

Montanez-Aguilera, F.J., Valtuena-Gimeno, N., Pecos-Martin, D., Arnau-Masanet, R., Barrios-Pitarque, C., and Bosch-Morell, F. 2010. Changes in a patient with neck pain after application of ischemic compression as a trigger point therapy. *Journal of Back & Musculoskeletal Rehabilitation*, 23(2): 101–104.

Mouton, J. 2001. *How to succeed in your masters and doctoral studies: A South African guide and resource book.* 1st ed. Van Schalk Publishers.

Mrozek, J., and Vernon, H. 2005. A Revised Definition of Manipulation. *Journal of Manipulative Physiological Therapeutics,* 28(1): 68-72.

Mulrow, C.D. 1994. Rationale for systematic reviews. *British Medical Journal,* Sep 3; 309(6954): 597-9.

Murray, E., Pollack, L., White, M., and Lo, B. 2007. Clinical decision-making: Patients' preferences and experiences. *Patient Education and counselling*, 65(2): 189–196.

Ndetan, H.T., Rupert, R.L., Bae, S., and Singh, K.P. 2009. Prevalence of musculoskeletal injuries sustained by students while attending a chiropractic college. *Journal of Manipulative Physiological Therapeutics,* 32(2): 140-148.

Oxman, A.D., Cook, D.J., and Guyatt, G.U. 1994. Users' guides to the medical literature VI. How to use an overview. Evidence-based medicine working group. *Journal of American Medical Association,* 272: 1367-1371.

PEDro. 1999. *PEDro scale (online).* Available: www.pedro.org.au/ (Accessed 23 July 2013).

Plaugher, G. 1993. *Textbook of clinical chiropractic: a specific biomechanical approach*. Philadelphia, Pennsylvania, USA. Lippincott, Williams & Wilkins.

Prentice, W.E. 2003. *Principles of Athletic Training.* McGraw Hill.

Redwood, D. and Cleveland, C.S. 2003. *Fundamentals of Chiropractic*. 2nd ed. Los Angeles, California, USA. Mosby.

Rhoades EA, 2011. Literature reviews. *The Volta Review,* 111(3): 353-368.

Richardson, G. 2007. The effect of differing clinical settings on chiropractic patients suffering from Mechanical Low Back Pain. MTech Chiropractic Dissertation, Durban University of Technology, South Africa.

Roston, J.B., and Haines, R.W. 1947. Cracking in the metacarpo-phalangeal joint. *Journal of Anatomy*, 81:165-173.

Rothman, K.J., Greenland, S., and Lash, T (eds). 2008*. Meta-Analysis in Modern Epidemiology.* 3rd ed. Lippincott Williams and Wilkins.

Rowell, R.M., and Polipnick, J. 2008. Apilot mixed methods study of patient satisfaction with chiropractic care for back pain. *Journal of Manipulative and Physiological Therapeutics*, 31(8): 602 – 610.

Sackett D., Rosenberg, W.M., Gray, J.A., Haynes, R.B., and Richardson, W.S. 1996. Evidence based medicine: what it is and what it isn't. *British Medicine Journal,* 312: 71-72.

Sackett, D.L., Richardson, W.S., Rosenberg, W., and Haynes, R.B. 1997. *Evidence-based medicine: How to practice and teach EBM*. New York: Churchill–Livingstone.

Sandoz, R. 1976. Some physical mechanisms and effects of spinal adjustments. *Annals of Swiss Chiropractic Association*, 6:91–142.

Schafer, R.C., and Faye, L.J. 1990. *Motion Palpation and Chiropractic Technic – Principles of Dynamic Chiropractic*. The Motion Palpation Institute.

Schiotz, E.H., and Cyriax, J. 1975. *Manipulation past and present*. London: William Heinemann Medical Books.

Schulz, C.A., Hondras, M.A., Gudavalli, M.R., Long, C.R., Owens, E.F., Wilder, D.G., and Bronfort, G. 2011. Chiropractic and self-care for back-related leg pain: design of a randomised clinical trial. *Chiropractic and Manual Therapies*, 19:8.

Scollen, R., and Scollen, W.S. 1995. *Intercultural Communication: A Discourse Approach.* Massachusetts. Blackwell.

Shaughnessy J, Zechmeister E and Zechmeister J, 2005. *Research methods in psychology.* 7th Edition. New York City. McGraw-Hill Company.

Skargren, E.I., Oberg, B.E., Carlsson, P.G., and Gade, M. 1997. Cost and effectiveness analysis of chiropractic and physiotherapy treatment for low back and neck pain: Six month follow-up. *Spine,* 22:2167–2177.

Stang, A. 2010. Critical evaluation of the Newcastle-Ottawa scale for the assessment of the quality of nonrandomized studies in meta-analyses. *European Journal of Epidemiology,* 25(9): 603-605.

Strunk, R.G., and Hawk, C. 2009. Effects of chiropractic care on dizziness, neck pain, and balance: a single-group, preexperimental, feasibility study. *Journal of Chiropractic Medicine*, 8: 156 – 164.

Travell, J.G., Simons, D.G., and Simons, L.S. 1999. *Travell & Simons' Myofascial Pain and Dysfunction: Upper half of body*. 2nd ed. Lippincott Williams & Wilkins.

Troyanovich, S.J., and Gibbons, R.W. 2003. Finding Langworthy: The last years of a chiropractic pioneer. *Chiropractic History*, 23: 9-17.

Tuscon, E.W.1841. *The cause and treatment of curvature of the spine, and diseases of the vertebral column*. London: John Churchill.

University of Johannesburg. 2011. Faculty of health sciences. Department of Chiropractic (online). Available: http://www.uj.ac.za/EN/Faculties/health/departments/chiropractic/coursesandprogrammes/Documents/Chiro%20Brochure%202014.pdf (Accessed 05 December 2013).

Unsworth, A., Dowson, D., and Wright, V. 1971. 'Cracking joints'. A bioengineering study of cavitation in the metacarpophalangeal joint. Annals of the Rheumatic Diseases, 30(4): 348-358.

Vernon, H., and Schneider, M. 2009. Chiropractic management of myofascial trigger points and myofascial pain syndrome: a systematic review of the literature. *Journal of manipulative and physiological therapeutics,* 32:1: 14-24.

Visible Body, 2013. Visible Body® Argosy Publishing Inc.

Waddell G, 2004. *The back pain revolution*. Churchill Livingston. London United Kingdom.

Wardwell, W.I. 1987. Before the Palmers: An overview of chiropractic's antecedents. *Chiropractic History*, 7(2):25-33.

Wardwell, W.I.1992. *Chiropractic: History and evolution of a profession*. St. Louis: Mosby.

Weerapong, P., Hume, P.A., and Kolt, G.S. 2004. Stretching: Mechanisms and Benefits for Sports Performance and Injury Prevention. *Physical Therapy Reviews,* 9(4):189–206.

Wells, G.A., Shea, B., O'Connell, D., Peterson, J., Welch, V., Losos, M., and Tugwell, P. 2003. *The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses* (online). Available: http://www.medicine.mcgill.ca/rtamblyn/Readings%5CThe%20Newcastle%20-%20Scale%20for%20assessing%20the%20quality%20of%20nonrandomised%20studies%20in%20meta-analyses.pdf (Accessed 11th March 2012).

Wilder, D.G., Vining, R.D., Pohlan, K.A., Meeker, W.C., Xia, T., DeVocht, J.W., Gudavalli, R.M., Long, C.R., Owens, E.F., and Goertz, C.M. 2011. Effect of spinal manipulation on sensorimotor function in back pain patients: study protocol for a randomised controlled trial. *Trials Journal*, 12:161.

World Federation of Chiropractic, 2013. *World Federation of Chiropractic* (online). Available: www.wfc.org (accessed 05 November 2013).

World Health Organisation. 2010a. Benchmarks for training in traditional / complementary and alternative medicine - Benchmarks for training in osteopathy. Switzerland. World health publishers

World Health Organisation. 2010b. Benchmarks for training in traditional / complementary and alternative medicine - Benchmarks for training in naturopathy. Switzerland. World health publishers.

World Health Organisation. 2010c. Benchmarks for training in traditional / complementary and alternative medicine - Benchmarks for training in tuina. Switzerland. World health publishers.

World Health Organisation. 2010d. Benchmarks for training in traditional / complementary and alternative medicine - Benchmarks for training in nuad thai. Switzerland. World health publishers.

World Health Organisation. 2005, *World Health Organisation* (online). Available: www.who.int (accessed 12 November 2013).

Zhao, C.Q., Wang, L.M., Jiang, L.S., and Dai, L.Y. 2007. The cell biology of intervertebral disc aging and degeneration. *Ageing Res Rev*, 6:247-261.

Zylbergold, R.S., and Piper, M.C. 1984. Cervical spine syndromes. A comparison of three types of traction. *Spine*, 10(10) 868-871.

Appendices

APPENDIX A

DATABASE LIST: Working list:

AUTHOR	YEAR	TITLE
Adams A, Mueller H		Chiropractic management of a patient with severe chronic back pain complicated by atypical Scheuermann's disease: A case report
Aspegren DC, Cox JM, Trier KK	1987	Short leg correction: a clinical trial of radiographic vs. non-radiographic procedures
Aspegren, Donald; Enebo, Brian A; Miller, Matt; White, Linda; Akuthota, Venu; Hyde, Thomas E ...(more)		Functional scores and subjective responses of injured workers with back or neck pain treated with chiropractic care in an integrative program: a retrospective analysis of 100 cases
Beira B, Peers A	1998	A study of the effects of chiropractic therapy on the diameter of the spinal canal in patients with low back pain and radiculopathy
BenEliyahu DJ	1996	Magnetic resonance imaging and clinical follow-up: study of 27 patients receiving chiropractic care for cervical and lumbar disc herniations
Bergmann T	1993	Manual force, mechanically assisted articular chiropractic techniques using long and/or short lever contacts
Bergmann TF, Jongeward BV	1998	Manipulative therapy in lower back pain with leg pain and neurological deficit
Beyerman *et al*.	2005	Efficacy of Treating Low Back Pain and Dysfunction Secondary to Osteoarthritis: Chiropractic Care Compared with Moist Heat Alone
Bronfort *et al.*	2004	Spinal Manipulation, Epidural Injections, and Self-Care for Sciatica: A Pilot Study for a Randomized Clinical Trial
Browning JE	1996	The mechanically induced pelvic pain and organic dysfunction syndrome: an often overlooked cause of bladder, bowel, gynecologic, and sexual dysfunction
Bulbulian R, Dishman JD, Burke J	1999	Neuroreflex modulation of the lumbar spine in flexion distraction
Cambron GA, Gudavalli MR, Hedecker D et al	2006	One-Year Follow-Up of a Randomized Clinical Trial Comparing Flexion Distraction with an Exercise Program for Chronic Low-Back Pain
Cambron GA, Gudavalli MR, McGregor M et al	2006	Amount of health care and self-care following a randomized clinical trial comparing flexion-distraction with exercise program for chronic low back pain
Charrette M		Mechanical disorders and organic dysfunctions of the pelvis
Cooperstein R, Perle SM, Gatterman MI, Lantz C, Schneider MJ	2001	Chiropractic technique procedures for specific low back conditions: Characterizing the literature
Cox J, Bakkum B	2005	Possible Generators of Retrotrochanteric Gluteal and Thigh Pain: The Gemelli–Obturator Internus Complex
Cox JM	2012	Chiropractic management of a patient with lumbar spine pain due to a synovial cyst: a case report
Cox JM	2006	Distraction manipulation: a review of the literature
Cox JM	2009	Editorial Response
Cox JM	2006	editorial response to Gay et al
Cox JM	1988	Letter to the editor

Cox JM	1985	Lumbosacral disc protrusion: a case report
Cox JM	1994	Patient benefits of attending a chiropractic low back wellness clinic
Cox JM	1979	Pedicogenic stenosis: its manipulative implications
Cox JM et al	1999	Grand Rounds Discussion: Patient with acute low back pain
Cox JM, Alter M	2001	Schwanoma: Challenging Diagnosis
Cox JM, Aspegren DC	1988	Degenerative spondylolisthesis of C7 and L4 in same patient
Cox JM, Aspegren DC, Trier K	1991	Facet tropisms comparison of plain film and computed tomography examinations
Cox JM, Aspegren DD	1987	A hypothesis introducing a new calculation for discal reduction: emphasis on stenotic factors and manipulative treatment
Cox JM, Bakkum B	2005	Possible tendon and bursae generators of retrotrochanteric gluteal and thigh pain: the Gemelli/Obturator Internus Complex
Cox JM, Cox II, JM	2005	Chiropractic Treatment of Lumbar Spine Synovial Cysts: A Report of Two Cases
Cox JM, Feller, J	1994	Chiropractic treatment of low back pain: a multi-center descriptive analysis of presentation and outcome in 424 consecutive cases
Cox JM, Fromelt KA, Shreiner S	1983	Chiropractic statistical survey of 100 consecutive low back pain patients
Cox JM, Hazen LJ, Mungovan M	1993	Distraction manipulation reduction of an L5-S1 disc herniation
Cox JM, Kreissman SG, Hazen LJ	1995	Eosinophilic granuloma of the thoracic and lumbar spine
Cox JM, Shreiner S	1984	Chiropractic manipulation in low back pain and sciatica: statistical data on the diagnosis, treatment, and response of 576 consecutive cases
Cox JM, Trier K	1991	Chiropractic adjustment results correlated with spondylolisthesis instability
Cox JM, Trier KK		Exercise and Smoking habits in patients with and without low back and leg pain
Cox, James M		A randomized controlled trial comparing 2 types of spinal manipulation and minimal conservative medical care for adults 55 years and older with subacute or chronic low back pain
Cox, JM, Feller JA, Cox JA	1996	Distraction Chiropractic Adjusting: Clinical Application, Treatment Algorithms, and Clinical Outcomes of 1000 Cases Studied
Crawford MC	1999	Chiropractic management of acute low back pain
Gray D, Montgomery P		Distraction/Flexion Side-Posture Manipulation for the treatment of low-back pain and lumbopelvic dysfunction
Dougherty P, Bajwa S, Burke J, Dishman JD	2004	Spinal Manipulation Postepidural Injection for Lumbar and Cervical Radiculopathy: A Retrospective Case Series
Dunn, Andrew S; Baylis, Shayne; Ryan, Danielle		Chiropractic management of mechanical low back pain secondary to multiple-level lumbar spondylolysis with spondylolisthesis in a United States Marine Corps veteran: a case report
DuPriest CM	1993	Nonoperative management of lumbar spinal stenosis
edwards et al		a comparison of chiropractic techniques as they relate to the intervertebral disc syndrome
gallucci		the effectiveness of chiropractic treatment for disc syndrome
Gay R, Bronfort G, Evans RE et al	2005	Distraction Manipulation of the Spine - a review of the literature
Gay, Ralph E and Brault, Jeffrey S	2007	Evidence-informed management of chronic low back pain with traction therapy
Greathouse, Jr, James E		Conservative management of a patient with lumbar disc

		disease: averting lumbar disc surgery
Guadagnino MR	1997	Flexion-distraction manipulation of a patient with a proven disc herniation
Gudavalli R, Cambron JA, McGregor M et al	2006	A randomized clinical trial and subgroup analysis to compare flexion–distraction with active exercise for chronic low back pain
Gudavalli S, Kruse R	2008	Foraminal stenosis with radiculopathy from a cervical disc herniaton in a 33-year-old man treated with flexion-distraction decompression manipulation
Hawk C, Azad A, Phongphua C, Long CR	1999	Preliminary study of the effects of a placebo chiropractic treatment with sham adjustments
Hawk C, Long C, Azad A	1997	Chiropractic care for women with chronic pelvic pain: a prospective single-group intervention study
Hawk C, Long CR	2000	Use of a pilot to refine the design of a study to develop a manual placebo treatment
Hawk *et al.*	2002	Issues in Planning a Placebo-Controlled Trial of Manual Methods: Results of a Pilot Study
Hawk C, Phongphua C, Bleecker J, Swank L, Lopez D, Rubley T	1999	Preliminary study of the reliability of assessment procedures for indications for chiropractic adjustments of the lumbar spine
hayen		multilevel degenerative disc disease: a case study
Hazen LJ, Cox, JM	1993	Lumbar intraspinal extradural synovial cyst: a case study
Hondras MA, Long CR, Cao Y, Rowell RM, Meeker WC	2009	A randomized controlled trial comparing 2 types of spinal manipulation and minimal conservative medical care for adults 55 years and older with subacute or chronic low back pain
Hubka MJ, Taylor JAM, Schultz GD, Traina AD	1991	Lumbar intervertebral disc herniation: chiropractic management using flexion, extension, and rotational manipulative therapy
Hultgren GM, Jeffers JS: Shamanism	1994	Shamanism, a religious paradigm: its intrusion into the practice of chiropractic
husbands, pokras		1991 year end compendium: the use of flexion distraction in a lumbosacral posterior arch defect with a lumbosacral disc protrusion: a case study
jette, falkel, trombly		effect of intermittent supine cervicla traction on the myoelectric activity of the upper trapezius muscle in subjects with neck pain
kekosv, hibert, tepperman		cervical and lumbo pelvic traction
krause, refshauge, dessen boland		lumbar spine traction: evaluation of effects and recommended application for treatment
Kruse R, Cambron J	2011	Chiropractic Management of Postsurgical Lumbar Spine Pain: A Retrospective Study of 32 Cases
Kruse R, Cambron J	2011	Cox decompression chiropractic manipulation of a patient with postsurgical lumbar fusion: a case report
Kruse R, Gudavalli S, Cambron J	2007	Chiropractic treatment of a pregnant patient with lumbar radiculopathy
Kruse RA, Gregerson D	2002	Cervical Spinal stenosis resulting in radiculopathy treated with flexion-distraction manipulation: A case study
Kruse RA, Imbarlina F, DeBono VF	2001	Treatment of cervical radiculopathy with flexion distraction
Kruse RA, Schliesser J, DeBono VF	2000	Klippel-Feil Syndrome with radiculopathy. Chiropractic management utilizing flexion-distraction technique: A case report
liyang dai, yinkan, wenming, zhihua		the effect of flexion extension motion of the lumbar spine on the capacity of the spinal canal
Ma, Sang-Yeol; Je, Hyun Dong; Kim, Hyeong-Dong	2011	A Multimodal Treatment Approach using Spinal Decompression via SpineMED, Flexion-Distraction Mobilization of the Cervical Spine, and Cervical Stabilization Exercises for the Treatment of Cervical Radiculopathy

Manison A	2011	Chiropractic management using Cox cervical flexion-distraction technique for a disk herniation with left foraminal narrowing in a 64-year-old man
Mootz RD, Waldorf T	1993	Chiropractic care parameters for common industrial low back conditions
Morris CE	1999	Chiropractic rehabilitation of a patient with S1 radiculopathy associated with a large lumbar disk herniation
Murphy, DR; Hurwitz, EL; Gregory, AA; Clary, R	2006	A non-surgical approach to the management of lumbar spinal stenosis: A prospective observational cohort study
nachemson, elfstrom		intradiscal dynaic pressure measurements in lumbar discs. A study of common movements, maneuvers and exercises
Neault CC	1992	Conservative management of an L4-L5 left nuclear disc prolapse with a sequestrated segment
Paulk, G Phillip and Harrison, Deed E		Management of a chronic lumbar disk herniation with chiropractic biophysics methods after failed chiropractic manipulative intervention
Radpasand, Mohsen		Use of a multimodal conservative management protocol for the treatment of a patient with cervical radiculopathy
Rowell and Polipnick	2008	A Pilot Mixed Methods Study of Patient Satisfaction With Chiropractic Care for Back Pain
Rowell RM, Rylander SJ	2012	Low-Back Pain, Leg Pain, and Chronic Idiopathic Testicular Pain Treated with Chiropractic Care
Saunders		use of spinal traction in the treatment of neck and back conditions
Schliesser JS, Kruse RA, Fleming Fallon L	2003	Cervical radiculopathy treated with chiropractic flexion distraction manipulation: a retrospective study in a private practice setting
Schwab, Matthew J		Chiropractic management of a 47-year-old firefighter with lumbar disk extrusion
Snow G	2001	Chiropractic management of a patient with lumbar spinal stenosis
Stoddard		traction of cervical nerve root irritaion
Strunk and Hawk	2009	Effects of chiropractic care on dizziness, neck pain, and balance: a single-group, preexperimental, feasibility study
Taylor, David N		Spinal Synovial Cysts and Intersegmental Instability: A Chiropractic Case
Wilder *et al.*	2011	Effect of spinal manipulation on sensorimotor function in back pain patients: study protocol for a randomised controlled trial
zylbergold, piper		cervical spine disorders. A comparion of three types of traction

APPENDIX B

MASTER LIST:

	AUTHOR(S)	YEAR	TITLE	REFERENCE	STUDY TYPE	INCLUDED
1	Beyerman *et al*.	2005	Efficacy of Treating Low Back Pain and Dysfunction Secondary to Osteoarthritis: Chiropractic Care Compared with Moist Heat Alone	Beyerman, 2005. Efficacy of Treating Low Back Pain and Dysfunction Secondary to Osteoarthritis: Chiropractic Care Compared with Moist Heat Alone. *Journal of manipulative and physiological therapeutics*, 29(2): 107 – 114.	RCT	YES
2	Bronfort *et al*.	2004	Spinal Manipulation, Epidural Injections, and Self-Care for Sciatica: A Pilot Study for a Randomized Clinical Trial	Bronfort. 2004. Spinal Manipulation, Epidural Injections, and Self-Care for Sciatica: A Pilot Study for a Randomized Clinical Trial. *Journal of manipulative and physiological therapeutics*, 27(8): 503 – 508.	RCT	YES
3	Cambron *et al*.	2005	A Randomized Clinical Trial and Subgroup Analysis to Compare Flexion-Distraction with Active Exercise for Chronic Low Back Pain	A Randomized Clinical Trial and Subgroup Analysis to Compare Flexion-Distraction with Active Exercise for Chronic Low Back Pain. *European spine journal*, 15(7): 1070 – 1082.	RCT	YES
4	Cambron *et*	2006	Amount of health care and	Amount of health care and self-care following	RCT	YES

	al.		self-care following a randomized clinical trial comparing flexion-distraction with exercise program for chronic low back pain	a randomized clinical trial comparing flexion-distraction with exercise program for chronic low back pain. *Chiropractic & osteopathy*, 14(1): 19		
5	Cambron *et al.*	2006	One-Year Follow-Up of a Randomized Clinical Trial Comparing Flexion-Distraction with an Exercise Program for Chronic Low-Back Pain	One-Year Follow-Up of a Randomized Clinical Trial Comparing Flexion-Distraction with an Exercise Program for Chronic Low-Back Pain. *Journal of alternative and complementary medicine*, 12(7): 659 – 668.	RCT	YES
6	Hawk *et al.*	2002	Issues in Planning a Placebo-Controlled Trial of Manual Methods: Results of a Pilot Study	Issues in Planning a Placebo-Controlled Trial of Manual Methods: Results of a Pilot Study. *Journal of alternative and complementary medicine*, 8(1): 21 – 32.	RCT	YES
7	Hawk *et al.*	2005	A Randomized Trial Investigating a Chiropractic Manual Placebo: A Novel Design Using Standardized Forces in the Delivery of Active and Control	A Randomized Trial Investigating a Chiropractic Manual Placebo: A Novel Design Using Standardized Forces in the Delivery of Active and Control Treatments. *Journal of alternative and complementary medicine*, 11(1): 109 – 117.	RCT	YES

			Treatments			
8	Hawk *et al.*	2007	Feasibility study of short-term effects of chiropractic manipulation on older adults with impaired balance	Feasibility study of short-term effects of chiropractic manipulation on older adults with impaired balance*. Journal of Chiropractic Medicine*, 6(4): 121 – 131.	RCT	YES
9	Hawk C and Long CR	2000	Use of a Pilot to Refine the Design of a Study to Develop a Manual Placebo Treatment	Use of a Pilot to Refine the Design of a Study to Develop a Manual Placebo Treatment*. Journal of the neuromusculoskeletal system*, 8(2): 39 – 48.	RCT	YES
10	Hawk *et al.*	1999	Preliminary Study of the Effects of a Placebo Chiropractic Treatment with Sham Adjustments	Preliminary Study of the Effects of a Placebo Chiropractic Treatment with Sham Adjustments*. Journal of manipulative and physiological therapeutics*, 22(7): 436 – 443.	RCT	YES
11	Hondras *et al.*	2009	A Randomized Controlled Trial Comparing 2 Types of Spinal Manipulation and Minimal Conservative Medical Care for Adults 55 Years and Older With Subacute or Chronic Low Back Pain	A Randomized Controlled Trial Comparing 2 Types of Spinal Manipulation and Minimal Conservative Medical Care for Adults 55 Years and Older With Subacute or Chronic Low Back Pain*. Journal of manipulative and physiological therapeutics*, 32(5): 330 – 343.	RCT	YES

12	Schulz *et al.*	2011	Chiropractic and self-care for back-related leg pain: design of a randomized clinical trial	Chiropractic and self-care for back-related leg pain: design of a randomized clinical trial. *Chiropractic and manual therapies*, 19(1): 8.	RCT	YES
13	Wilder *et al.*	2011	Effect of spinal manipulation on sensorimotor function in back pain patients: study protocol for a randomised controlled trial	Effect of spinal manipulation on sensorimotor function in back pain patients: study protocol for a randomised controlled trial. *Trials*, 12(1): 161.	RCT	YES
14	Zylbergold RS and Piper MC	1985	Cervical Spine Disorders: A Comparison of Three Types of Traction	Cervical Spine Disorders: A Comparison of Three Types of Traction. *Spine*, 10(10):867-71.	RCT	YES
15	Bulbulian *et al.*	2002	Spinal Reflex Excitability Changes After Lumbar Spine Passive Flexion Mobilization	Spinal Reflex Excitability Changes After Lumbar Spine Passive Flexion Mobilization. *Journal of Manipulative and Physiological Therapeutics*, 25(8): 526 – 532.	n-RCT	YES
16	Strunk RG and Hawk C	2009	Effects of chiropractic care on dizziness, neck pain, and balance: a single-group, preexperimental, feasibility study	Effects of chiropractic care on dizziness, neck pain, and balance: a single-group, preexperimental, feasibility study. *Journal of Chiropractic Medicine*, 8(4): 156 – 164.	n-RCT	YES
17	Hawk *et al.*	1997	Chiropractic Care for Women	Chiropractic Care for Women with Chronic	n-RCT	YES

			with Chronic Pelvic Pain: A Prospective Single-Group Intervention Study	Pelvic Pain: A Prospective Single-Group Intervention Study. *Journal of manipulative and physiological therapeutics*, 20(2): 73 – 79.		
18	Rowell RM and Polipnick J	2008	A Pilot Mixed Methods Study of Patient Satisfaction With Chiropractic Care for Back Pain	Rowell, R.M., and Polipnick, J. 2008. A Pilot Mixed Methods Study of Patient Satisfaction With Chiropractic Care for Back Pain. *Journal of manipulative and physiological therapeutics*, 31(8): 602 – 610.	n-RCT	YES

APPENDIX C

Newcastle-Ottawa Scale:

Non-Randomised studies

The Newcastle-Ottawa is composed of 8 questions, that pertain to the following 3 categories; selection, comparability and exposure.

For the selection and exposure sections, one response per question is required (a, b, or c, etc.) For the comparability section, multiple or no responses can be made.

One star can be presented per question, except comparability, where two stars may be awarded. The maximum amount of stars that a study can be awarded is nine stars.

Should a study contain only one group of subjects, comparability cannot be done, and should be omitted from the scale.

Definition: Ascertainment: To discover with certainty, as through examination or experimentation. (The free dictionary (online))

Reference:

Stang, A. 2010. Critical evaluation of the Newcastle-Ottawa scale for the assessment of the quality of nonrandomized studies in meta-analyses. *European Journal of Epidemiology.* 25(9): 603-605.

Newcastle-Ottawa Quality Assessment Scale:
Non-Randomised Studies

Reviewer:	
Article Title:	

A study can be awarded a maximum of one star for each numbered item within the **selection** and **exposure** categories. A maximum of 2 stars can be awarded for **comparability**.

Please circle the letter you award for each point:

SELECTION:

1. Is the case definition adequate?
    a. Yes, with independent validation *
    b. Yes, e.g. record linkage or based on self-reports
    c. No description
2. Representativeness of the cases
    a. Consecutive or obviously representative series of cases *
    b. Potential for selection biases or not stated
3. Selection of controls
    a. Community controls *
    b. Hospital controls
    c. No description
4. Definition of controls
    a. No history of disease (endpoint) *
    b. No description of source

COMPARABILITY:

1. Comparability of cohorts on the basis of design or analysis
    a. Study controls for _____(Select most important factor) *
    b. Study controls for **any** additional factor *

EXPOSURE:

1. Ascertainment of exposure
    a. Secure record (e.g. surgical records) *
    b. Structured interview where blind to case/control status *
    c. Interview not blinded to case/control status
    d. Written self-report or medical record only
    e. No description
2. Same method of ascertainment for cases and controls
    a. Yes *
    b. No
3. Non-response rate
    a. Same rate for both groups *
    b. Non respondents described
    c. Rate different and no designation

Adapted from: Wells *et al.*, 2003. *The Newcastle-Ottawa Scale (NOS) for assessing the quality if nonrandomized studies in meta-analyses*.

APPENDIX D

PEDro Scale:

Randomised Controlled Clinical Trial Rating

The PEDro scale is centred on the Delphi list (Delphi list: a criteria list for quality assessment of RCTs for conducting systematic reviews developed by the Delphi consensus. Journal of Clinical Epidemiology, 51(12): 1235-1241).

The PEDro scale contains 11 criterions. Criterion 1 aims to evaluate the applicability of the trial. Criterion 2-9 looks at the "internal validity," while criteria 10-11 evaluate the statistical information of the RCT and determines whether those statistics are interpretable.

The area labelled "Reference Page" is provided in the event that discordance is found between reviewers; this will be used to find where the information was accessed from.

1 point may be awarded should a criterion be appropriately met. Should a "yes" answer be required, 1 point will be awarded for that criterion.

Definitions:

*Blinding: r*efers to the person (subject, therapist or assessor) not knowing which group the subject had been assigned to.

A *point measure:* measures the magnitude of the treatment outcome/effect.

Measures of variability: comprises of standard errors, confidence intervals, standard deviations, ranges and interquartile ranges (or other quantile ranges).

A between-group statistical comparison: comprises statistical comparison of one group with another (control or treatment).

Intention to treat: Fisher et al., (1990) defines intention to treat as a method for the examination of RCTs. This policy links patients to the groups that they were initially randomly allocated to. In general, this is understood as comprising all patients, irrespective of whether;

- They satisfied the inclusion criteria
- Treatment was inferred
- Withdrawal from the study
- Derivation from the procedure

Without the intention to treat protocol, the Clinical effectiveness of an RCT can be overemphasized.

References:

Fisher, L.D., Dixon, D.O., Herson, J., Frankowski, R.K., Hearon, M.S. and Pearce, K.E. 1990. Intention to treat in clinical trials. In: Pearce, K.E., ed. *Statistical issues in drug research and development. Marcel Decker Inc – New York. 331-350.*

PEDro scale (online). 1999. Available at: www.pedro.org.au (Accessed 06 June 2011).

PEDro Scale:

Reviewer:	
Article Title:	

Please select YES or NO for each criterion:

CRITERION:				REFERENCE PAGE:
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 analysed 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). 1999.

Appendix E:

Memorandum of Agreement

Title of Research Study: A systematic review to determine the evidence to support the use of flexion distraction Chiropractic technique

Principle investigators: Mr Dillon Cuppusamy (Researcher)

Co-investigators: Dr. C. Korporaal (Supervisor); Dr. L. O'Connor (co-supervisor)

Brief Introduction and Purpose of the Study:

This study is a systematic review of literature pertaining to the flexion distraction technique. Articles are collected electronically via databases by the researcher, the articles included into the study are divided into different study types, of those only randomised controlled clinical trials and non-randomized clinical trials are included in this study. Grouped articles are to be reviewed by a panel of three of five blinded reviewers, using rating scales (specific to the study types listed above) and feedback from reviewers is collated and presented in a statistical presentation.

Outline of Procedures:

Reviewers will receive articles which have been grouped according to study type (Randomized clinical trials or Non-randomised clinical trials CT's) as well as the corresponding scale rating sheet (Randomized clinical trials – PEDro scale or Non-randomised clinical trials – Newcastle-Ottawa scale) as well as an explanation sheet for each scale. The reviewer will then individually rate the articles according to its corresponding scale. Rating sheets are collected and collated for statistical analysis. A determined time period will be recommended for each article/group of articles review for feedback.

Benefits: Publication of the study: Should this study be published, all persons participating in the study will be included in the publication. Should the reviewer wish to be exempt from this, please strike through the paragraph and initial alongside.

Remuneration: An honorarium of R1, 000.00 will be awarded to each reviewer in appreciation of their time and dedication to this project. This will be made at the conclusion of this research project once submission for final marking has been completed.

Contact persons: Please do not hesitate to contact either the supervisor and/or researcher regarding any questions or queries via the following methods:

Dr. Charmaine Korporaal (Supervisor):
Telephone: 031 373 2611
Cell no.: 083 463 3562
E-mail: Charmak@dut.ac.za

Dr. Laura Wilson (Supervisor):
E-mail: lauraw@dut.ac.za
Telephone no: 031 373 2923

Mr Dillon Cuppusamy (Researcher)
Cell No.: 084 408 8118
E-mail: dcuppusamy@yahoo.com

Statement of Agreement to Participate in the Research Study:

I …… (Subject's full name), ……(Identity number), have read this document in its entirety and understand its contents. Where I have had any questions or queries, these have been explained to me by …… to my satisfaction. Furthermore, I voluntarily agree to participate in this study as a reviewer.

Reviewer's name:……Reviewer's signature:……...Date:……

Supervisor name:……Supervisor signature:……...Date:……

Researcher name:…….....Researcher signature:…….....Date:……..

APPENDIX H

GROUP 1 ARTICLE ALLOCATION:

RANDOMISED CONTROLLED CLINICAL TRIALS:

ARTICLE NUMBER:	ARTICLE AUTHOR(S):	YEAR:	ARTICLE TITLE:
1	Hawk *et al.*	2007	Feasibility study of short-term effects of chiropractic manipulation on older adults with impaired balance
2	Hawk C and Long CR	2000	Use of a pilot to refine the design of a study to develop a manual placebo treatment
3	Hawk *et al.*	1999	Preliminary study of the effects of a placebo chiropractic treatment with sham adjustments
4	Hondras *et al.*	2009	A randomized controlled trial comparing 2 types of spinal manipulation and minimal conservative medical care for adults 55 years and older with subacute or chronic low back pain
5	Schulz *et al.*	2011	Chiropractic and self-care for back-related leg pain: design of a randomized clinical trial
6	Wilder *et al.*	2011	Effect of spinal manipulation on sensorimotor function in back pain patients: study protocol for a randomised controlled trial
7	Zylbergold RS and Piper MC	1985	Cervical spine disorders: a comparison of three types of traction

NON-RANDOMISED CONTROLLED STUDIES

1	Hawk *et al.*	1997	Chiropractic care for women with chronic pelvic pain: a prospective single-group intervention study
2	Rowell RM and Polipnick J	2008	A pilot mixed methods study of patient satisfaction with chiropractic care for back pain

APPENDIX I

GROUP 2 ARTICLE ALLOCATION:

RANDOMISED CONTROLLED CLINICAL TRIALS

ARTICLE NUMBER:	ARTICLE AUTHOR(S):	YEAR:	ARTICLE TITLE:
1	Beyerman *et al*.	2005	Efficacy of treating low back pain and dysfunction secondary to osteoarthritis: chiropractic care compared with moist heat alone
2	Bronfort *et al*.	2004	Spinal manipulation, epidural injections, and self-care for sciatica: a pilot study for a randomized clinical trial
3	Cambron *et al*.	2005	A randomized clinical trial and subgroup analysis to compare flexion-distraction with active exercise for chronic low back pain
4	Cambron *et al*.	2006	Amount of health care and self-care following a randomized clinical trial comparing flexion-distraction with exercise program for chronic low back pain
5	Cambron *et al*.	2006	One-year follow-up of a randomized clinical trial comparing flexion-distraction with an exercise program for chronic low-back pain
6	Hawk *et al*.	2002	Issues in planning a placebo-controlled trial of manual methods: results of a pilot study
7	Hawk *et al.*	2005	A randomized trial investigating a chiropractic manual placebo: a novel design using standardized forces in the delivery of active and control treatments

NON-RANDOMISED CONTROLLED STUDIES

ARTICLE NUMBER:	ARTICLE AUTHOR(S):	YEAR:	ARTICLE TITLE:
1	Bulbulian *et al*.	2002	Spinal reflex excitability changes after lumbar spine passive flexion mobilization
2	Strunk RG and Hawk C	2009	Effects of chiropractic care on dizziness, neck pain, and balance: a single-group, preexperimental, feasibility study

DUT
DURBAN
UNIVERSITY OF
TECHNOLOGY

FACULTY OF
HEALTH
SCIENCES

12 September, 2013

Student No: 20430781

Mr D Cuppusamy
1 San Diego
295 Effingham Road
Durban
4051

Dear Mr Cuppusamy

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 to determine the evidence to support the use of flexion distraction Chiropractic technique.

Please note: ANY PROPOSED CHANGES in the DISSERTATION TITLE require the approval of your supervisor and the Faculty Research 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;

(e) Should you find any of the terms above not acceptable then you are given the option to decline the Research budget award to your project in writing.

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