A systematic review of the effectiveness of the use of the Activator Adjusting Instrument in treating spinal pain.

By

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

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DEDICATION

I dedicate this dissertation to my husband and my family.

Rich, this would really not have been possible without you by my side. Thank you for the endless support, love, motivation, and encouragement you have given me. Thank you for always encouraging me to follow my dreams.

My family. Mom, Dad, Chan and Mike, thank you for being there for me with love and support every step of the way.

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Rich, my husband and my best friend. Thank you for the endless love and support. You've motivated me, encouraged me and held my hand through it all. I'll eternally be grateful for the part you have had in this journey so far and I hope to make you proud.

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ABSTRACT

Background:

Spinal pain is commonly encountered by chiropractors and there are several adjustment techniques used to treat spinal pain. Practitioners are required to practice evidence-based chiropractic care in order to best care for their patients and to provide information to guide informed consent. A systematic review provides a well-structured summation and analysis of the available evidence and the effectiveness of the intervention. An analysis would be able to determine the level of evidence in support of the use of the Activator Adjusting Instrument (AAI) in treating spinal pain. The AAI can be used as an adjustment tool (as the AAI technique) outside of the AMCT protocol and the AAI can be used within the AMCT protocol. Both of these uses of the AAI are included in this study.

Objectives:

The aim of this dissertation was to review published literature regarding the use of the AAI in treating spinal pain. The effectiveness of the use of the AAI in treating spinal pain was evaluated to present current evidence available for its use to treat the different areas of the spine in clinical practice.

Method:

A literature search was conducted with the following key terms: “Activator”, “Instrument Adjusting”, “Joint Dysfunction”, “Manual Therapy”, “Activator Technique”, “Activator Adjusting” and “Instrument assisted manipulation”. Databases searched were PubMed and Scopus. The articles were screened according to inclusion and exclusion criteria, after which a secondary hand and reference searches were performed. All electronic or paper English articles, which possessed the required key indexing terms, met inclusion and exclusion criteria, and represented randomised controlled study, non-randomised controlled study and observational study designs, were included.

Data Collection and Analysis:

Blinded review of the articles was then conducted by six independent reviewers, as well as the researcher, utilising the PEDro Scale (for randomised controlled trials), Newcastle-Ottawa Scale for (non-randomised controlled trials) and Liddle Scale (for observational studies). This allowed the methodological rigour of each article to be ranked. The 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 to use the AAI in treating spinal pain.

Results:
A total of 23 articles were identified and included in this systematic review. The review and ranking of these articles revealed limited evidence in support of the use of the AAI outside of the AMCT protocol (AAI technique) in the lumbar spine, sacroiliac, and coccygeal regions; however, there was no evidence in support of or against its use in the cervical, thoracic and full spinal regions. There is limited evidence supporting the use of the AAI within the AMCT protocol in treating the cervical spine. There is no evidence supporting or against the use of the AAI within the AMCT protocol for the remaining spinal regions.

In the areas where limited evidence is available, spinal pain reduction as a result of the intervention (either AAI technique or AAI within the AMCT protocol) is comparable with the findings of manual manipulation. However, the majority of the spinal regions have no evidence available to base treatment guidelines and informed consent on, in clinical practice.

Conclusion:
Until further research is conducted surrounding the use of the AAI technique and the AAI within the AMCT protocol in the spinal areas where there is no evidence, practitioners are advised to use the AAI sparingly in these spinal regions, informing the patient of a lack of evidence, until such time as further studies have been carried out that produce reliable and valid evidence in these regions.

It is evident that future research is required surrounding the use of the AAI technique as well as the AAI within the AMCT protocol in order for practitioners to apply evidence-based practice and compete informed-consent procedures with patients. Having more evidence in these domains will strengthen the literature and allow for improved clinical decision-making based on evidence that is of high quality and practical value.

Key words: spinal pain, chiropractic, activator adjusting instrument, evidence-based care, informed consent, systematic review.

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DEFINITIONS

Activator adjusting instrument: This is a handheld instrument with a blunt stylus which is used to deliver a specific, controlled thrust to a vertebral subluxation/fixated vertebra (Killinger 2004; Fuhr and Menke 2005).

Activator Methods Chiropractic Technique: This consists of the assessment (the protocol) and the intervention (technique). The protocol can be used without the technique and vice versa. (Fuhr and Menke 2005).

Activator Protocol: This is the analysis and assessment of a patient involving prone leg length assessment. A series of manoeuvres are completed with the patient and the apparent and relative leg length is constantly rechecked with the patient prone. (Huggins *et al.* 2012).

Activator Technique: This is the intervention used involving the use of the AAI during treatment. It is using the AAI to deliver a specific controlled thrust. (Huggins *et al.* 2012).

Allocation bias: This type of bias arises when there is no randomisation when allocating participants into groups in clinical trials. This may occur if the investigator foresees or recognises which treatment the participant would most likely have the best outcome with and this may have an impact on the results. (Nunan, Aronson and Bankhead 2018).

Case study: A case study is a detailed and in-depth study of a particular case, which is different to studying a broad group of subjects. A case series is different as it follows more than one subject. (Mathes and Pieper 2017).

Chiropractic adjustment: A term used by chiropractors to describe manual manipulation of the joints and articulations of the body (Haldeman 2005). It is a “specific form of joint manipulation using either long- or short-leverage techniques with specific anatomic contacts. It is

characterized by a low-amplitude dynamic thrust of controlled velocity, amplitude, and direction. (Bergmann and Peterson 2011).

Citation bias: The probability of being cited depends upon the outcome of the said study. The number of times a research study is cited seems to be predisposed to positive results associated with said study. (Urlings *et al.* 2021).

Data: Refers to a collection of statistics or facts collected together for the purpose of analysis or reference (Mouton 1996).

Fixated: A chiropractic term used to describe a joint in the spinal column that has an abnormal position and restricted motion (Gatterman 1990).

Hawthorne Effect: In research participation the participant may have awareness of being studied, which may have an impact on the participant's behaviour. (McCambridge, Witton and Elbourne 2014).

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

Language bias: The publication of research findings that are specific to language which in turn results in bias (Stern and Kleijnen 2020).

Mobilisation: An augmented soft tissue technique which can be delivered to the patient and directed at the soft tissue or the joints in the body, with the aim of restoring movement. (Lefebvre, Peterson and Haas 2012).

Motion Segment: Describes a spinal unit which consists of two adjacent vertebrae and the soft tissues which connect them (Gatterman 1990).

Non-Randomised Controlled Trial: Studies in which participants were not randomly assigned into different groups. The researcher controls allocation of participants into groups. (Schmidt 2017).

Observational study: Researchers observe the effect of a treatment or other intervention without trying to change who is or is not exposed to it. Cohort studies and case control studies are two types of observational studies. (Song and Chung 2010).

Randomised Controlled Trials: Studies in which participants are randomly assigned into different groups. This type of study is known as the gold-standard for a clinical trial. (Spieth *et al.* 2016).

Sample: A small part or amount considered to be representative of the larger body or community (Mouton 1996).

Spinal manipulation: A physical procedure which is performed on the spine of the patient by chiropractors, osteopaths and physical therapists (Gatterman 1990; Haldeman 2005).

Spinal pain: Pain caused by the vertebra, the intervertebral discs, intervening soft tissues and the nerves that are associated with the spine (Cramer and Darby 2013).

Subluxation: A chiropractic term used to describe a dysfunctional biomechanical spinal segment which is fixated (Gatterman 1990; Leach 2004).

Systematic review: A review of the literature which aims to identify, collate, appraise, and present all the evidence on a specific subject (Liberati *et al.* 2009).

Translation bias: Translation may be subjective and allows for interpretation by the individual performing the translation which results in a level of bias (Kirkpatrick and van Teijlingen 2009).

ABBREVIATIONS

AAI:	Activator Adjusting Instrument
AMCT:	Activator Methods Chiropractic Technique
CS:	Case Series/Study
DASS21:	Disability Anxiety Stress Scale
DHI:	Dizziness handicap inventory
DUT:	Durban University of Technology
FES-I:	Falls Efficacy Scale International
HVLA:	High-Velocity, Low-Amplitude
IAM:	Instrument Assisted Manipulation
MAI:	Mechanically Assisted instrument
MAM:	Manually Applied Manipulation
MFMA:	Mechanical Force, Manually Assisted
MoCA:	Montreal Cognitive Assessment
MVC:	Maximum Voluntary Contraction
NDI:	Neck Disability Index
NPRS:	Numerical Pain Rating Scale
NRCT:	Non-Randomised Controlled Trial
NRCTs:	Non-Randomised Controlled Trials
NRS:	Numerical Rating Scale
ODI:	Oswestry Disability Index
ORS:	Orthopaedic Rating Scale
PGIC:	Patient Global Impression of Change
PRISMA:	Preferred reporting items for systematic reviews and meta-analyses
RCT:	Randomised controlled trial
RCTs:	Randomised Controlled Trials
ROM:	Range of Motion
sEMG:	Surface Electromyography
SF12:	12-Item Short Form Survey
SF-36:	RAND 36-Item Short Form Health Survey
SIJ:	Sacroiliac Joint
SMT:	Spinal Manipulative Therapy
TUG:	Timed Up and Go
VAS:	Visual Analog Scale

CHAPTER ONE INTRODUCTION

1.1 Introduction

Spinal pain is a common condition for which people seek care (Casiano *et al.* 2022). It has various causes and may result from structural spine-related problems or a musculoskeletal concern in an area of the spine. It is important for these concerns to be addressed in the best possible manner and in the most effective way possible, in order to restore a patients' wellbeing (Bergmann and Peterson 2011; Dagenais and Haldeman 2011; Byfield 2012).

One method in addressing spinal pain is manual therapy, which involves the application of a combination of conservative therapies to the patient. This includes different techniques applied after a thorough assessment of the patient, outlined in Figure 1.1 as taken from Bergmann and Peterson (2011).

Treatment procedures							
Joint manipulation procedures				**Soft tissue manipulation procedures**			
Manipulation	**Assisted manipulation**	**Mobilisation**	**Traction**	**Point pressure techniques**	**Massage**	**Therapeutic muscle stretching**	**Visceral manipulation**
Osteopathic manipulation	Activator	Long-lever mobilisation	Manual traction	Ischemic compression	Swedish massage	Static stretch	Osteopathic techniques
Manipulation under anaesthesia	Neuroimpulse	Oscillatory mobilisation	Leander traction	Active release techniques	Muscle manipulation (grip and rip)	Proprioceptive neuromuscular techniques	Traditional techniques
Chiropractic manipulation (adjustments)	Orthogonal technique		Cox-flexion dis-traction			Contract – antagonist relax – contract	
Medical manipulation	Upper cervical technique		McManis traction				

Figure 1. 1: Classification of manual therapies.

Figure 1.1 shows that there are interventions applied by hand (e.g. manual traction) as well as interventions applied with the aid of a mechanical device (e.g. Leander traction). The various manual therapy professions apply different combinations of these hand based versus mechanical device based therapies, dependent on their education and training as well as legal scope of practice/practice limitations (e.g. the majority of osteopathic techniques applied are applied by hand; by contrast the chiropractic profession applies both hand and mechanically assisted techniques (Huggins *et al.* 2012; Kendall *et al.* 2018)).

Thus, the use of mechanical devices and instrument assisted techniques to aid in treating spinal pain is not novel and one that is commonly utilised in the chiropractic profession is the activator adjusting instrument (AAI) (Huggins *et al.* 2012). The AAI technique is the most common instrument-adjusting intervention used amongst chiropractors (Read, Wilson and Gemmell 2006), particularly by older professionals who have developed work related musculoskeletal disorders of the hands (Mathews 2006) and in the treatment of patients with contraindications to manual manipulative interventions (Cooperstein *et al.* 2001; Hawk *et al.* 2010; Gleberzon *et al.* 2012)). However, the evidence in support of this tool is very limited, which prompted a systematic review of the AAI in the management of musculoskeletal disorders (Huggins *et al.* 2012). This systematic review by Huggins *et al.* (2012) was limited to the evaluation of prospective or retrospective articles including RCTs, controlled clinical/quasi-experimental trials, cohort, case control and case series; articles using some

type of outcome measure for determining the effect of chiropractic care and concluded that the AAI technique showed no greater benefit than other standard manual therapies (Huggins *et al.* 2012) (see Table 1.1).

Table 1. 1: Articles reviewed by Huggins *et al.* (2012).

Osterbauer *et al.*	1993
Gemmell *et al.*	1995
Yurkiw and Mior	1996
Wood *et al.*	2001
Shearar *et al.*	2001
DeVocht *et al.*	2003
Gemmell and Allen	2009
Schneider *et al.*	2010

In contrast to the above, the articles in Table 1.2, which could provide valuable contributions to the literature but did not form part of Huggins *et al*. (2012) review as they did not conform to the inclusion criteria, were not considered. In addition, the systematic review by Huggins *et al.* (2012) did not differentiate between the use of the AAI within the AMCT protocol (the assessment) and/or the AAI technique (the intervention) within the Activator Methods Chiropractic Technique (Fuhr and Menke 2005). Thus, there is an argument for the individual review of the AMCT protocol or the use of the AAI technique (using the AAI as an adjustment tool in a diversified manner). Additionally, the structured inclusion of articles other than RCTs in systematic reviews, particularly in the manual therapies where there is a small body of literature to review and because true RCT design is difficult to achieve in manual therapy studies (Moher *et al.* 1999) is important when evaluating evidence.

Table 1. 2: Articles excluded from Huggins *et al.* (2012).

Polkinghorn	1998
Polkinghorn and Colloca	1998
Polkinghorn and Colloca	1999
Keller and Colloca	2000
Symons *et al*	2000
Polkinghorn and Colloca	2001
DeVocht, Pickar and Wilder	2004
Roberts and Wolfe	2009

Therefore, this study as an updated systematic review, fills the void that currently leaves the chiropractic practitioners with limited evidence-based resources for the use of the AAI technique (i.e. outside of the protocol) or the AAI within the AMCT protocol to achieve the best clinical outcomes for the patient. This lack of clarity runs contradictory to the increasing use of the AAI technique and the AAI within the AMCT protocol in the chiropractic profession (Tinetti *et al.* 2016). This increased use is apparent for two reasons:

- the increasing age of the chiropractors within the chiropractic profession, who are turning to aids when adjusting patients due to their own musculoskeletal ailments (Mathews 2006; Tinetti *et al.* 2016).
- the need to address an aging population of patients that may have contra indications for hands-on manual therapy interventions (Huggins *et al.* 2012; Tinetti *et al.* 2016), which are perceived to impart greater forces when applied as compared to instrument assisted therapy.

Additionally, the increased use of the AAI technique does not always come with the increase training within the AMCT protocol, implying that practitioners apply the AAI technique within the context of a diversified approach (Fuhr and Menke 2005) in place of using their hands to impart the required forces to the spinal joints (viz. in a diversified approach to treatment of the patient) (Bergmann and Peterson 2011).

These fundamental external pressures and the need to validate these two AAI applications in clinical practice (technique and protocol), has encouraged research since the 2012 systematic review of Huggins *et al*. (2012). There has been no concurrent systematic review of this new research (Table 1.3) or the research excluded in the 2012 systematic review by Huggins *et al.* (2012) in order to critically evaluate and summarise the information pertaining to the use of the AAI technique and the AAI within the AMCT protocol. Also, there has been no systematic review done differentiating between the AAI technique and the use of the AAI within the AMCT protocol (Gemmell and Miller 2006; Huggins *et al.* 2012).

Table 1. 3: Composite of articles excluded from and more recent articles not available to Huggins *et al.* (2012).

Polkinghorn	1998
Polkinghorn and Colloca	1998
Polkinghorn and Colloca	1999
Keller and Colloca	2000
Polkinghorn and Colloca	2001
Gillespie	2003
DeVocht, Pickar and Wilder	2004
Roberts and Wolfe	2009
Gemmell and Miller	2010
Roberts and Wolfe	2012a
Roberts and Wolfe	2012b
Coetzee	2013
Norton and Callanan	2013
Gorrell, Beath and Engel	2016
Russell *et al.*	2016
Hardas and Murrell	2018
Kendall *et al.*	2018

Finally, two articles, identified in the review of the literature and were included in Huggins *et al. (*2012), focus on the use of the AAI on non-spinal pain, with the:

- Gemmel and Allen (2009) article excluded from the present study due to it being based on the effect of the AAI on muscular trigger points and not on the spine or spinal joints (Gemmell and Allen 2009).
- And De Vocht *et al.,* (2003) article excluded from the present study due to it not assessing spinal pain but rather focussing on temporomandibular dysfunction (Devocht *et al.* 2003).

Therefore, an updated systematic review of the literature outlined in Table 1.3 along with six of the eight articles Huggins *et al.* (2012) reviewed, would enable an aggregation, summation and synthesis of the research in a methodological manner in order to create a systematic review that looks at the effectiveness of the use of the AAI in treating spinal pain and guides future evidence-based practice (Liberati *et al.* 2009). This is imperative in the health care sector as it collates large amounts of research and assesses inconsistencies as well as strengths in the research and the importance of their outcomes (Liberati *et al.* 2009; Moher *et*

al. 2009; Lasserson, Thomas and Higgins 2019). In this systematic review, the AAI technique is looked at, separately to the protocol. The research surrounding its use in treating spinal pain is collated and reviewed, assessing how much evidence there is behind the effectiveness of the AAI technique and the AAI within the AMCT protocol and its use in treating spinal pain in patients. The results of this systematic review may guide future research by exposing where further research is needed and where evidence is lacking (Liberati *et al.* 2009).

Therefore, this systematic review of the AAI technique and the AAI within the AMCT protocol set out to determine the level of rigour within each article and its contribution to the evidence available in favour/not in favour of the AAI technique and the AAI within the AMCT protocol in treating spinal pain (Liberati *et al.* 2009; Moher *et al.* 2015). This provides evidence-based practice information that can inform the consent process (Shah *et al.* 2022); the practitioners choice of modality in clinical practice (Clijsters, Fronzoni and Jenkins 2014); clinical guideline development (Canadian Chiropractic *et al.* 2005) and future researchers' protocol development (Moher *et al.* 2015; Liberati *et al*. 2009).

1.2 Aims and objectives of this study

The *research question* asked what level of evidence is available for the use of the AAI technique and the AAI within the AMCT protocol in treating spinal pain in clinical practice.

The *aim* of the study was to determine the level of evidence available to support the use of an AAI technique and the AAI within the AMCT protocol in the management of spinal pain.

The *objectives* were:

- To systematically identify appropriate articles which would be included in the systematic review based on inclusion and exclusion criteria.
- To critically assess each of the included articles by use of standard assessment tools (for example: PEDro Scale (PEDro scale 2012), Newcastle Ottawa Scale (Wells *et al.* 2000), Liddle Scale (Liddle, Williamson and Irwig 1996)) to evaluate the rigour of the articles and their contribution to the evidence pool.
- To summarise the evidence that relates to the clinical outcomes per article with the use of an AAI technique on spinal pain.
- To collate articles within similar regions of the spine (cervical, thoracic, lumbar and pelvic) to aggregate the level of evidence available for the treatment of each spinal

region with the AAI technique, according to the GRADE (Brozek *et al.* 2009)) and the AGREE grading system noted in Dagenais and Haldeman (2011).

1.3 Rationale and benefits of this study

One way of deciding if the AAI technique and the AAI within the AMCT protocol are clinically effective and can be used in evidence-based practice is through a systematic review, which provides a consolidation of the research in this field. This was achieved by reviewing current evidence and research for the clinical use of the AAI technique and the AAI within the AMCT protocol in treating spinal pain; compiling the information and presenting it systematically as a basis for a clinical guideline. This also develops a starting point for future research and in turn improves the use of the AAI technique and the AAI within the AMCT protocol (Moher *et al.* 2015; Liberati *et al*. 2009).

This research project aimed to serve as a summation of available scientific evidence regarding the use of the AAI technique and the AAI within the AMCT protocol in the treatment of spinal pain in order to develop a platform for future research (Moher *et al.* 1999; Liberati *et al*. 2009).

Currently there is no substantial evidence that states that the use of the AAI technique or the AAI within the AMCT protocol is safer in certain patients or more favourable for the treatment of certain individuals and/or cases. A systematic review that collates all the previous research and creates a summation of the evidence pertaining to this subject will allow a chiropractor to ethically suggest a treatment method that is evidence-based (Huggins, *et al.* 2012).

Once evidence pertaining to the use of the AAI technique and the AAI within the AMCT protocol in clinical practice has been reviewed and the evidence for its uses has been assessed, there will be information that can be relayed to patients in order to inform them of available treatment options and the evidence related to its use. This underpins the practitioner's ethical responsibility to use treatment methods that have evidence to support its uses (Lefebvre, Peterson and Haas 2012). This systematic review addresses these concerns by providing a summation of the evidence available for the AAI technique and the AAI within the AMCT protocol and its use in a clinical setting in treating spinal pain.

Should the evidence support the use of the AAI technique or the AAI within the AMCT protocol in clinic practice following this systematic review, the AAI technique or the AAI within the AMCT protocol could be included in treatment guidelines for evidence-based practice. (Lefebvre, Peterson and Haas 2012). This could impact on future chiropractic treatment and

management of patients. A better understanding of the AAI technique and the AAI within the AMCT protocol, the uses and effects will be available for practitioners to use in order to provide evidence-based care to their patients.

1.4 Limitations/acknowledged biases of this study

This systematic review included literature that pertained to the use of the AAI in terms of the AAI technique and also literature in which the AAI was used within the AMCT protocol.

In terms of the included articles, selection bias is acknowledged due to the fact that only English articles or articles that had been translated into English were utilised in this systematic review (Moher *et al.* 1999) in order to eliminate translation bias (Jüni *et al.* 2002). Therefore, this created a limitation as there may have been articles excluded from this systematic review during the article selection process as a result of language that would have met the inclusion criteria and thus affected the outcomes of this systematic review. It is therefore recommended that future systematic reviews assessing the effectiveness of the AAI include non-English articles to assess for and reduce the language bias (Moher *et al.,* 1999), when compared to this systematic review, which only looked at English articles, or those which had been translated into English.

Publication bias is also acknowledged in this study, this is when more favourable results may be found more readily whereas those with negative results may be withheld or remain unpublished (Higgins and Green 2009). Grey literature, by contrast, tends to be more balanced with both favourable and unfavourable outcomes of articles available (although in some instances these are not peer-reviewed) (Moher *et al.,* 1999). Grey literature has been included in this study in order to minimise publication bias (Auger 1998).

1.5 Conclusion

Based on the overview and introduction presented in this chapter, Chapter Two presents a literature review outlining the use of the AAI technique and the AAI within the AMCT protocol in treating spinal pain in clinical practice as well as the importance of a systematic review of this topic. Chapter Three outlines the methods of this study. Chapter Four presents the results. Chapter Five presents the discussion of the results and findings. Chapter Six presents the conclusion and recommendations that are derived from this systematic review.

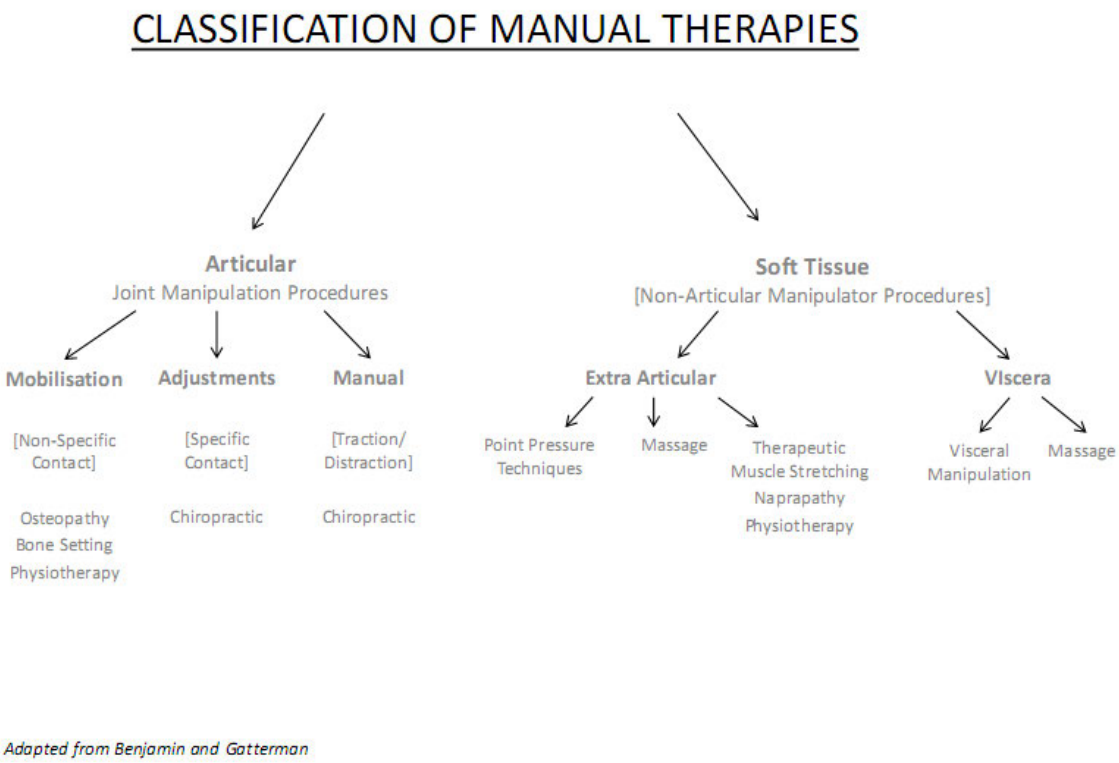
CHAPTER TWO LITERATURE REVIEW

2.1 Introduction

This chapter reviews the history of manual therapy, the history and development of the AAI technique (distinguishing it from the use of the AAI within the AMCT protocol), its uses and indications, discussions on spinal pain and the effect and importance of manual therapies in treating it. Thereafter, the evidence supporting the use of the AAI technique and the AAI within the AMCT protocol is presented in order to contextualise the rationale for this study.

2.2 Manual Therapy

Manual therapy takes various forms and has many uses. Joints can be mobilised, manipulated or given traction; soft tissue can have many massage forms performed on it; neural tissue can also be targeted and mixed therapies can be given, containing a variety of exercises. (Kuligowski, Skrzek and Cieślik 2021). (Figure 2.1).



Adapted from Benjamin and Gatterman

Figure 2. 1: Classification of Manual Therapies: An overview (Gatterman 1990).

Manual therapy has no single origin, however manual procedures are evident from over 4000 years ago in Thai artwork (e.g. origins of Nuad Thai). Records also show that manual procedures were used in ancient Egyptian (e.g., reflexology), Turkish, Chinese (e.g. Tuina), Japanese (e.g. Anma; Shiatsu) and Tibetan (e.g. Ku Ney) history to treat various diseases (Basmajian an Nyberg 1993). Manual therapy is also apparent in the Middle Ages in the eastern and western worlds. North and South American cultures used forms of manipulation as a form of treatment. Hippocrates (460-355BC), Galen (131-202 AD), Celsus, and Orbasius made mention of manipulation in their respective times. (Pettman 2007; Bergmann and Peterson 2011).

Manipulation went “underground” during the seventeenth century, survived principally in the texts of Abu’Ali ibn Sina (980-1037) and through passing of information down paternal familial lines (Basmajian an Nyberg 1993). Thereafter it evolved and resurfaced, developing from the peasant revival as “bone setting” used by Sir Herbert Barker, Sarah Mapp and others (Basmajian and Nyberg 1993), which was used to treat various ailments. In the nineteenth century the popularity of bone setters increased, with the most well-known being the Hutton family (Pettman 2007; Bergmann and Peterson 2011).

From a rich manual therapy history, osteopathy and chiropractic are two of the most popular forms of manual therapy in the Western world (Pettman 2007; Bergmann and Peterson 2011). They have similar origins (Andrew Taylor Still and David Daniel Palmer were friends and lived in the same era) and similar beliefs (Law of the artery and Law of the nerve separated the two originators of their manual therapies) and treatment protocols (Basmajian and Nyberg 1993; Pettman 2007). However, over the years they have evolved into two separate entities of manual therapy entirely (Klein 1998). Manipulation is associated with both professions. Both professions focus on the musculoskeletal system, only slightly differently – osteopathy places emphasis on the somatic component of disease (law of the artery), whereas chiropractic focuses on innate intelligence (law of the nerve), the ability of the body to heal itself and the effect that a misplaced/dysfunctional joint (subluxation) can have on the neurological system (Maigne and Vautravers 2003; Bergmann and Peterson 2011).

Chiropractic itself is a form of manual therapy and involves assessing the musculoskeletal system and the effects that disorders of this system have on the neurological system (Meeker and Haldeman 2002; Maigne and Vautravers 2003). The WFC defines Chiropractic as *“a health profession concerned with the diagnosis, treatment and prevention of mechanical disorders of the musculoskeletal system, and the effects of these disorders on the function of*

the nervous system and general health. There is an emphasis on manual treatments including spinal adjustment and other joint and soft-tissue manipulation."

Chiropractic was developed in the United States of America under Daniel David Palmer along with his son, Bartlett Joshua Palmer; his daughter-in-law Maribel Palmer and their children. This was expanded to then include the first graduates of DD Palmer's Chiropractic College. (Pettman 2007; Gyer, Michael and Davis 2017; Johnson 2020). Daniel David Palmer, along with Andrew Taylor Still familiarised themselves with bone setting and bone setting techniques, as well as magnetic healing, and later developed a system which lead to the founding of chiropractic and osteopathy respectively (Johnson 2020). The development of both professions in the nineteenth century were largely American, however there were developments occurring elsewhere in the world. Bone setting still is being used in certain areas around the world – principally Africa, South America and some Asian countries. (Nwachukwu *et al.* 2011; Aderibigbe, Agaja and Bamidele 2013).

Although chiropractic was founded in 1895, manipulation has been used to treat human ailments since antiquity (Pettman 2007; Bergmann and Peterson 2011). There are various manipulation techniques, all which serve their purpose and function in the treatment of a patient. Having a variety of manipulation techniques at hand, allows the practitioner to create a tailored-made treatment for the patient, considering their individual needs and treatment requirements; as well as allowing the practitioner to use techniques that are suitable for them to execute or apply to the particular patient. (Maigne and Vautravers 2003; Gyer, Michael and Davis 2017).

DD Palmer, the founder of Chiropractic, reportedly restored the hearing in his deaf patient by applying a manipulative thrust to the fourth dorsal vertebra, which improved and restored motion in that segment of the spine and the patient had improvement in hearing. (Chapman-Smith and Jonas 2000; Redwood 2003). From this, Palmer believed that most diseases were caused by abnormal nerve signals, caused by dysfunctional joints in the spine, which he termed "vertebral subluxations". He believed that these vertebral subluxations caused interference with the nerves, and their signal conduction, and in turn caused disease. (Chapman-Smith and Jonas 2000; Leach 2004). Theoretically, these vertebral subluxations have been explained as joints that are dysfunctional, with abnormal motion and/or physiological function (Leach 2004), with the concomitant changes in the biochemistry and histology of the region affecting muscles, nerves, ligaments/connective tissue and vessels (Maigne and Vautravers 2003). A subluxation syndrome is when these changes bring about clinical symptomatology (Bergmann and Peterson 2011). There will be spinal joint dysfunction,

associated swelling/oedema, muscle spasm which may be aggravated upon palpation of the affected segment. (Haldeman 2005; Bergmann and Peterson 2011). (Figure 2.2).

Chiropractors use their hands to do a thorough manual assessment of a patient and then apply manual therapy using their hands or instruments to correct joint dysfunctions, alignment issues, improve function increase mobility and reduce pain and discomfort (Wardwell 1992; Cramer *et al.* 2006). Dysfunctions in the body and kinematic chains can be treated throughout the body using various forms of manual therapy. In turn, the body is able to function as a well aligned unit, more effectively and efficiently. (Pettman 2007; Bergmann and Peterson 2011).

Manual therapy includes the use of mechanical devices to aid in treating spinal pain, one of which is the AAI (Read, Wilson and Gemmell 2006; Huggins *et al.* 2012). The AAI is the most commonly used instrument-adjusting intervention amongst chiropractors to manipulate a joint dysfunction (Huggins *et al.* 2012; Clijsters, Fronzoni and Jenkins 2014).

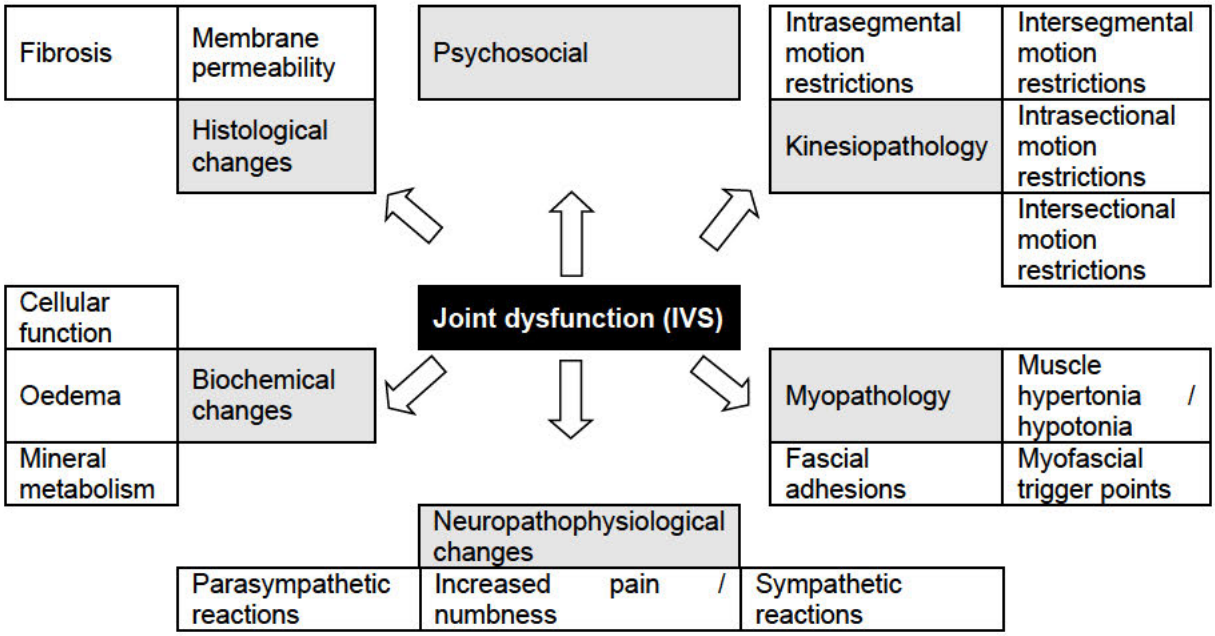


Figure 2. 2: Joint dysfunction (Leach 2004; Bergmann and Peterson 2011).

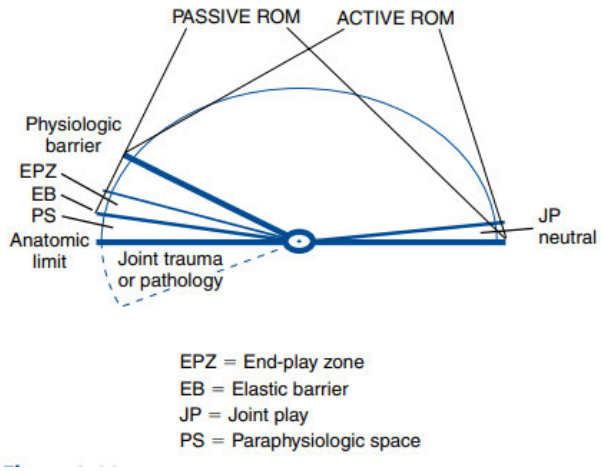


Figure 2. 3: Joint motion starting from neutral position (Sandoz 1969; Bergmann and Peterson 2011).

A patients' range of motion is assessed, actively (patient moves through their range of movement) and passively (overpressure at the end range of active movement applied by the practitioner) and motion palpation of the joints also takes place. Static palpation is done of the soft tissue and bones whilst the patient and joints are static. Motion palpation is done to assess the quality and quantity of joint movement whilst the palpator feels for restrictions, areas where the joints are not moving optimally, indicating areas where there are joint dysfunctions. Restrictions in the motion of the joint are possible at any point in the joints range of motion and it may be within the joints active or passive range – hence all need to be assessed in the patient to identify the restriction as accurately as possible. (Vernon and Mrozek 2005; Bergmann and Peterson 2011).

Due to the decreased muscle activity during passive motion, there is usually more movement when compared to active motion. During passive joint movement, a resistance will be felt as one reaches the limits of passive movement in the joint, this is when the joints elastic limits are being reached. This is known as the end-play zone. The joint can be moved into this zone by overpressure from the practitioner to move the joint further. When the overpressure is released, the joint will spring back from its elastic limits. (Figure 2.3). Elastic properties of the joint capsule and its periarticular soft tissues are assessed through assessing the movement in this region/zone. (Vernon and Mrozek 2005; Bergmann and Peterson 2011).

The clinical features of joint dysfunctions may include a combination of (Vernon and Mrozek 2005; Bergmann and Peterson 2011):

1. Local pain: commonly changes with activity,
2. Local tissue hypersensitivity,
3. Decreased, increased, or aberrant joint movement,
4. Altered or painful joint play,
5. Altered and/or painful end-feel resistance,
6. Altered alignment and/or
7. Local palpatory muscle hypertonicity.

Spinal pain is often the symptom with which a patient presents, as a result of the subluxation syndrome and dysfunction within the spinal joints (Cramer *et al.* 2006). It is a common condition for which people seek care. Spinal pain has various causes which are categorised into mechanical and pathological in nature (Dagenais and Haldeman 2002). People of any age can suffer spinal pain of a mechanical nature, which is pain caused by the vertebrae, the intervertebral discs, intervening soft tissue and the nerves that are associated with the spine (Cramer and Darby 2013). The pain is often a result from impaired functioning or movement of the spine (Parkin-Smith *et al.* 2015), hence joint dysfunctions need to be identified and treated. It is important for these concerns to be addressed in the best possible manner and in the most effective way possible in order to restore a patients' wellbeing. (Dagenais and Haldeman 2002; Bergmann and Peterson 2011).

When treating spinal pain there are the following outcome measures (Bergmann and Peterson 2011):

1. Regional mobility measurements
2. Pain reporting instruments
3. Physical capacity questionnaires
4. Physical performance measures
5. General health status

Manipulation is one of the main techniques/procedure's chiropractors use to treat patients with joint dysfunctions and associated spinal pain. Manipulation can be applied manually (by hand) or by instrument-assisted methods (Huggins *et al.* 2012; Clijsters, Fronzoni and Jenkins 2014), such as the AAI.

2.3 The Chiropractic Manipulation and Adjustment

“Spinal manipulation”, also known as the “Chiropractic adjustment” is a form of treatment which involves correcting the alignment of spinal joints by manual or by instrument-assisted manipulative techniques, in order to improve neurological function. The philosophy behind this is that the nervous system controls the body and by restoring/improving neurological function, dysfunction or disease may be helped and treated in patients. (Plaugher and Lopes 1993; Bergmann and Peterson 2011).

There are numerous theories and philosophies behind the adjustment of dysfunctional joints and the effect that the adjustment has on various structures. There are apparent effects on the vertebral bodies, the facet joints, the intervertebral discs, the paraspinal muscles and the blood flow in the area as a result of an adjustment. There is associated pain reduction through restoring movement and stretching ligaments, discs, joint capsules or muscles. The pain reduction is also related to the activation of the diffuse descending pain inhibitory system during an adjustment. (Maigne and Vautravers 2003).

According to Bergman and Peterson (2011), “joint manipulative therapy is broadly defined and includes all procedures in which the hands are used to mobilise, adjust, manipulate, apply traction, stimulate, or otherwise influence the joints of the body with the aim of influencing the patient’s health; a manual procedure that involves a directed thrust to move a joint past the physiologic ROM without exceeding the anatomic limit; skilful or dexterous treatment by the hand. In physical therapy, the forceful passive movement of a joint beyond its active limit of motion.”

The chiropractic adjustment is perceived to be the centre of the practice in chiropractic. According to Bergman and Peterson (2011), an adjustment is a “specific form of joint manipulation using either long- or short-leverage techniques with specific anatomic contacts. It is characterized by a low-amplitude dynamic thrust of controlled velocity, amplitude, and direction. Adjustments are commonly associated with an audible articular crack (cavitation). Chiropractors commonly use such procedures to influence joint and neurophysiologic function.”

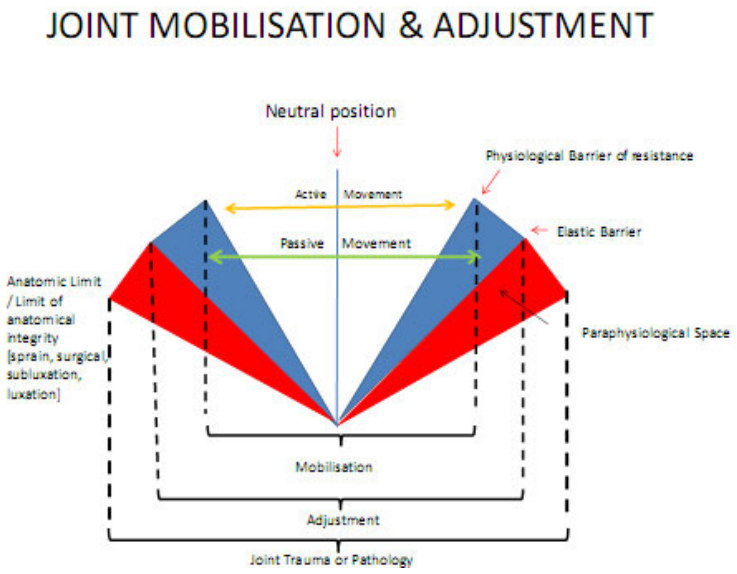


Figure 2. 4: Schematic Outline of Mobilisation and Manipulation (Bergmann and Peterson 2011).

Movement beyond the end-play zone is possible and is usually associated with an “articular crack”, generally only after the fluid tension between the synovial surfaces has been overcome (Sandoz 1969; Flynn *et al.* 2003; Vernon and Mrozek 2005; Bergmann and Peterson 2011). This is known as the zone of paraphysiologic movement and its boundaries are the elastic and anatomic barriers (Sandoz 1969). Movement into this space does not cause joint injury as it is still within the joints elastic range and anatomic limits. From here additional movement is possible after joint surface separation, usually after joint cavitation, the “articular crack”. This extends the passive range of motion of the joint. If the joint capsule is highly flexible, the “articular crack” may not occur, this is a result of joint separation occurring without fluid tension build up between the two surfaces. (Haas and Peterson 1992; Flynn *et al.* 2003). Should the anatomic limit of the paraphysiologic space be breached, joint trauma and plastic deformation may result (Figure 2.4) (Sandoz 1969; Vernon and Mrozek 2005; Bergmann and Peterson 2011).

When joints are being palpated, alignment, tenderness and anomalies are being assessed as well as motion and movement. Since the spine is treated as a kinematic chain, with one area affecting others, the spine needs to be motion palpated in order to distinguish normal compensation from joint dysfunction in addition to primary and secondary joint dysfunctions. (Thomson, Haig and Mansfield 2009; Bergmann and Peterson 2011).

Shortening of muscles often results in restrictive barriers during active range of motion whereas restrictive barriers to movement at the end range of passive motion generally indicate shortening of the periarticular soft tissues and in the joint capsule (Bergmann and Peterson 2011).

Joint dysfunctions, the dysfunctional motion segments, are treated using a chiropractic adjustment. A specific adjustment is delivered to the dysfunctional joint. The force is directed into the restriction in order to increase the range of motion within the joint, whilst avoiding additional harm to the supporting ligamentous structures. This is a specific adjustment, protecting normal joints and joints that are not dysfunctional, from the adjustive thrust. (Plaugher and Lopes 1993). Neuromusculoskeletal dysfunction is the main reason for which chiropractors are consulted. There is a link between the structure and function of the neuromuscular system and one's health and homeostatic regulation. (Maigne and Vautravers 2003). Chiropractic care is reported to be more effective than medical care for back pain. (Thomson, Haig and Mansfield 2009; Bergmann and Peterson 2011).

The term manipulation does not always imply or refer to a thrust technique or adjustment. The term manipulation is quite broad and is used quite widely: it makes reference to using ones hands to move, rearrange and alter objects. (Bergmann and Peterson 2011).

There are many different manipulative techniques that can be used, all with the common goal of restoring motion, reducing oedema, muscle spasm and pain to the segment involved, which in turn results in the restoration of normal physiology and function. (Plaugher and Lopes 1993; Chapman-Smith and Jonas 2000; Maigne and Vautravers 2003; Leach 2004; Thomson, Haig and Mansfield 2009). There are long and short lever techniques, techniques applied and carried out by the hands manually, delivering a HVLA thrust in a specific direction to a specific joint. Adjustments may also be instrument assisted, such as the AAI, to deliver a controlled force in a particular direction to a specific dysfunctional joint. (Bartol 1991; Bergmann and Peterson 2011).

Adjustments can be specific or general, with specific adjustments focusing the force/thrust onto the joint that is dysfunctional, being more precise in nature than a general adjustment. A general mobilisation mobilises more than one joint at a time, usually uses a broad and long-lever contact, having broader effects, but less specificity. A general mobilisation is usually done to induce movement or reduce stiffness and reduce muscle spasms. (Thomson, Haig and Mansfield 2009). Painful neuromuscular conditions (e.g. joint sprain) are treated by chiropractic manipulation, successfully. (Pellow and Brantingham 2001). Spinal manipulative

therapy is also said to be a safe and effective treatment choice, along with being cost-effective (Haas, Sharma and Stano 2005; Bergmann and Peterson 2011).

The chiropractic profession places emphasis on short lever techniques, delivering more specificity, with the ability to localise the delivery of the adjustment to the affected joint. This results in less stress placed on adjacent joints that are not dysfunctional and becomes important to consider when there is joint instability near the joint being adjusted. (Bergmann 1992; Bergmann and Peterson 2011).

Many different manipulative techniques have become apparent in the profession. The variety of manipulative techniques gives the practitioner variety when treating a patient, with options to draw from, depending on the patients' size, shape, preference, co-morbidities, age, presenting complaint as well as the practitioners preferences, injuries, size, space. (Bergmann and Peterson 2011; Byfield 2012; Schneider *et al.* 2015).

There are certain instances in which an adjustment would not be the indicated intervention for a patient with a joint dysfunction. There are contraindications to adjustments (Table 2.1) that need to be considered in clinical practice in order to minimise harm and maximise benefit to the patient. (Anderson-Peacock *et al.* 2005).

Table 2. 1: Conditions that contraindicate or require modification to High-Velocity Low Amplitude Spinal Manipulative Therapy (Canadian Chiropractic *et al.* 2005; Batavia 2006; Bergmann and Peterson 2011).

Atherosclerosis of major blood vessels	Coagulopathy
Vertebrobasilar insufficiency	Osteopenia
Aneurysm	Space occupying lesions
Tumours	Diabetes (neuropathy) – no pain response
Fractures	Malingering hysteria hypochondriasis
Severe sprains/trauma	Alzheimer's disease – no response to pain
Osteoarthritis (late stage)	Hypertension
Local infection	VAD or CAD
Uncarthrosis	Surgical spinal fusion
Acute cardiac disease	Active inflammatory arthrotides
Obvious medical emergencies	Recent severe haemorrhage

Given that manual adjustments (hands on therapy) may be contra-indicated in some instances of a patient's unique presentation; the chiropractic profession as well as other professions have developed mechanical devices that may be used for inducing the same outcomes with either less force or more specificity; or both. One of these devices in the chiropractic profession is the Activator Adjusting Instrument (AAI).

2.4 The Activator Adjusting Instrument

2.4.1 The History and development of the Activator Adjusting Instrument and its uses in treating spinal pain

The AAI was originally derived from a dental impactor in the 1960s, by Warren Lee and Arlan Fuhr, however it was only in the 1970s that the AAI became commercially available. Since its development various generations of the AAI have been developed with the force, frequency and design being altered and improved on, in each iteration of the AAI (Fuhr and Menke 2005).

The AAI is a handheld instrument with a blunt stylus to apply a thrust in order to correct the vertebral joint movement (Fuhr and Menke 2005). A specific, consistent, reproducible, controlled, high-velocity, low-amplitude thrust is provided by the AAI (Killinger 2004) to the dysfunctional joint (Fuhr and Menke 2005). According to Fuhr and Menke (2005), activator thrust produced measurable neuromuscular responses in a patient, muscle stiffness can be eased and there is temporary increase in trunk musculature tone after an AAI adjustment. This may be achieved by both the AAI (mechanical device) as well as the neuro-impulse adjuster (electric mechanical device) (Colloca *et al.* 2005).

The AAI can be used on patients rather than, or in conjunction with, the typical high velocity, low amplitude (HVLA) thrust that is used to deliver an adjustment on a patient manually. Manual adjustments and adjustments delivered by the AAI have similar frequencies, however it is noted that they deliver forces that differ in amplitude or quantity. The AAI provides a low risk of injury due to the small amplitude it delivers within the short excursion induced (Fuhr and Menke 2005). Adjusting with the AAI minimises rotation and vertebral artery injury (Bergmann and Peterson 2011). Joint specificity can be obtained using the AAI (Huggins *et al.* 2012) as well as localised neural responses. Spinal resonance is reduced when using the AAI technique versus HVLA manipulation. The total force at the target segment is the same with both of the above-mentioned techniques, however it is noted that the total adjustive force

is greater in manual HVLA adjustments when compared to an AAI adjustment. (Fuhr and Menke 2005).

The Activator Methods Chiropractic Technique (AMCT) is composed of a protocol and a technique. Activator Methods Chiropractic Technique was developed by Arlan Fuhr in 1967, and the AAI, which forms part of this techniques' intervention, is one of the most widely used instruments in chiropractic care (Huggins *et al.* 2012).

Activator Methods Chiropractic Technique (AMCT) consists of two procedures: the assessment (protocol) and the intervention (technique) (Fuhr and Menke 2005).

> The activator protocol associated with AMCT is the analysis and assessment involving prone leg length assessment (Huggins *et al.* 2012). A series of manoeuvres are completed with the patient and the apparent and relative leg length is constantly rechecked with the patient prone (Fuhr and Menke 2005). This is believed to give direction to the practitioner as to dysfunction in the joints of the spine and pelvic rotation - without the use of an x-ray. After the assessment various isolation, pressure and stress tests can be performed on the patient before commencing treatment. (Fuhr and Menke 2005).
>
> Whereas the activator (AAI) technique itself is the intervention used. The AAI technique uses the AAI as a substitute for a manual HVLA manipulation, or in conjunction with HVLA manipulation. The AAI technique uses the AAI as an adjustment tool with or without the use of the protocol (Huggins *et al.* 2012).

The AMCT protocol can be used without the AAI technique and vice versa (Fuhr and Menke 2005).

The AAI is the most commonly used therapeutic intervention device for patient care by Chiropractors, second to the Diversified technique, which involves manual thrusting (Huggins *et al.* 2012). The AAI is used commonly in the chiropractic profession, particularly by older professionals who have developed work-related musculoskeletal disorders of the hands (Mathews 2006), by practitioners at times of personal injury or strain or when dealing with a large patient (Taylor *et al.* 2004) and in patients with contraindications to manual manipulative interventions (Cooperstein *et al.* 2001; Hawk *et al.* 2010; Gleberzon *et al.* 2012).

Thus, in terms of utilisation, the percentage of chiropractors using activator methods increased in the USA from 51,2% in 1991 to 69,9% in 2003 (associated with the aging chiropractic practitioner population) (Read, Wilson and Gemmell 2006). This concurs with Huggins *et al.* (2012) who indicate that there is a high use of the AAI worldwide with an estimated 40% of Chiropractors using the AAI in Canada, 82% in the UK, 72,7% in Australia and 54,3% in New Zealand. The increase in its use is in line with the aging population (Tinetti *et al.* 2016) as well as aging chiropractors (Mathews 2006). It is also noted that there is a higher usage of the AAI amongst female chiropractors versus male chiropractors. In a questionnaire, it was reported that 88% of females used the AAI in the treatment of their patients and 79% of males use the AAI in the treatment of their patients. (Read, Wilson and Gemmell 2006).

Chiropractors that treat elderly patients with various comorbidities also seem to prefer to use the AAI rather than a manual adjustment due to it providing a more controlled force (Huggins *et al.* 2012). This is particularly true in patients that have contra-indications to manual/hand manipulative techniques (such as osteoporosis) (refer to Table 2.1) (Cooperstein *et al.* 2001; Hawk *et al.* 2010; Gleberzon *et al.* 2012), but it is equally true for any patient that presents with contra-indications to manual/hand manipulative techniques where alternate treatment techniques are sought (Dagenais and Haldeman 2002; Bergmann and Peterson 2011; Byfield 2012). Thus, AAI is popularly used in cervical pain patients, given the concerns around vertebrobasilar artery insufficiency. In a questionnaire, 82% of respondents who use the AAI in the treatment of their patients, have made use of the AAI in the treatment of the cervical pain. (Read, Wilson and Gemmell 2006). As a result, the AAI is thought to be a good treatment option for certain patients contra-indicated to manual HVLA adjustments (Fuhr and Menke 2005).

The AAI is also a treatment of choice in infants (Todd, Carroll and Mitchell 2016) and patients who are nervous of physical touch or even joint cavitation can also benefit from the use of AAI in treatments (Bigna, Um and Nansseu 2016).

The AAI may also be beneficial for future research that looks at physical and physiological responses to thrusts since the AAI provides a controlled and measurable speed and force on the impulse whereas manual thrusts are variable and not controlled. (Fuhr and Menke 2005).

Given the above contexts, the instrument is often used in conjunction with other treatment techniques. Up to 60% of those using the AAI do so in combination with other treatment techniques (e.g. Diversified technique) (Read, Wilson and Gemmell 2006). It also indicates that AAI can be combined with various Chiropractic techniques to treat a variety of conditions

and ailments successfully and help in pain relief (outside of the AMCT protocol, just as the AAI technique).

Although it has been reported to be a safe and effective treatment method, with its use across the globe increasing annually (Read, Wilson and Gemmell 2006), further studies need to be done around the AAI technique and the AAI within the AMCT protocol to allow it to be better understood, accepted and used (Fuhr and Menke 2005). Its increase in use has not been associated with concomitant clinical evaluation of its safety and effectiveness in a clinical setting (Read, Wilson and Gemmell 2006). Because of the AAI being a popular device and the activator technique intervention being so commonly used (as part of the AMCT protocol or as the AAI technique in conjunction with other protocols or as the AAI technique alone), the effectiveness of its clinical use needs to be fully understood (Taylor *et al.* 2004).

Randomised clinical trials may be done to provide a greater degree of internal and external validity, case studies may be done to illustrate clinical possibilities and iterations in some cases; all of these studies will help further the future of the AAI and allow it to better conform with evidence-based practice entirely (Fuhr and Menke 2005). The AAI is a tool that needs to have adequate evidence-based research that is available to practitioners so that proper understanding can be reached around the AAI. This serves two purposes in that it underpins the principles of evidence-based practice and it allows practitioners to be fully able to implement informed consent as required by many jurisdictions (Cleary-Holdforth 2017).

Given that it seems that the evidence in support of this device is limited, a systematic review of the AAI in the treatment of spinal pain would not only allow for the development of research projects targeting areas of need but it would also allow for the basis of guideline development for the use of AAI in practice. (Medina and Barría 2010; Perestelo-Pérez 2013; Moher *et al.* 2015; Bigna, Um and Nansseu 2016; Cleary-Holdforth 2017).

2.4.2 Previous studies regarding the Activator Adjusting Instrument

The AAI is a commonly used manual manipulative instrument used to provide a consistent, controlled force adjustment at a precise and specific line of drive at a high speed. It is commonly used to treat spinal and extremity disorders. (Taylor *et al.* 2004). When using the AAI as an adjustment tool (AAI technique) as part of a Diversified technique, the AAI is applied to the dysfunctional joint and a number of high-velocity, low amplitude thrusts are delivered. (Fuhr and Menke 2005; Coetzee 2013). The AAI delivers a force that is enough to produce relative movement of the dysfunctional joint and the associated vertebra yet not enough force

to cause injury. The hypothesised effects of the AAI is to restore joint movement, resulting in an increase of the mechanoreceptor effect (Gate control theory and integrated pain theory) (Melzack and Wall 1962; Leach 2004) thereby reducing pain and inflammation within the joint(s) (Haldeman 2005).

The AAI delivers relatively low peak forces and has the lowest thrust duration when compared to other techniques. Evidence suggests that certain vibratory frequencies have the ability to promote healing or inflict harm, with those that closely match the natural resonance of body tissues being conducted more efficiently through the body. The effective transmission of adjustive forces may be as a result of matching spinal resonant frequencies in addition to force magnitude and amplitude and this is possible to achieve with the AAI. (Fuhr and Menke 2005).

Research has been conducted looking at the use of the AAI and its effectiveness, however it is often being used and researched in conjunction with the AMCT protocol itself. Published research has focused on reliability and validity of the prone leg length assessment which is used as part of the AMCT protocol as well as focusing on the reliability and validity of the diagnostic tests unique to the protocol of AMCT, such as isolation, stress and pressure tests). (Huggins *et al.* 2012).

The research by Gleberzon (Gleberzon 2000; Gleberzon 2001), reported on the use of the AAI within the AMCT protocol, not the AAI technique itself.

A review by Taylor *et al*. (2004) concluded that the AAI was as effective as manual procedures in producing clinical benefit. According to Gemmell and Miller (2006) future studies directly comparing mobilisation, manipulation and instrument assisted manipulation should pay attention to the clinical effectiveness and risks.

Limitations in the five–publication systematic review conducted by Gemmell and Miller (2006) were that only English papers were included and there is a lack of grey literature. The methodological quality and resultant outcomes resulted in poor evidence and inconclusive results in favour/not in favour of AAI (Gemmell and Miller 2006).The more recent systematic review and meta-analysis of the AAI by Huggins *et al.* (2012) revealed eight studies that showed benefit that was not dissimilar to Gemmell and Miller (2006), showing that manual manipulative or trigger point AAI intervention had poor/no evidence in its favour, given the limitations of the study types. In essence, the meta-analysis found that the AAI had a non-statistical clinical benefit in patients with spinal pain. This review recommended further studies with larger sample sizes and improved rigour (Huggins *et al.* 2012).

In this meta-analysis, the articles reviewed required the inclusion of a specific outcome measure (i.e. pain reporting) that was consistently reported in all the studies (i.e. omitting articles that did not have this inclusion), thereby excluding grey literature and other evidence that may support or negate the findings of the study (Huggins *et al.* 2012). This also implies that the meta-analysis did not look at composite clinical findings and/or the homogeneity of the patients included into these respective studies (thus limiting the ability of the meta-analysis in terms of applicability to generalised patient populations). Additionally, the review by Huggins *et al.* (2012) did not differentiate between and separate the AMCT protocol (assessment of the patient) and the AAI technique (applied intervention); the outcomes obtained in the review are unclear. In order to inform best practice guidelines, a systematic review of the AAI technique outside of the AMCT protocol would allow a collation of evidence either in support or not in support of the technique specifically.

Finally, articles have been published after this systematic review by Huggins *et al.* (2012), which excluded any articles after 2010 (Table 2.2), therefore an update in reviewing the evidence in support of the use of the AAI, was required.

Table 2. 2: Articles published after 2010 relating to this systematic review.

Gemmell and Miller	2010
Roberts and Wolfe	2012a
Roberts and Wolfe	2012b
Coetzee	2013
Norton and Callanan	2013
Gorrell and Engel	2016
Russell *et al.*	2016
Hardas and Murrell	2018
Kendall *et al.*	2018

Since there are numerous articles that have been published since the systematic review by Huggins *et al.* (2012), it is evident that this systematic review is needed in order to summate all the research that has been completed to date.

2.5 Systematic reviews

2.5.1 Summarised overview of a Systematic Review

Moher *et al.* (2009) defined a systematic review as an unambiguous technique that attempts to identify, appraise and synthesise all the empirical evidence that meets pre-specified eligibility criteria to answer a clearly articulated question. It involves critique and synthesis of existing evidence to draw conclusions to answer this specific clinical question (Moher *et al.* 2009; Harris *et al.* 2013). A clearly defined clinical question needs to be asked, creating a purpose for the review (Medina and Barría 2010) and the literature is then searched accordingly (Liberati *et al.* 2009). It is a retrospective, observational scientific process (Cook, Mulrow and Haynes 1997), analysing the results of many primary investigations, limiting bias and random error (Mulrow 1987; Cook, Mulrow and Haynes 1997).

A systematic review is a rigorous, systematic process by which an exhaustive selection of all available articles in the literature using predefined criteria and methods, is completed. A lot of focus is placed on finding the articles to be included in the systematic review. The articles are to meet certain criteria (inclusion and exclusion criteria) in order to be included in the systematic review. These criteria are outlined by the researcher. Numerous databases are searched, and a hand search is also completed to ensure bias is limited as much as possible. (Fox 2005; Medina and Barría 2010).

A systematic review involves a process which is a thorough and efficient research method which aims at identifying, selecting and critically assessing previously conducted research, by conducting in depth critical review (systematic review) and/or analyses of the data obtained (meta-analysis) from the included studies (Buchbinder *et al.* 2006). Once the articles have been obtained, they are categorized by a pre-set criterion, defined by either study type (qualitative or quantitative or randomised controlled trial, non-randomised controlled trial, observational studies (as examples)) or by study topic area (Oxman, Sackett and Guyatt 1993).

Reviewers are appointed and are each asked to independently review articles that fit the criteria (Medina and Barría 2010). Each article is reviewed by at least two reviewers, creating a platform for discussion in the systematic review, also known as a “synthesis of best evidence”. (Fox 2005; Liberati *et al.* 2009). The articles are critically assessed in terms of their rigour and its impact on the outcomes. The data is collected from the reviewers and this feedback is compiled into tables. The data is then analysed and synthesised, any reporting

biases are important to note. A discussion of the results follows along with strengths and weaknesses of the evidence. Thereafter, a summary is made of the evidence found as the results are interpreted and conclusions and drawn. (Higgins and Green 2009; Liberati *et al.* 2009; Medina and Barría 2010).

2.5.2 Outline of a systematic review

A detailed description of the methodology of this particular systematic review is offered in Chapter Three of this study. The study protocol is in line with the gold standard of systematic reviews as set out by the Cochrane Collaboration (Higgins *et al.* 2011). More than 31 000 healthcare specialists who systematically review RCTs of the effects of preventions, interventions and health systems form part of the Cochrane Collaboration. The checklist from the PRISMA statement has been used when reporting in this systematic review (Liberati *et al.* 2009).

The Cochrane Handbook (Higgins *et al.* 2011) outlines eight general steps for conducting a systematic review. These are as follows:

1. Define the review question and develop criteria for including and excluding articles.
2. Search for articles: from electronic databases to manual “hand searches” of paper articles.
3. Select articles based on specified criteria and collect data.
4. Assess the quality as well as the levels of bias in the included articles
5. Analyse data and conduct meta-analyses (where appropriate).
6. Identify and address reporting biases.
7. Summarise findings, describe strengths and weaknesses of the evidence, and present results in well-described tables.
8. Interpret results and draw conclusions

2.5.3 The Role of Systematic Reviews

Systematic reviews aim to identify, evaluate and summarise the findings of articles relevant to the study topic. Through doing this, it provides practitioners and the public with unbiased summaries of available information pertaining to the topic of the systematic review. (Higgins and Green 2009; Fox 2011). It is a process of summarising information and evidence reliably

and accurately (Liberati *et al.* 2009), via the appropriate scales per study type (Liddle, Williamson and Irwig 1996; Wells *et al.* 2000; PEDro scale 2012).

The extent and level of research evidence in a particular area/field is reviewed using various methods and techniques to reduce bias, reduce error and produce findings that are reliable and that can guide future research, treatment guidelines and inform decision-making and evidence-based practice. By following major guidelines in completing a systematic review, the evidence and results from a systematic review provide professionals and the public with an unbiased summation of the evidence in a particular area/field. (Higgins and Green 2009). Systematic reviews are deemed the strongest form of medical evidence available to both practitioners and the public, provided the review is conducted correctly and in line with guidelines. A summation of evidence is created, combining many articles and their results and conclusions whilst assessing the level of rigour in each of them. Through doing this, systematic reviews assist in implementing informed consent, guidelines for evidence-based practice can be created and gaps in research can be identified and can therefore guide future research studies and paths. (Medina and Barría 2010; Perestelo-Pérez 2013; Moher *et al.* 2015; Bigna, Um and Nansseu 2016; Cleary-Holdforth 2017).

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

1. A more accurate source of information in comparison to a single publication related to a particular topic (individual article) (Egger 2001; Haynes and Wilczynski 2010).
2. Confidence in the expectations of a particular intervention (Mulrow 1994).
3. An increased efficacy with regards to time usage (Mulrow 1994).
4. A better structured analysis of data than that provided by a single article. (Light and Pillemer 1986; Mulrow 1994).

2.5.4 The Study Type Hierarchy

The table below (Table 2.3) presents the hierarchy of the different study types according to the level of evidence (validity of results) that they each produce. The following figure (Figure 2.5) illustrates the schematic relationship between various forms of literature.

Table 2. 3: Levels of Evidence, adapted from (Sackett 1989).

Level I	Systematic reviews, meta-analyses, randomised controlled trials
Level II	Cohort studies (Prospective: cohort has been exposed to risk. Observe for outcome of interest)
Level III	Case control studies (Retrospective: subjects have the outcome of interest; looking for a risk factor)
Level IV	Case report or case series
Level V	Narrative reviews, expert opinions, editorials

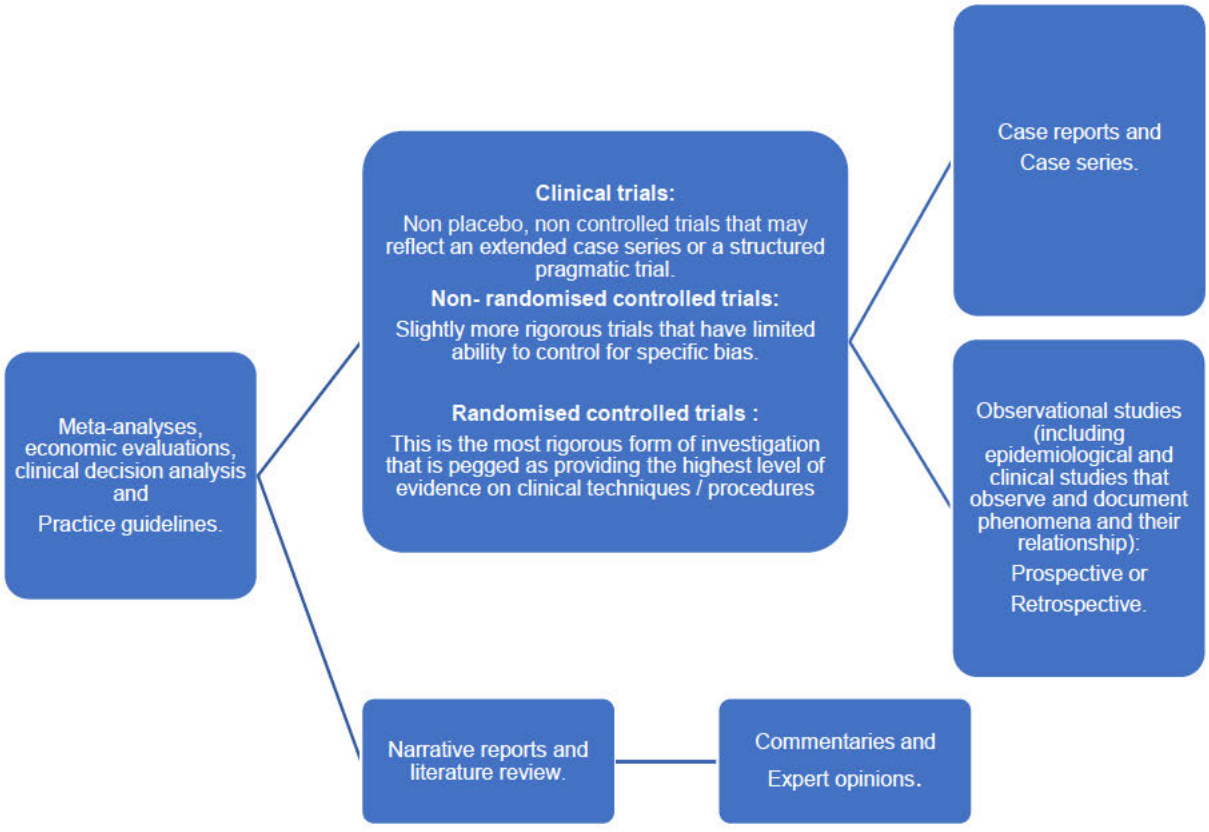


Figure 2. 5: Schematic relationship of various literature (Sacket 1989).

2.5.5 Study Biases

The strength of evidence produced by an article depends on its ability to limit the level of bias. The more the bias is minimised (internal validity), the stronger the evidence produced by the article is, but by the same token the external validity in terms of generalisability to the population in question is reduced. Study methods need to be adhered to and followed in order to reduce bias and increase a study's reliability and strength of evidence produced. In order to limit bias, subjective judgement needs to be decreased in studies. (Harbour and Miller 2001). Therefore, a balance needs to be struck between these two entities to produce evidence that is clinically relevant in practice, but also of a high rigour in order to ensure that the clinical outcomes obtained from a specific intervention are indeed as a result of the intervention.

Randomised controlled trials and meta-analysis based systematic reviews of such trials produce the most reliable form of evidence and carry the lowest risk of bias, however, true RCTs cannot always be carried out and therefore other forms of research need to be considered in systematic reviews, especially when reviewing manual therapies.

With a large number of participants in a RCT, the outcomes of the article can be linked and attributed to the intervention itself, with the results being a casual effect of the intervention itself. This causal relationship can be influenced, and the validity can be undermined through study bias, with flaws in study design, conduct, analyses and reporting. (Higgins *et al.* 2011). These outcomes are however limited by the populations defined in the included studies and their lack of homogeneity or their clear homogeneity (as a separate subgroup within a designated population), decreases the ability of the generalizability of the intervention outcomes. This latter limits the applicability of the outcomes in clinical practice.

As previously mentioned, there are fields of study, such as manual therapy interventions, where true RCTs cannot always be carried out due to lack of blinding, patient naivety to the intervention and possibly ethical concerns. Therefore, other study types are sometimes more appropriate and available evidence needs to be contextualised in the risk of bias to determine the clinical effect of the intervention. (Harbour and Miller 2001).

To cater for these varied situations, there are many tools available to assess the bias in a range of study types. The Cochrane Collaboration has created methods and checklists to assess the risk of bias in randomised control studies, non-randomised controlled trials, case studies and case series among the clinical intervention studies. In essence, these tools assess

six domains of bias: selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias. (Higgins *et al.* 2011).

A list of the potential sources of bias in clinical trials was also compiled by the Cochrane Collaboration in 2005 (Higgins *et al.* 2011), that are required when considering internal validity of an article (also summarised in Table 2.4) (Higgins *et al.* 2011):

- Selection bias (viz. generation of the allocation sequence and concealment of the allocation sequence)
- Performance bias (viz. blinding of participants and personnel)
- Detection bias (viz. blinding of outcomes assessment)
- Attrition bias (viz. attrition and exclusions, sample size, dropouts)
- Reporting bias (viz. biases that might be specific to a clinical specialty)
- Biases specific to the trial design (such as crossover or cluster randomised trials, non-randomised trials and other trial types)
- Other generic sources of bias

Table 2. 4: Study biases that require deliberation when conducting systematic reviews (Higgins *et al.* 2011).

Bias domain	**Source of bias**	**Support of judgement**	**Review authors' judgement**
Selection bias	Random sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence
	Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrolment	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment
Performance bias	Blinding of participants and personnel*	Describe all measures used, if any, to blind trial participants and researchers from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study
Detection bias	Blinding of outcome assessment*	Describe all measures used, if any, to blind outcome assessment from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	Detection bias due to knowledge of the allocated interventions by outcome assessment
Attrition bias	Incomplete outcome data*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition or exclusions where reported, and any re-inclusions in analyses for the review	Attrition bias due to amount, nature, or handling of incomplete outcome data
Reporting bias	Selective reporting	State how selective outcome reporting was examined and what was found	Reporting bias due to selective outcome reporting
Other bias	Anything else, ideally pre-specified	State any important concerns about bias not covered in the other domains in the tool	Bias due to problems not covered elsewhere
*Assessments should be made for each main outcome of class of outcomes.			

2.5.5.1 Grey Literature

The inclusion of “grey literature”, specifically in systematic reviews, is recommended in order to achieve a comprehensive overview of the available literature pertaining to the study topic. (Dickersin, Scherer and Lefebvre 1994). However, by including this literature the researcher may potentially increase the possibility of bias, thus, decreasing the credibility of the systematic review if the biases are not considered. (Higgins *et al.* 2011). The incorporation of “grey literature” may present systematic reviews with the following biases:

a. “Publication bias”: due to the fact that “grey literature” may not be peer reviewed. In some circumstances, the literature may not have received journal publication, but rather exist in the format of a thesis or another form of academic publication and may have a negative impact on the systematic review. (Dickersin, Scherer and Lefebvre 1994). It is important to consider this literature as there is a possibility that literature with negative outcomes may not have been published. Therefore, a balance between peer reviewed and the “grey literature” is important.

b. “Language bias” (Dickersin, Scherer and Lefebvre 1994) needs to be taken into consideration when studies are excluded based on language restrictions, imposed either by the review design, the aptitude of the reviewer, or both. The limiting of a systematic review in terms of language is a common practice, with English publications being predominantly included. (Stern and Kleijnen 2020)

c. “Sensitivity and precision of searching”: (Dickersin, Scherer and Lefebvre 1994). An inclusion of “grey literature” may prove to be rather difficult and requires refined and specified searches, meaning search terms would need to be adjusted and adapted to find and include this “grey literature”. By adapting the search terms used in the data collection phase, a risk of bias is introduced into the systematic review. (Dickersin, Scherer and Lefebvre 1994). It has been suggested that a variety of search terms may be used to alleviate this problem, however, it is inconclusive. (Cook, Sackett and Spitzer 1995).

Whilst potential biases may be introduced into a systematic review through the inclusion of “grey literature”, a full set of available research on the study’s defined question should be included in order to produce the highest value from the systematic review. Therefore, it is suggested that grey literature is included as well as various study types, to ensure that there is a full representation of the available research. (Liberati *et al.* 2009; Moher *et al.* 2009).

2.5.6 Systematic reviews for different study types

2.5.6.1 Systematic Analysis of Randomised Controlled Trials

The PEDro scale (PEDro scale 2012) (Appendix E) is commonly used as a quality measure in the systematic review of RCTs. The function, accuracy and validity of this scale has been researched and the use of it to evaluate the quality and methodological rigour of RCTs has been appraised and recommended for use in systematic reviews. (de Morton 2009; Maher *et al.* 2011).

The scale includes eleven specific criteria/questions (Table 2.5) which are to be applied to the RCT being reviewed, assessing and interrogating the methodological rigour (internal validity) of the article. Each question can be answered with either a “yes” or a “no” with this scale. A point is rewarded for each ‘yes’ question and zero points are rewarded for each ‘no’ question. The maximum score an article can receive is eleven, and this is seen to be the most reliable, with reliability decreasing as the overall score decreases. (PEDro scale 2012).

Table 2. 5: Explanation of each individual criterion in the PEDro Scale.

Criterion 1	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	*Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site".
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented. 7-11 *Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 5	*Blinding* means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (e.g., visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 4, 7-11	*Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 8	This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An *intention to treat* analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group × time interaction). The comparison may be in the form of hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
Criterion 11	A *point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.

2.5.6.2 Systematic Analysis of Non-Randomised Controlled Trials

The Newcastle-Ottawa Quality Assessment Scale (NOS) (Appendix F) is the most frequently used tool in analysing non-RCTs (Wells *et al.* 2000; Farrah *et al.* 2019). This scale is seen as the gold standard in evaluating the quality, methodological rigour and risk of bias in NRCTs in systematic reviews. The reported inter-rater reliability is good for this tool and it is the most popular, suitable and the easiest to use. (Wells *et al.* 2000; Higgins and Green 2009; Stang 2010).

This scale consists of three basic sections:

a) selection
b) comparability
c) exposure

Each of these three sections have sub-sections. There are a total of eight sub-sections. Stars are rewarded for each sub-section, with a maximum of one star per sub-section under the selection and exposure selections and a maximum of two stars per subsection under the comparability section. An article that is reviewed may be awarded a maximum total of nine stars. (Higgins and Green 2009; Hartling *et al.* 2010).

The method by which the reviewer awards stars with this scale involves the reviewer assessing whether the article being reviewed meets each of the criteria listed. The reviewer awards stars where criteria has been met. A score of nine implies that the article being reviewed is reliable and has been carried out with methodological rigour, as the score decreases, so does the reliability and level of methodological rigour of the article being reviewed.

2.5.6.3 Systematic Analysis of Observational Studies and case studies/case reports

The Method for Evaluating Research and Guideline Evidence (MERGE) was established by the Cochrane Collaboration, the New South Wales Health Department as well as individuals including epidemiologists and clinicians (Liddle, Williamson and Irwig 1996). The MERGE principles are clear and standardised guidelines for reviewing case reports, case series and observational studies. The Liddle scale was in turn formulated, using MERGE principles, to assess case reports and observation studies in terms of their level of evidence and methodological rigour, as well as their level of bias. The Liddle Scale is the scale most utilised for the analysis of case reports, case series and observational studies and is the most effective

when reviewing these categories of articles. This scale assesses the quality of evidence in the article under review and assess the article for any biases and the effects of these potential biases on the outcome and results in the article. (Liddle, Williamson and Irwig 1996).
The Liddle Scale is comprised of twelve or thirteen individual criteria to evaluate in an article under review. The reviewer is required to select one of the code options for each of the evaluation criteria (Table 2.6 and Table 2.7).

Table 2. 6: Codes for evaluation criteria (Liddle, Williamson and Irwig 1996).

Evaluation criteria are coded according to the extent to which the criteria are fulfilled	**Code**
Criterion entirely fulfilled	A
Criterion mostly fulfilled	B1
Criterion mostly not fulfilled	B2
Criterion not at all fulfilled	C
Criterion not described adequately to classify as a, b1, b2 or c	I
Criterion not applicable	n/a

Table 2. 7: Codes for overall assessment of quality of study checklists (Liddle, Williamson and Irwig 1996).

Low risk of bias	A	All or most evaluation criteria from the checklist are fulfilled. Where evaluation criteria are not fulfilled, the conclusions of the study are thought very unlikely to alter.
Low-moderate risk of bias	B1	Some evaluation criteria from the checklist are fulfilled. Where evaluation criteria are not fulfilled or are not adequately described, the conclusions of the study are thought unlikely to alter.
Moderate to high risk of bias	B2	Some evaluation criteria from the checklist are fulfilled. Where evaluation criteria are not fulfilled or are not adequately described, the conclusions of the study are thought likely to alter.
High risk of bias	C	Few or no evaluation criteria fulfilled. Where evaluation criteria are not fulfilled or are not adequately described, the conclusions of the study are thought very likely to alter.

Given the different evaluation tools the following outcomes are possible:

Table 2. 8: Determining the study structure of an article.

	Good internal validity as measured by reviewers	Poor internal validity as measured by reviewers
Good external validity as assessed qualitatively	Good study structure	Average study structure
Poor external validity as assessed qualitatively	Average study structure	Poor study structure

Table 2. 9: Determining the level of evidence of an article.

	Good clinical outcomes	Poor clinical outcomes
Good study structure	Evidence in favour of the intervention for use in clinical practice	Evidence against the use of the intervention in clinical practice
Average study structure	Limited evidence in favour of the use of the intervention in clinical practice	Limited evidence against the use of the intervention in clinical practice
Poor study structure	Evidence undefined for the use of the intervention in clinical practice	Evidence definitely not in favour of the use of the intervention in clinical practice

2.6 Reporting

Data needs to be presented consistently from the data collection tools when reporting outcomes and the analyses need to be consistent in their application of the principles associated with the articles' limitations (Kirkham *et al.* 2010). Thereafter, the overall grading of the evidence in support of an intervention requires the consistent application of a ranking system, such as the GRADE (Brożek *et al.* 2009) or AGREE (Dagenais and Haldeman 2011) or through other systems such as Foley *et al.* (2003a). These data tools rank evidence per intervention (thus, via an aggregate of articles that test the same treatment). A conclusion based on these grading systems describes the strength of evidence for or against a clinical intervention grouping in terms of the modality and treatment site. In some grading systems the conclusion also indicates whether the evidence is homogenous or heterogenous in terms of the evidence available.

2.7 Conclusion

One of the ways to decide if the AAI technique and the AAI within the AMCT protocol, are clinically effective and can be used in evidence-based practice, would be through a systematic review, which would provide a consolidation of the research in this field. This is achieved by reviewing current evidence and research for the clinical use of the AAI technique and the AAI within the AMCT protocol in treating spinal pain, compiling the information and presenting it systematically as a basis for a clinical guideline. This develops a starting point for future research and in turn improves the use of the AAI technique and the AAI within the AMCT protocol (Liberati *et al.* 2009; Moher *et al.* 2015).

This systematic review looks at the relevant articles and uses the relevant scales to determine each article's level of rigour, risk of bias and the evidence they produce in favour/not in favour of the AAI technique and the AAI within the AMCT protocol in treating spinal pain. (Liberati *et al.* 2009; Moher *et al.* 2015). This then provides evidence-based practice information that can guide the informed consent process and provide clinical outcomes that are acceptable, as more understanding will be gathered by practitioners as well as the public.

This research project aims to serve as a summation of available scientific evidence regarding the use of the AAI technique and the AAI within the AMCT protocol in the treatment of spinal pain in order to develop a platform for future research and to provide evidence to guide treatment protocols (Liberati *et al.* 2009; Moher *et al.* 2015).

CHAPTER THREE RESEARCH METHODOLOGY

3.1 Introduction

This chapter provides a detailed discussion of the methodology used during this systematic review. It includes the search for literature, identifying the article selection, defining the inclusion and exclusion criteria, the data collection, the data evaluation and the production of the results. The above is done in order to provide a view of the study and the research design behind the study. (Liberati *et al.* 2009; Smith *et al.* 2011).

3.2 Research Design and Overview

The study design is a systematic review of the effectiveness of the use of the Activator Adjusting Instrument (AAI) in treating spinal pain. Both the AAI technique and the use of the AAI within the AMCT protocol is included.

All publications with regards to the topic were obtained through a systematic and methodological process. An exhaustive selection of all available articles in the literature using predefined criteria and methods was completed, including a hand search of the literature as well as recommendations from the appointed reviewers prior to beginning the review process.

Once all the articles were obtained, they were categorized into particular categories (viz. randomised controlled trial, non-randomised controlled trial, observational studies and case publications/case series) (Oxman, Sackett and Guyatt 1993). Each category of article was provided with a suitable scale for the reviewers to use to review the article (Liddle, Williamson and Irwig 1996; Wells *et al.* 2000; PEDro scale 2012).

The total number of articles was obtained, and six reviewers were appointed. The articles were split into three groups and each group of articles were reviewed by two reviewers as well as the researcher. The articles were then reviewed and ranked using a specific scale which was specifically selected for each category of article.

- PEDro Scale (PEDro scale 2012),
- Newcastle-Ottawa Scale (Wells *et al.* 2000) or
- Liddle Scale (Liddle, Williamson and Irwig 1996).

The reviewers as well as the researcher reviewed the articles using the given scales and provided feedback. Feedback was then analysed, evidence that was related to the clinical

outcomes of the use of the AAI in treating spinal pain was summarised and the rigour of the intervention was assessed (Moher *et al.* 1999).

Based on the above structure, this research was approved by the Durban University of Technology, Faculty of Health Sciences Research Committee (FRC) (Appendix A).

3.3 The Research Question

The research question: What level of evidence supports the use of the AAI technique and the use of the AAI within the AMCT protocol in treating spinal pain.

Thus, the aim of this systematic review was to collect, review, collate and evaluate the research evidence available in the literature to determine the effectiveness of the use of the AAI in treating spinal pain.

3.4 The Research Methods

3.4.1 Research procedure

3.4.1.1 Article sourcing/systematic search procedures

This procedure included four steps.

Step 1:
The first step was a review of the literature, with a view to collecting citations through the use of key search terms in electronic media and search engines (PubMed and Scopus). These citations were then screened for eligibility through the following inclusion and exclusion criteria.

Inclusion of citations:

- The citations and full text articles were required to be available in electronic format in order to access the citation (Huggins *et al.* 2012).
- Title needed to include one or more of the following terms
    a. “Activator”, “Instrument Adjusting”, “Joint Dysfunction”, “Manual Therapy”, “Activator Technique”, “Activator Adjusting” and “Instrument assisted manipulation” (Huggins *et al.* 2012).

Exclusion of citations:

- Any citations that indicated it is a review, conference paper, letter, erratum, book, chapter in book, note, survey, editorial, unpublished dissertation, government gazette, newspaper article, or opinion paper, non-full text articles.

Full number of citations available per search engine that were found, included those represented in Table 3.1.

Table 3. 1: Numbers of citations per search engine.

Search engine	Scopus	PubMed
Citation number	32 402	22 064

Step 2:

The second step included a review of the abstracts of the articles that were identified in citation form (from step 1), to meet the following criteria:

Inclusion of abstracts:

- Needed to have been complied with citation inclusion requirements.
- Comply with search terms including “Activator”, “Instrument Adjusting”, “Joint Dysfunction”, “Manual Therapy”, “Activator Technique”, “Activator Adjusting” and “Instrument assisted manipulation”
- The abstract needed to identify the use of AAI as a clinical tool to treat human subjects/participants.
- The abstract needed to state that spinal pain was treated by the AAI.
- Articles were required to be in English or translated to English.
- Randomised controlled trials, non-randomised controlled trials, observational studies (case series or case report) were included in the study.

Exclusion of abstracts:

- The abstract defined the use of the AAI as a clinical tool employed in the article to treat non-human subjects/patients and/or in instances where it was utilised as a placebo treatment.
- Any abstract that indicated that the initially reviewed citation was in fact a meta-analysis, systematic review, commentary or government publication (i.e. not one of the categories in the inclusion criteria).
- Any non-English articles.

Full number of abstracts available per search engine that were found included those represented in Table 3.2.

Table 3. 2: Numbers of abstracts per search engine.

Search engine	Scopus	PubMed
Abstract number	218	38

Step 3:

The third step included a review of all the full text articles that were identified in abstract form (from step 2), to meet the following inclusion criteria:

Inclusion of full text articles:

- Needed to have been complied with abstract inclusion requirements.
- The full text articles were required to be available in English (citations and abstracts are often available in English but accompanying full text articles are in another language).
- The full text article was required to be available in an electronic form.
- The full text article needed to confirm the article as a randomised controlled trial, non-randomised controlled trial, observational study (case series or case report).
- The full text article was required to include the term “activator”.

Exclusion of full text articles:

- The abstract defined the use of the AAI as a clinical tool employed in the article to treat the non-human subjects/patients and/or in instances where it is utilised as a placebo/sham/non-active intervention.
- Any duplicate full text articles.

Full number of full text articles available per search engine that were found included those represented in Table 3.3.

Table 3. 3: Numbers of full text articles per search engine.

Search engine	Scopus	PubMed
Full text articles number	19	4

Step 4:

This included a hand search. This procedure utilised all full text articles that were secured for the study (Table 3.3), whose references were reviewed for inclusion into the current systematic review. These hand searched articles needed to comply with the Steps 1-3 outlined above for consideration of inclusion. These articles were also sourced through the reviewers, who were provided with a list of articles for review and were requested to submit any additional articles they deemed would be appropriate.

The final number of articles was 23, as represented in Table 3.4.

Table 3. 4: Number of articles per study type.

Study type	RCT	NRCT	Case series/Case studies
Full text articles number	10	2	11

A flow diagram is available of Steps 1- 4 as Appendix B.

3.4.1.2 Reviewer appointment process

Important considerations in terms of the reviewer appointment process included that reviewers were not aware of the names of the other reviewers, nor were the names of reviewers made public. In addition, the researcher was required to ensure that the comments made by reviewers during the analysis of articles were not linked to the reviewer directly. And finally, to avoid bias, any reviewer who was an author in an article that was being reviewed was not involved in the review of his/her own article. (Guyatt *et al.* 2008; Higgins and Green 2009; Moher *et al.* 2009).

Step 1:

Attained Durban University of Technology, Faculty of Health Sciences Research Committee (FRC) approval (Appendix A).

Step 2:

Identified possible reviewers for the study.

a. Through the systematic literature search outlined under Research Procedure: Article sourcing/systematic search procedures (see 3.4.1.1).
b. Contacted special interest groups – chiropractic specific (e.g. World Federation of Chiropractic, International Chiropractic Programmes).

c. Contacted special interest groups – systematic review specific (e.g. CCGPP, Cochrane Collaboration Centres).

Cognisance of author affiliation to the topic and possible publications was made, in order to eliminate reviewer bias (Guyatt *et al.* 2008; Higgins and Green 2009; Moher *et al.* 2009).

Step 3:

Six reviewers were appointed and assigned into three groups, ensuring that each group had at least one reviewer with a PhD (Table 3.5). The reviewers were unaware of which review group they were placed in or who else was in the assigned review group.

Table 3. 5: Reviewer mix and grouping.

Group		Highest Qualification	Research Experience	Academic Experience	Clinical Experience	Activator Experience
1	Reviewer 1	PhD	X	X		
	Reviewer 2	MHSc	X	X	X	X
	Researcher	B.Tech				
2	Reviewer 3	PhD	X	X	X	X
	Reviewer 4	MD	X	X	X	X
	Researcher	B.Tech				
3	Reviewer 5	PhD	X	X	X	X
	Reviewer 6	PhD	X	X		
	Researcher	B.Tech				

Step 4:

Once the proposal was approved, potential reviewers were contacted via email until the requirements for Table 3.5 were met, outlining (by means of the MoA - Appendix C and the covering email - Appendix D) the following:

a. The study aims and objectives.
b. Outline of the procedure.
c. The role of the reviewers.
d. The expectation of the reviewers.
e. Process confidentiality, blinding and anonymity.
f. Resolution of discrepancies in reviews submitted.
g. Timelines for the above processes and procedures.

In the email the potential reviewers were asked to review the MoA and if in agreement, sign the MoA and return by fax or electronically (scanned or secured PDF). Within a week after the reviewers were sent the MoA, they were sent a follow up email to confirm the receipt of the documentation, as well as to check if they had any problems or concerns.

Once the reviewers agreed, then the allocation of reviewers to review groups and to article grouping occurred (Table 3.5). The reviewers had an eight-week deadline to complete the review process post receipt.

Step 5:

Allocation of reviewers occurred as per Table 3.5, to ensure that the spread of reviewers was equitable between the different review groups. The table below (Table 3.6) shows the number of articles each reviewer reviewed. One reviewer with a Master's (or higher) and clinical experience and one with a PHD and research experience in each group. Qualification, geographical location and experience with systematic reviews and publications and/or supervision experience were all considered when reviewers were appointed.

Table 3. 6: Article allocation.

Group		Article allocation
1	Reviewer 1	1-8
	Reviewer 2	1-8
	Researcher	1-8
2	Reviewer 3	9-16
	Reviewer 4	9-16
	Researcher	9-16
3	Reviewer 4	17-23
	Reviewer 5	17-23
	Researcher	17-23

Step 6:

The reviewers then received their respective research articles (as indicated by the group they had been allocated to); they also received the respective checklists/scales appropriate to the study types represented by the articles. These checklists/scales were accompanied by an explanation of the checklist/scale to facilitate common understanding between the reviewers (Guyatt *et al.* 2008; Higgins and Green 2009; Moher *et al.* 2009).

This process was a blinded process, to ensure that the reviews were independent (Moher *et al.* 2009).

Step 7:

The reviewers were then

1. Asked to confirm receipt of the articles, Checklists and explanation of the Checklists.
2. Reminded at weeks four and six (post receipt) that their submissions were due by week eight.

Concurrently the researcher completed her reviews of the selected articles.

- In order to limit researcher bias, earlier submission (i.e. prior to week eight), made by the reviewers were submitted to the research supervisor in order to ensure that the researcher did not have access to the review outcomes prior to the completion of her own independent reviews.

Once all reviews were completed, an analysis of the review outcomes was completed per article.

3.4.1.3 Review Procedure and Tools

The literature around the development and implementation of systematic reviews indicated that there are numerous tools that can be utilised in the review of articles. Some suggested that there are tools like the Newcastle Ottawa Scale that can be utilised to review RCTs, NRCTs and observational studies (case series and case reports) (Zeng *et al.* 2015); however for the majority of scales utilised in the systematic review domain, they have specific application either by field of research, type of study and/or purpose for which the systematic review is being done. (Guyatt *et al.* 2008; Higgins and Green 2009; Moher *et al.* 2009; Zeng *et al.* 2015). As a result of this, each study type was considered and the most suitable scale for reviewing each study type was selected and used for this systematic review.

3.4.1.3.1 Review Tools for RCTs

These may include the following scales (Olivo *et al.* 2008; Zeng *et al.* 2015) for manual therapies:

- Back pain: Masstricht-Amsterdam List (original and modified), Van Tulder scale
- Non-pharmacological interventions: Sindhu scale
- Pain research: Jadad scale (original and modified versions)
- Patellofemoral pain: Bizzini scale
- Physical therapy: Maastricht scale, PEDRo scale
- Therapeutic studies: Reisch scale, Tyson scale
- Unspecified: Delphi List, The Cochrane Collaboration Tool, CASP Checklist for RCTs, NICE methodology checklist for RCTs

Given that this research study aimed to evaluate a specific intervention (AAI technique and the AAI within the AMCT protocol) in the treatment of spinal pain, the use of specific pain research scales, those related to specific conditions (patellofemoral pain syndrome) and those that were adapted for determining specific therapeutic effect were not considered.

Given the options for the evaluation of RCTs, a review of the various scales was done in terms of the reliability, validity and applicability. The PEDro Scale was selected as the effectiveness of a single intervention (AAI technique and the AAI within the AMCT protocol) is being researched in this systematic review, where the validity of the research done in this field is being reviewed in order to assess the effectiveness of this intervention in patient treatment. (PEDro scale 2012).The reliability and quality of the PEDro Scale has been assessed and the reliability of the total PEDro score was “fair” to “good”, indicating that it is an acceptable scale to use (Maher *et al.* 2003).

3.4.1.3.2 Review Tools for NRCTs

These include the following scales (Deeks *et al.* 2003; Zeng *et al.* 2015):

Nonspecific scales (i.e., not specific to NRCTs)

- Chalmers scale (with and without modifications)
- Maastricht Criteria List (two versions)
- Reisch scale
- MINORS (Methodological item for non-randomized studies)
- CASP Checklist for Cohort study (last amended in 2014)
- NICE Methodology Checklist for Case control or Cohort study
- CASP Checklist for Case-control study (last amended in 2014)

Specific scales (i.e., specific to NRCTs)

- Newcastle – Ottawa Scale (NRCTs, Case-control and Cohort studies)
- Anders Scale
- Baker Scale
- Bracken Scale
- Critical Appraisal Skills Programme (CASP)
- Cowley Scale
- Downs Scale
- Du Rant Scale
- Fowkes Scale
- Hadorn Scale
- Spitzer Scale
- Thomas Scale
- Vickers Scale
- Weintraub Scale
- Zaza Scale

Given that this research study aimed to evaluate a specific intervention (AAI technique and the AAI within the AMCT protocol) in treating spinal pain, non-specific scales were excluded as well as scales that did not relate to clinical outcomes that are relevant to this systematic review. Ease of use, paired with quality assessment of the NRCTs was considered when considering the scale to be used to review the NRCTs in this systematic review.

After assessing all the scales that could be used for the evaluation of NRCTs, the Newcastle-Ottawa Scale was selected, with this scale being successful at evaluating the methodological quality of the articles being reviewed in this category (NRCTs) (Cook and Reed 2015). This scale has been used widely since at least 2004 to assess the quality of NRCTs (Margulis *et al.* 2014). It was selected due to its inter-reliability, good validity and evaluation time (Wells *et al.* 2000). This scale has been supported and endorsed by the Cochrane Collaboration and was critically evaluated by Deeks *et al*. (2003). It was concluded that the Newcastle-Ottawa Scale is reliable and effective in reviewing NRCTs. (Deeks *et al.* 2003).

3.4.1.3.3 Review Tools of observational studies (case studies and case series) (Zeng *et al.* 2015)

These include the following scales

- Downs and Black
- Carmen Moga and his colleagues
- NICE Methodology Checklist for case control
- Newcastle – Ottawa Scale (case-control)
- SIGN
- Liddle Scale

Given that this research study aimed to evaluate a specific tool (AAI technique and the AAI within the AMCT protocol) in treating spinal pain, methodological rigour needed to be accessed when reviewing the articles along with bias and ethical considerations.

The scales to review the observational studies (case series and case studies) were reviewed and the Liddle scale was selected to be used in this systematic review. This scale was selected to assess the quality of each individual article being reviewed in this category. (Liddle, Williamson and Irwig 1996; Harbour and Miller 2001). The Liddle Scale was developed using the Method for Evaluating Research and Guideline Evidence (MERGE) principles. In this respect, the MERGE sets out a standardised approach to reviewing evidence in the process of creating clinical guidelines. It ensures guidelines are based on the best available evidence and assesses the strength of evidence available to support these guidelines. The MERGE was written as a collaboration between epidemiologists, the Cochrane Collaboration and New South Wales Health Department's expert panel – thus it has been subjected to a wide evaluation. (Liddle, Williamson and Irwig 1996).

3.4.1.4 Scale to be used per study type

Therefore, the conclusion of the scale choice is summarised in Table 3.7 below.

Table 3. 7: Scales per study type.

Type of study	**Scale**	**Reliability and validity of the scale**
Randomised clinical trials	PEDro Scale (PEDro scale 2012) Appendix E	(Bhogal *et al.* 2005; Moreira *et al.* 2012; da Costa, Hilfiker and Egger 2013)
Non-randomised control studies	Newcastle-Ottawa Scale (Wells *et al.* 2000) Appendix F	(Wells *et al.* 2000; Deeks *et al.* 2003; Stang 2010; Margulis *et al.* 2014; Cook and Reed 2015)
Case series and case studies	Liddle Scale (Liddle, Williamson and Irwig 1996) Appendix G	(Harbour and Miller 2001; Stein *et al.* 2005; Kempen 2011; Guo *et al.* 2016; Murad *et al.* 2018)

3.4.1.5 Analysis

The analysis process began with the reviewers and researcher rating the publications using the above-mentioned validated scales (Table 3.7). Once the data was received from the reviewers this was captured on MS Excel and analysed (e.g. see Table 4.2).
Majority consensus was used to rank the articles, and this was then linked to the outcomes obtained by each of the articles. An analysis table was compiled for each article as well as a discussion table, which are presented in Chapter Four (e.g. see Table 4.3). This allowed the researcher to rank the articles in a methodological way in order to draw useful results from the data.

The data was analysed by recording reviewer responses to each of the scales, analysing discordance between the reviewers and then the data was formulated in Chapter Four.
In Chapter Five, after the review process, the effectiveness of AAI technique and the AAI within the AMCT protocol in treating spinal pain was discussed. A well-structured, unbiased summary of the evidence was created (Chapter Five). Therefore, the Chapter Five discussion has considered the levels of evidence criteria as proposed by:

- Foley *et al*. (2003)
- Dagenais and Haldeman, (2011) and / or
- GRADE System - Grades of Recommendation, Assessment, Development, and Evaluation

All three grading systems provide guidelines for determining the level of evidence within a specific domain Foley *et al.* (2003) – stroke rehabilitation; Dagenais and Haldeman (2011) – manual therapy and GRADE system (Brozek *et al.* 2009) – clinical interventions and clinical practice guidelines.

These guidelines have different approaches to evaluating the evidence, the first two tend to be applicable in the context of providing information to practitioners and are simpler in their approach, where the GRADE system is mainly utilised in the context of developing health care guidelines/governmental guidelines and is more rigorous and less pragmatic in its application. Unlike the simpler version suggested by Dagenais and Haldeman (2011), Foley *et al*. (2003) indicates a further three successive categories which show whether the evidence presented (as per the prior paragraph), agrees or conflicts within the clinical category. As a result of the above, the systems by Foley *et al.* (2003) and Dagenais and Haldeman (2011) have been utilised in the context of this study to determine the clinical effectiveness of the AAI in the

context of the clinical conditions for which research has been completed (spinal pain). (Foley *et al.* 2003b; Dagenais and Haldeman 2011).

3.4.2 Ethical considerations

Respect for autonomy was carried out in this study, reviewers were voluntarily a part of the study; they were invited to be involved and had the right to withdraw at any time. A MoA (Appendix C) was signed by the reviewers once they had accepted the invitation to be a reviewer. (Section 3.4.1.2. Step 4).

The principle of justice was applied, all articles relevant to this systematic review were included, articles were distributed as equally as possible to the reviewers (Section 3.4.1.2. Step 5) and the reviewers all received the same MoA. (Section 3.4.1.2. Step 4). Copyright permissions for all articles being reviewed in this study were obtained prior to distribution of the articles to the reviewers. (Appendix H). The study was registered with PROSPERO (Appendix I).

Confidentiality was maintained in this study; reviewers were unaware of the names of the other reviewers, nor were the names of reviewers made public, and their reviews were not shared with the other reviewers (Section 3.4.1.2 prior to Step 1).

The principles of beneficence and non-maleficence are apparent, this systematic review adds to the body of knowledge within this area of Chiropractic, it causes no harm.

3.5 Conclusion

This Chapter formulates the methodology for this systematic review. This Chapter has set parameters for this study, outlined the process of identifying suitable articles to be included in this study, how the articles will be reviewed and how the data from the review process will be analysed and synthesised into meaningful data.

CHAPTER FOUR RESULTS

4.1 Introduction

The results of the review process as well as the data extracted from the various articles is presented in this chapter. This chapter contains the feedback collected from the reviewers for each article. The data is presented sequentially for randomised controlled trials (Tables 4.1-4.22), followed by non-randomised controlled trials (Tables 4.23-4.28), observational studies and case studies/case reports (Table 4.29-4.52).

At the beginning of each section representing the various study types, is a summary table that provides an overview of the various articles within that section and indicates which tables are relevant to which article(s) in that section.

Each article that was analysed is represented by two tables:

- The first table represents a summary of the quantitative reviewer feedback (e.g., Table 4.2) from the scale utilised to assess the methodological rigour (internal validity) of the article under discussion. This analysis assessed predominantly the internal factors or structural factors of the research design, methodology and analysis. These tables containing the reviewer feedback are entitled “Tabulated Feedback Data”. In these tables, the overall ranking of each study is presented as well as overall percentage agreement between the reviewers.
- The second table (e.g., Table 4.3) presents a qualitative analysis of the same article by presenting and interrogating the following article properties: forms of measurement, frequency of measurement, duration of the study, number of participants, blinding of research personnel, whether a control has been used and randomisation of the participants. These extracted properties are discussed with a view to identifying both external factors that may have affected the methodological rigour of the study. Therefore, the determination made under this section of the discussion includes both the reviewers’ quantitative analyses as well as the qualitative evaluation of the article culminating in an overall evidence evaluation. The specific studies are discussed, highlighting:
    - Contextual limitations as identified by authors as well as the researcher that do not form a specific criterion in the scales but may affect the outcomes of the study.
    - The outcomes attained, which are contextualised within rigour of the article.

- The overall outcomes of the review of the article with a conclusion.

A synopsis of the article analysis per section is then represented in a summary table (e.g., Table 4.22), where the article authors, article publication date, article title, the quantitative methodological rigour outcomes obtained, the qualitative analysis as well as the clinical outcomes for the article as well as the final or overall evidence evaluation is presented.

In this context the overall evidence evaluation is the determination made as a result of this systematic review indicating the level of evidence that the article, as a whole, contributes to the understanding of the effectiveness of the AAI technique and the AAI within the AMCT protocol in treating spinal pain.

4.2 Data

4.2.1 Primary data

After the primary and secondary searches were completed for this study, a final list of articles was compiled. This final list of articles was then divided among the seven reviewers (including the researcher) such that each article group had three reviewers (two reviewers and the researcher) allocated to it. The articles were then reviewed, and the reviewer's response has been entered into the first table (Tabulated Feedback Data Table e.g. Table 4.2) associated with each of the articles. In each of these tables, the feedback from each individual reviewer is displayed, along with a majority ranking (reported as the majority outcome from the three reviewers) and a percentage of agreement (determined from the total of the scores displayed in the majority column).

The percentage agreement was calculated for each individual criterion for each scale and thus represents the agreement between the reviewers for each specific criterion. Therefore, when all three reviewers agreed, a 100% percent agreement was recorded. By contrast, when all reviewers disagreed, a 33% percent agreement was calculated.

From these percentages an overall percentage agreement for the article was calculated. In this context, the overall article percentage represented the degree of cohesiveness between reviewer responses. Literature indicates that an article with a 70% or more percentage agreement (Liberati *et al.* 2009), is one in which the overall article is deemed to have a good

level of methodological rigour (internal validity) which was well presented and clear; allowing for uniform identification and understanding of the required criteria by the reviewers.

4.2.2 Secondary data

Secondary data was obtained via several sources. These included books, referenced journal articles and systematic reviews. Most of the information was sourced from online articles, as well as through the Durban University of Technology (DUT) library.

4.3 Abbreviations

These abbreviations are specific to Chapter Four and are therefore included here as a point of reference for this chapter.

AAI: Activator Adjusting Instrument
AMCT: Activator Methods Chiropractic Technique
DASS21: Disability Anxiety Stress Scale
DHI: Dizziness handicap inventory
DUT: Durban University of Technology
FES-I: Falls Efficacy Scale International
HVLA: High-Velocity, Low-Amplitude
IAM: Instrument Assisted Manipulation
MAI: Mechanically Assisted instrument
MAM: Manually Applied Manipulation
MFMA: Mechanical Force, Manually Assisted
MoCA: Montreal Cognitive Assessment
MVC: Maximum Voluntary Contraction
NDI: Neck Disability Index
NRCT: Non-Randomised Controlled Trial
NRCTs: Non-Randomised Controlled Trials
NPRS: Numerical Pain Rating Scale
NRS: Numerical Rating Scale
ODI: Oswestry Disability Index
ORS: Orthopaedic Rating Scale
PGIC: Patient Global Impression of Change
RCT: Randomised Controlled Trial

RCTs: Randomised Controlled Trials

ROM: Range of Motion

sEMG: Surface Electromyography

SF12: 12-Item Short Form Survey

SF-36: RAND 36-Item Short Form Health Survey

SIJ: Sacroiliac Joint

SMT: Spinal Manipulative Therapy

TUG: Timed Up and Go

VAS: Visual Analog Scale

4.4 Results

This section has been divided into three sections (Sections 4.4.1-4.4.3): randomised controlled trials, non-randomised controlled trials and observational studies, case studies/case reports respectively. Each of these sections provides a small introduction followed by a summary table which provides an overview of the articles which are discussed thereafter in each section, followed by a table summarising the results of each section.

4.4.1 Randomised controlled trials

4.4.1.1 Tabulated feedback data and analysis of RCTs

The PEDro Scale (Maher *et al.* 2003; Bhogal *et al.* 2005; PEDro scale 2012) (Appendix E) was utilized to review the RCTs associated with the use of the AAI technique as well as the use of the AAI within the AMCT protocol in treating spinal pain. Briefly, the scale consists of eleven criteria, by which the reviewers rate the article; of which a total of one score is allocated to each criterion where "yes" is answered (a maximum ranking for the PEDro Scale is eleven).

Table 4. 1: List of the table numbers for RCTs.

Tabulated feedback data:	**Analysis of article:**	**Author(s):**	**Year:**	**Title:**
Table 4.2	Table 4.3	Coetzee	2013	The effect of the activator adjusting instrument in the treatment of chronic sacroiliac joint syndrome.
Table 4.4	Table 4.5	Gemmell, Jacobson	1995	The immediate effect of activator vs. meric adjustment on acute low back pain: a randomised controlled trial.
Table 4.6	Table 4.7	Gemmell, Miller	2010	Relative effectiveness and adverse effects of cervical manipulation, mobilisation and the activator instrument in patients with sub-acute non-specific neck pain: results from a stopped randomised trial.
Table 4.8	Table 4.9	Gillespie	2003	The Effectiveness of Manual Manipulation versus the Activator Adjusting Instrument in the Management of Acute Facet Syndrome of the Lumbar Spine.
Table 4.10	Table 4.11	Gorrell, Beath, Engel	2016	Manual and Instrument Applied Cervical Manipulation for Mechanical Neck Pain: A Randomized Controlled Trial.

Table 4.1 List of the table numbers for RCTs continued

Tabulated feedback data:	Analysis of article:	Author(s):	Year:	Title:
Table 4.12	Table 4.13	Hardas, Murrell	2018	Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Trial Assessing the Effects of Applying a Force to C5 by a Mechanically Assisted Instrument on Referred Pain to the Shoulder.
Table 4.14	Table 4.15	Kendall, French, Hartvigsen, Azari	2018	Chiropractic treatment including instrument-assisted manipulation for non-specific dizziness and neck pain in community-dwelling older people: A feasibility randomised sham-controlled trial.
Table 4.16	Table 4.17	Shearar	2003	The Relative Effectiveness of Manual Manipulation versus Manipulation using the "Activator Adjusting Instrument" in the Management of Acute on Chronic Sacroiliac Syndrome.
Table 4.18	Table 4.19	Wood, Colloca. Matthews	2001	A pilot randomized clinical trial on the relative effect of instrumental (MFMA) versus manual (HVLA) manipulation in the treatment of cervical spine dysfunction.
Table 4.20	Table 4.21	Yurkiw, Mior	1996	Comparison of two chiropractic techniques on pain and lateral flexion in neck pain patients: a pilot study.

Table 4. 2: Tabulated Feedback Data for RCT: Article 1

AUTHOR(S):	Coetzee					
YEAR:	2013					
TITLE:	The effect of the activator adjusting instrument in the treatment of chronic sacroiliac joint syndrome					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	Yes	Yes	Yes	Yes	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Yes	Yes	Yes	Yes	100%
3	Allocation was concealed	Yes	Yes	Yes	Yes	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	Yes	Yes	Yes	Yes	100%
5	There was blinding of all subjects	No	Yes	No	No	66%
6	There was blinding of all therapists who administered the therapy	No	No	No	No	100%
7	There was blinding of all assessors who measured at least one key outcome	Yes	Yes	Yes	Yes	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Yes	Yes	Yes	Yes	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	Yes	Yes	Yes	Yes	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	No	Yes	Yes	Yes	66%
11	The study provides both point measures and measures of variability for at least one key outcome	No	Yes	Yes	Yes	66%
	TOTAL SCORE	**7**	**10**	**9**	**9**	
		OVERALL PERCENTAGE AGREEMENT:				**90.7%**

Table 4. 3: Analysis of RCT: Article 1

AUTHOR(S):	Coetzee
YEAR:	2013
TITLE:	The effect of the activator adjusting instrument in the treatment of chronic sacroiliac joint syndrome

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**
NRS, Revised Oswestry Disability Questionnaire and algometer.	Pre-intervention at consult one, again at consult three and five post-intervention.	Two weeks.	40 participants.	No. The researcher was the assessor for entry into the study, the person that applied the activator (or treatment) and took measurements.	Placebo group.	Randomisation table.	9	90.7%

LIMITATIONS:	This study was based at a university, with majority of the advertisement of this study being on the university grounds, resulting in majority of the participants being recruited from within the university. This is a limitation of this study as the sample used for this study is not an accurate representation of the general population. Whilst there were participants who weren't students, the mean age of the participants in this study was 33.55 years in the AAI group and 31.65 years in the placebo group. Therefore the results are limited to a younger population. (Ebrahim Valojerdi, Tanha and Janani 2017). In favour of the homogeneity of the groups, participants were excluded if they used medication for their low back pain or did not comply with a three day wash out period prior to entering the study. By contrast medications for systemic conditions were not considered. Ethnicity, parity, and various other lifestyle factors were not considered or taken into account in this study, therefore affecting the homogeneity between groups, this compromises the outcomes as a direct measure of the intervention. (Corfman 1995; Kabisch *et al.* 2011). The sample size was small with twenty participants per group. The study initially started with forty-four participants, however four participants dropped out of the study. One of these participants dropped out due to the perception that he/she was not benefiting from the treatment and the remaining three participants that dropped out did so due to the fact that they could not fulfil their commitment to the study due to personal reasons not mentioned. No participants withdrew due to adverse effects. The intention to treat analysis could not be utilised to retain the data from these participants as they had not reached the point of having their second readings taken. Further, the statistical analysis is based on non-parametric parameters, this may result in a type two error (based on trends).

	(Vickers 2005; Akobeng 2016). These collective concerns may incorrectly accentuate the effects of the interventions. (Columb and Atkinson 2015; Ebrahim Valojerdi, Tanha and Janani 2017). The novice researcher may be perceived to have influenced the admission of participants (patient assessment) and this may have affected homogeneity. (Chu *et al.* 2017). However, the stated criteria for admission were clear and would have mitigated some of these concerns. By contrast the fact that the researcher was the assessor for entry into the study, the person that applied the activator (or treatment) and took measurements, compromising the level of blinding and thus introducing bias in this study. As a result, the bias introduced by this lack of practitioner blinding begs whether the outcomes do indeed measure the actual intervention. (Moustgaard *et al.* 2020). This was potentially further compromised by the Hawthorne or Observer effect, where the patient may have wished to please the researcher. The Hawthorne effect may have resulted in an inflated estimate of effect size in routine clinical settings by over-estimating response in both groups. (McCarney *et al.* 2007). The Hawthorne effect may have influenced the results of this study as the level of care and level of compliance between the groups differed. The participants, knowing they were being observed, may have altered their behaviours and therefore introduced a further level of bias into this study. (Elston 2021). From the perspective of the intervention, the AAI did not make contact with the patient in the placebo group, merely the researcher's finger made contact with the patient. This may have confounded patient perception of treatment, especially if they were not naïve, however this latter concern is not documented in the study. It could potentially be argued though that the use of the activator as a tool in general chiropractic practice in eThekwini is infrequent and therefore it is likely that patients were naïve (Lamprecht and Padayachy 2019). Subjective outcome measures may have been subjected to patient perception of care, patient satisfaction, patient expectation and researcher patient interaction influencers as well as patient culture and pain threshold differences all increase the level of bias in this study (Moustgaard *et al.* 2014; Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020). These were not controlled as there was no practitioner blinding, no documented control of naivety, no indication if patients knew which group they were in (i.e. post intervention question) and Hawthorne effects cannot be excluded (McCarney *et al.* 2007; Moustgaard *et al.* 2020; Elston 2021). Therefore, it is suggested that the study outcomes may measure a component of this impact as compared to the impact of the intervention alone. This study and its results were limited to short term outcomes due to the duration of the study being only two weeks. Long term treatment and measurement may have altered or amplified the findings in this study. (Nair 2019).
OUTCOME:	NRS scores followed a trend between measurement two and three for the pain to decrease in the AAI treatment group and it plateaued in the AAI placebo group. After the second treatment the AAI treatment group continued to improve whilst the AAI placebo group achieved plateau in the algometer readings. The Oswestry noted significant improvement in both groups, yet this was due to the Hawthorne and Observer effects in this study. The author suggested that AAI had a clinical effect greater than a placebo, in terms of pain reduction in the treatment of chronic sacroiliac joint syndrome (based on NRS and algometer ($p=0.037$) measurement tools).
DISCUSSION:	In this study, the lack of comparability between participants at baseline reduces the external validity. The potentially disproportionate representation of the variables within the already small sample size, compromises the external validity (ability to extrapolate the results to patients in practice given the unclear composition of the groups). Thus, the patient to whom the intervention can be applied successfully as suggested by the author of the study is limited. This is compounded by the lack of practitioner blinding and lack of patient naivety in this study. Thus, although this study reports to have achieved significant findings, these need to be considered with caution and further investigations, with greater compliance to RCT protocols as outlined in the checklists available (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022) are needed that address the pitfalls of this study.
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.2) the internal validity of the study is shown as 9/11 with a 90.7% agreement between reviewers, which indicates a good level of internal validity. However, in the context of the limitations that presented in the study, there is a significant argument that the outcomes were not necessarily only as a result of the intervention and were affected by issues of sample size, type two error acceptance and then also the lack of homogeneity of the sample groups. Therefore, the external validity is considered poor. Thus, the level of evidence that the study produces in favour of the AAI technique is limited, indicating that further research is required.

Table 4. 4: Tabulated Feedback Data for RCT: Article 2

AUTHOR(S):	Gemmell, Jacobson					
YEAR:	1995					
TITLE:	The immediate effect of activator vs. meric adjustment on acute low back pain: a randomised controlled trial					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	Yes	Yes	Yes	Yes	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Yes	Yes	Yes	Yes	100%
3	Allocation was concealed	No	Yes	No	No	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	Yes	Yes	Yes	Yes	100%
5	There was blinding of all subjects	No	No	No	No	100%
6	There was blinding of all therapists who administered the therapy	No	No	No	No	100%
7	There was blinding of all assessors who measured at least one key outcome	No	No	No	No	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Yes	Yes	Yes	Yes	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	Yes	Yes	Yes	Yes	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Yes	Yes	Yes	Yes	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Yes	Yes	Yes	Yes	100%
	TOTAL SCORE	**7**	**8**	**7**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**96.9%**

Table 4. 5: Analysis of RCT: Article 2

AUTHOR(S):	Gemmell, Jacobson
YEAR:	1995
TITLE:	The immediate effect of activator vs. meric adjustment on acute low back pain: 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**
VAS	Pre-intervention and immediately post-intervention (within five minutes of treatment).	Unknown.	30 participants.	No. The same investigator provided both the examinations and the treatments.	The participants were randomly divided into two groups: one group receiving meric adjustment and the other group receiving Activator adjustment.	Randomisation table.	8	96.9%

LIMITATIONS:	This study included established patients as participants in the study. The participants of this study were existing patients of the practitioner conducting this study; hence bias may have been introduced into the study as a result of this. Participants may have noted inflated outcomes when recording scores on the VAS as a result of knowing the researcher prior to participation in this study (as participants were already established patients), introducing response bias and participation bias into this study (Mazor *et al.* 2002). Related to this too, there is a possibility of the Hawthorne and Observer effects in this study (McCarney *et al.* 2007; Elston 2021). Since the outcome measure was purely subjective (only VAS was used), there is no balance between objective and subjective outcome measures in this study. Therefore this study was subject to patient perception of care, patient satisfaction, patient expectation and researcher patient interaction influencers as well as patient culture and pain threshold differences all increase the level of bias in this study (Moustgaard *et al.* 2014; Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020). Although the above inclusion criteria were considered, the ethnicity, occupation, parity (for the women), level of activity and other lifestyle factors were not considered or taken into account in this study, therefore affecting the homogeneity between participants and between groups, the reproducibility of the results when compared between the groups (Corfman 1995; Kabisch *et al.* 2011). This impact on the external validity, limits identifying which patients in the general population would benefit from interventions presented. The sample size was small in this study, only thirty participants (sixteen participants received meric adjustments and fourteen participants received Activator adjustments) leading to a risk of type two error (Akobeng 2016), thus reducing the study's ability to infer specific outcomes based on the statistical analysis (i.e. most likely non-parametric, trend based analysis) (Columb and Atkinson 2015; Ebrahim Valojerdi, Tanha and Janani 2017). This study noted the risk of a type two error as a limitation (Gemmell and Jacobson 1995). A power analysis was conducted, and a sample of 1200 would be required to detect a significant difference between groups at an alpha of .05 and a power of 80%.

	The mean age of the participants in the meric group was 51.8 years and the mean age of the participants in the Activator groups was 53.5 years of age. In terms of the presenting condition, factors such as cause of recent onset of pain (other than participants needing to present with a current episode of low back pain) and previous or current medication use was also not considered. The study does however consider that participants were required not to have sought treatment during the six months prior to the study. In addition, it was required that participants had no prior experience with meric or Activator adjustments and that they had to have been pain free for six months prior to the onset of the current episode of low back pain. The exclusion criteria only seemed to suggest that patients with neurological deficits, history of surgery in the lumbar region, history of a fracture in the lower thoracic or lumbar spine or presence of systematic disease such as ankylosing spondylitis were excluded. This patient matrix does not improve homogeneity between the groups, making it increasingly difficult to ascertain whether improvement or regression in the outcomes were as a result of the intervention or specific condition/patient characteristics. (Corfman 1995; Kabisch *et al.* 2011). The publication suggested that the same person provided both the treatments and completed the measurement outcomes with the participants. This may have influenced the results of this study due to lack of blinding (Mazor *et al.* 2002; Moustgaard *et al.* 2020). There was a lack of blinding of both the participants as well as the examiner. Even though the participants in this study had no previous exposure to the adjustment techniques being used, the participants knew which adjustment they were receiving and knew which group they were placed into (meric or Activator). Whilst this reduces the risk of bias as a result of lack of patient naivety, there was still a lack of blinding in this study. As a result, the bias introduced begs whether the outcomes do indeed measure the actual intervention versus the measurement of responses related to researcher participation. (Krauss 2018; Moustgaard *et al.* 2020) There was subjective input from the practitioner as well as skill set that was involved in this study due to the practitioner assessing the participant for the dysfunctional joint and then delivering the adjustment to the level, he/she identified. This study involved palpation for tenderness between T12/L1 to the L5/S1 motion segment using a method described by Lewit and Magarey (Magarey 1986; Lewit 1999). There is a possibility that results may not be reproducible should this study be executed by a different practitioner as these techniques were not discussed in this study or how they were applied or used when assessing participants, hence the validity and reliability of the outcomes are questionable. There is no placebo group or group receiving no treatment, with no indication in the publication to state that either intervention was indeed better than placebo, thus it is unclear whether the outcomes obtained did indeed have an effect greater than placebo/natural history alone (Deaton and Cartwright 2018).
OUTCOME:	Participants presented with acute low back pain. In this study the adjustments were delivered to the posterior joints found to be dysfunctional in each participant. The one group received a meric adjustment (HVLA) and the other group received an Activator adjustment (outside of the AMCT protocol). The mean VAS score decreased by 22.2mm in the Activator group and 21.8mm in the meric group. Both groups reported a reduction in pain immediately after the adjustment was given. The results of this study reveal no significant difference between meric and Activator adjustments in reducing acute LBP, both interventions were effective in reducing perceived pain. The outcomes of the study do not favour either treatment option, they both produced favourable results in participants with acute low back pain and thus one intervention cannot be suggested or recommended over the other.
DISCUSSION:	The external validity of this study needs to be considered when using the results or conclusions of this study. Many factors have impacted the level of external validity of this study such as lack of comparability between participants at baseline, no consideration with regards to ethnicity, occupation, level of activity and other above-mentioned factors, such as the lack of blinding. The outcomes of this study may not be as a direct result of the interventions used as many factors may have influenced the findings in one or both of the groups in this study. Therefore, the results of this study need to be considered with caution, with cognisance that the external validity of this study is poor.
CONCLUSION:	Given the outcomes of the reviewers in the previous table (Table 4.4) the internal validity of the study is shown as 8/11 with a high percentage agreement of 96.9% between reviewers. These both suggest that there is a good level of internal validity in this study and clear methodological rigour. The external validity of this study is poor, and this affects the validity of these findings and outcomes. The limitations in this study suggest that the outcomes of this study may not be an accurate representation of outcomes should the study be repeated with the limitations and pitfalls having been addressed. Thus, the level of evidence that this study produces in favour of the AAI technique is limited.

Table 4. 6: Tabulated Feedback Data for RCT: Article 3

AUTHOR(S):	Gemmell, Miller					
YEAR:	2010					
TITLE:	Relative effectiveness and adverse effects of cervical manipulation, mobilisation and the activator instrument in patients with sub-acute non-specific neck pain: results from a stopped randomised trial					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	Yes	Yes	Yes	Yes	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Yes	Yes	Yes	Yes	100%
3	Allocation was concealed	Yes	Yes	Yes	Yes	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	No	Yes	No	No	66%
5	There was blinding of all subjects	No	No	No	No	100%
6	There was blinding of all therapists who administered the therapy	No	No	No	No	100%
7	There was blinding of all assessors who measured at least one key outcome	No	No	No	No	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Yes	Yes	Yes	Yes	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	Yes	Yes	Yes	Yes	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Yes	Yes	Yes	Yes	100%
11	The study provides both point measures and measures of variability for at least one key outcome	No	Yes	Yes	Yes	66%
	TOTAL SCORE	**6**	**8**	**8**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**93.8%**

Table 4. 7: Analysis of RCT: Article 3

AUTHOR(S):	Gemmell, Miller
YEAR:	2010
TITLE:	Relative effectiveness and adverse effects of cervical manipulation, mobilisation and the activator instrument in patients with sub-acute non-specific neck pain: results from a stopped randomised 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
PGIC, SF-36v2, the Neck Bournemouth Questionnaire and NPRS.	Pre-intervention, post-intervention (end of treatment) and 3, 6 and 12 months thereafter.	Twelve months.	47 participants started the study, only 41 participants completed the study.	No.	Group one: HVLA manipulation. (diversified technique) Group two: specific segmental. mobilisation Group three: AAI technique.	Block design.	8	93.8%

LIMITATIONS:	This study was conducted in the outpatient clinic of AECC, a chiropractic college in Bournemouth. This area is a lot smaller than London and resulted in a limitation in recruiting participants for this study and as a result, this study was stopped. (Gemmell and Miller 2010). The baseline for participants was not standardised as there were variables in the inclusion criteria for the condition (e.g. presence of headaches and referral pain) and patients (e.g. ethnicity, occupation, lifestyle and daily activity) that did not seem to be controlled. (Corfman 1995; Kabisch *et al.* 2011). With these not being standardised, there is a lack of homogeneity between participants and between the groups in this study. Although participants agreed to not take medication during the duration of the study (paracetamol and rescue were allowed), there is no mention of a wash out period, along with this, there was no information as to which participants (in which group) stopped medication prior to participation in this study. There was no consideration of chronic medication use either. These factors all affect the baseline and homogeneity of participants, impacting on the subjective outcome measures. (Corfman 1995; Kabisch *et al.* 2011; Moustgaard *et al.* 2014; Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020). The non-specific neck pain treated in this study was subacute in nature, limiting the application of the outcomes of this study. Anyone who received treatment six-months prior to this study were excluded, again, limiting the application of the outcomes of this study. Whilst this is an important baseline to have in this study amongst participants, there is a risk of a lack of patient naivety in this study if participants have had previous chiropractic care. This study was aimed at patients with non-specific neck pain, and this was in the inclusion criteria for participants, however it is possible that patients with specific causes of neck pain may have been included in the study. (Corfman 1995; Kabisch *et al.* 2011). Two chiropractor practitioners delivered all study treatments to the participants in this study. The first practitioner has 30 years of experience in general chiropractic practice. The second practitioner 15 years of experience in chiropractic practice and for the past 6 years had tutored adjustive technique. Both practitioners have experience in using the methods and interventions used in this study. (Gemmell and Miller 2010) There was subjective input from each

	practitioner as well as clinical judgement and skill set of each practitioner that was involved in this study, due to the practitioner assessing the participant for the dysfunctional joint and then delivering the treatment to the level, he/she identified. There are different approaches to determine where to apply the adjustment in a patient and various techniques to motion palpate a patient. Whilst this study mentions that the same clinical assessment was used for all three groups, there is no information given that suggests the practitioners perform the assessment in the same manner or treat the participants in the same manner. No information was given that suggests the practitioners did any form of training or induction prior to initiating this study and assessing and delivering the interventions to the participants. (Nyberg and Russell Smith 2013). This is a limitation in this study. There is a possibility that results may not be reproducible should this study be executed by a different practitioner and hence the validity and reliability of the outcomes noted in this study are questionable and these outcomes need to be considered with caution. The participants were not only treated with an adjustment or mobilisation, but myofascial complaints were also treated (trigger point therapy) and home care advice in the form of exercise advice and ergonomic advice were given to participants (i.e. a programme of intervention), therefore the results of the study would not have been able to measure the activator treatment or each intervention directly (Deaton and Cartwright 2018; Kaiser *et al.* 2018). The level of blinding in this study was compromised as participants knew what form of treatment they were receiving, there was a lack of a control group, and the practitioner's knew which intervention they are delivering. (Moustgaard *et al.* 2020). As a result of this there is a risk of the Hawthorne and Observer effects which may have impacted the results noted in this study, especially since there were subjective measurements used and a lack of objective measurements. (McCarney *et al.* 2007; Moustgaard *et al.* 2014; Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020; Elston 2021). Since the outcome measures were only subjective - the impact of a lack of naivety as well as a lack of blinding and patient perception of prior (pre-study) care would have potentially played significant roles in the outcomes of the study. (Hariton and Locascio 2018). The researchers had a major problem in recruiting participants to participate after the initial influx of willing participants. According to the authors, the effect of advertising may have been overestimated. Initially, there was a large influx of willing participants, that resulted in a waiting list (due to researcher's time constraints at that time) that by the time the patients were able to be assessed, they did not meet the eligibility criteria. Once the researchers had devoted more time to the study, there was a lack of participants. The area of Bournemouth may have limited this study as the population is not as large as an area such as London. The trial eventually had to be stopped due in inability to advertise further due to a lack of funding. (Gemmell and Miller 2010). There were six participants that dropped out of this study. This could possibly be related to the long period of measurement of clinical outcomes. There is a disproportionate dropout rate for the AAI group in this study when compared to the other groups. The author suggests that participants may have perceived the AAI to be harmful due to a lack of information given to the participants – information was given to the participants to make informed decisions however no great detail of each treatment was given. (Gemmell and Miller 2010). The AAI has a mechanical and surgical appearance and makes a 'clicking' noise which the author suggests, may have added to the participants concerns. It should also be considered that results of the participants that dropped out were not included in this study and therefore there is a possibility that the data noted in the outcomes may be skewed as a result of this (Bell *et al.* 2013). The sample size was small in this study, with a possibility of a type two error. (Columb and Atkinson 2015; Akobeng 2016; Ebrahim Valojerdi, Tanha and Janani 2017). At a power of 0.80 and an alpha of 0.05, eighteen subjects per group were needed. This study had a power of 0.75 and was therefore underpowered and the outcomes cannot be generalised. (Columb and Atkinson 2015). There is no placebo group or group receiving no treatment, this limits the use of the outcomes of this study as one does not know if each of these interventions used is any better than placebo. (Deaton and Cartwright 2018).
OUTCOME:	Initially, sixteen participants were in the HVLA manipulation group, one dropped out during the study; sixteen participants were in the AAI technique group, three dropped out during the study; and fifteen participants were in the mobilisation group, two dropped out during the study. All three methods/interventions used in this study provided long-term, favourable results in treating subacute neck pain in the participants, according to the authors. The mobilisation group was the only group to show significant improvement on the subscales of the SF-36v2. Comparison between the groups on the PGIC adjusted for baseline co-variants showed no significant difference for any of the endpoints between the three groups. No group provided results more significant than the other, in this study. HVLA manual manipulation, AAI technique and mobilisation all produced similar results in participants and all results were favourable. Adverse effects were reported by participants in this study, fifteen with manual therapy, seven with activator and four with mobilisation. These adverse effects were all minor and resolved within a few days. This study had a small sample size, had a total of six participants withdraw, and was stopped before its completion due to a lack of funding which resulted in an ability to continue advertising to recruit participants

DISCUSSION:	This study did not account for participant selection factors (viz. presence of a headache was not homogenous amongst the participants, patient characteristics), patient naivety and blinding affect the baseline and repeated measures, negatively affecting the external validity of this study. With the small sample size that is not homogenous, the outcomes are less representative of the general population's possible outcomes. Given that two practitioners were involved in treating participants in this study, the resultant variables introduced further compound the outcome measures. Principally, this trial was not designed to evaluate individual components of each treatment, but to compare the relative effect of adding a different form of spinal dysfunction correction to a programme of care. (Gemmell and Miller 2010). This package of care consists of trigger point therapy, exercise advice and ergonomic advice. These may have their own beneficial effects and this study aimed to determine the effect of adding different spinal dysfunction correction techniques to this programme of care rather than identify the effectiveness of one intervention over the another.
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.6), the internal validity of the study is shown as 8/11 with a high percentage agreement between reviewers of 93.8%. This indicates a good level of internal validity in this study. However, considering the limitations in this study such as small sample size, dropouts that are not explained, lack of baseline standardisation and homogeneity between participants, one cannot directly relate the outcomes in this study to the intervention used in each group. Since this study incorporated a programme of care for participants, no causal relationship can be concluded. The results of this study need to be used with caution. There is no evidence in support for or against the use of the AAI technique in treating spinal pain.

Table 4. 8: Tabulated Feedback Data for RCT: Article 4

AUTHOR(S):	Gillespie					
YEAR:	2003					
TITLE:	The Effectiveness of Manual Manipulation versus the Activator Adjusting Instrument in the Management of Acute Facet Syndrome of the Lumbar Spine					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	Yes	Yes	Yes	Yes	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Yes	Yes	Yes	Yes	100%
3	Allocation was concealed	No	Yes	No	No	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	Yes	Yes	Yes	Yes	100%
5	There was blinding of all subjects	No	No	No	No	100%
6	There was blinding of all therapists who administered the therapy	No	No	No	No	100%
7	There was blinding of all assessors who measured at least one key outcome	No	No	No	No	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	No	Yes	Yes	Yes	66%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	Yes	Yes	Yes	Yes	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Yes	Yes	Yes	Yes	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Yes	Yes	Yes	Yes	100%
	TOTAL SCORE	**6**	**8**	**7**	**7**	
		OVERALL PERCENTAGE AGREEMENT:				**93.8%**

Table 4. 9: Analysis of RCT: Article 4

AUTHOR(S):	Gillespie
YEAR:	2003
TITLE:	The Effectiveness of Manual Manipulation versus the Activator Adjusting Instrument in the Management of Acute Facet Syndrome of the Lumbar Spine

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
McGill Short-Form Pain Questionnaire, NPRS-101, pain sensitivity (digital algometer), range of motion (digital inclinometer).	All measurements were done prior to the first treatment and after the last treatment, except the NPRS-101, which was done after the first and after the last treatment.	Two weeks.	60 participants (six were excluded).	No.	Group one received manually administered chiropractic adjustments Group two: received adjustments with the AAI	Envelope consecutive randomised allocation method.	7	93.8%

LIMITATIONS:	The study was based at a university, there is a possibility that majority of the participants were recruited from within the university. The age distribution of participants doesn't reflect that only students were involved, however if majority of the participants were recruited from within the university, factors such as ergonomics, level of activity, day to day tasks and work-place environment should have been considered. This is a limitation of this study as the sample used for this study is not an accurate representation of the general population. (Corfman 1995; Kabisch *et al.* 2011; Columb and Atkinson 2015; Ebrahim Valojerdi, Tanha and Janani 2017). In favour of the homogeneity of the groups in this study, the participants were not included if they used medication and did not comply with a forty-eight hour wash out period prior to entering this study. The participants in this study needed to have acute low back pain, however cause of onset and duration were not considered. Ethnicity, occupation, parity (for the women), level of activity, weight and other lifestyle factors were not taken into account in this study (as mentioned above), therefore affecting the homogeneity between groups, the reproducibility of the results and applicability of the results on the general population are therefore questionable. (Corfman 1995; Kabisch *et al.* 2011). With respect to age, gender, race, occupation and the extent of pain and disability, more closely defined parameters could be used in future studies in order to enhance study strength and improve homogeneity within the two groups and improve the comparability of baseline characteristics. (Gillespie 2003). The fact that the researcher was also a master's student at the time of the research, implying that he was a relative novice in patient assessment, re-enforces the concerns around the homogeneity of the participants with respect to the homogeneity of the low back pain and lumbar facet syndrome that each participant presented with. (Nyberg and Russell Smith 2013; Chu *et al.* 2017).

	The researcher was the assessor for entry into the study, the person that applied the activator (or treatment) and took measurements. Therefore, the level of blinding in this study is compromised with respect to the assessor, therapist and measurements assessor being blinded (Moustgaard *et al.* 2020). The lack of blinding introduces a level of bias into this study. The outcomes noted in this study therefore need to be considered with caution as the outcomes may not only have measured the outcome of the intervention due to being influenced by biases such as the lack of blinding. (Krauss 2018; Moustgaard *et al.* 2020). Hawthorne and Observer effects are apparent in this study due to insufficient blinding of the researcher and the participants as well as a lack of patient naivety. (McCarney *et al.* 2007; Moustgaard *et al.* 2020; Elston 2021). The examiner knew which group was assessed and viewed previous treatment readings. This, along with the sample size being small, introduces the possibility of type two error into the study (Akobeng 2016), in addition to researcher bias being reflected in the results. (Columb and Atkinson 2015; Ebrahim Valojerdi, Tanha and Janani 2017). There is no placebo group or group receiving no treatment, which hinders the ability of the study to determine whether the outcomes are actually better than placebo and how they may impact the patient clinically. (Deaton and Cartwright 2018). Of the sixty participants in this study, six dropped out due to non-compliance. There is a lack of further information given about the dropouts in this study and it is not noted as to what occurred with the data and outcomes noted with these participants. (Bell *et al.* 2013). The intervention was not applied to a set segment of the lumbar spine, the segment that was adjusted was determined by the practitioner through an assessment of the participant and motion palpation of the participant. Since the practitioner was a student, this process may have influenced and affected the outcomes of this study due to lack of experience of the researcher in conducting research, participant interaction and the palpation and treatment of participants. (Chu *et al.* 2017). Treatments were not spaced out uniformly for all participants in this study. With the lack of uniformity and homogeneity between the groups, the applicability of the outcomes to clinical practice are reduced as the external validity of the study is reduced by these factors. Direct and accurate comparisons between the groups in this study is limited due to the reduced external validity and therefore the comparison and the effect of the efficacy of each treatment is limited. This study has a balance between objective and subjective outcome measures. This balance is favourable in this study. since there is a lack of blinding and a lack of patient naivety in this study, introduces objective measurements when assessing outcomes reduces the level of bias in the noted outcomes. (Mazor *et al.* 2002; Moustgaard *et al.* 2014; Thornton *et al.* 2017; Hariton and Locascio 2018; Tempelaar, Rienties and Nguyen 2020).
OUTCOME:	Within both group one and two there was an improvement in pain (NPRS) between the first and final treatment. (p= 0.00). The MSFPQ noted an improvement between the first and final treatment in both groups (p= 0.008). The digital algometer readings showed that there was no significant improvement between the first and final treatment in either group (p = 0.077). The readings of the digital inclinometer revealed that there was no significant improvement between the first and final visit in either group in forward flexion (p= 0.279), left lateral flexion (p = 0.260) and left rotation (p= 0.099). There was improvement noted in both groups in extension (p = 0.006), right lateral flexion (p = 0.620) and right rotation (p = 0.016). Whilst both groups had favourable outcomes, the differences between the groups were not significant enough to conclude that one treatment was more effective that the other. Also, since there was no placebo group in this study, one cannot conclude that either intervention is better than placebo.
DISCUSSION:	In this study the lack of homogeneity of patient characteristics between participants at baseline reduces the external validity. Given this context, with uncontrolled variables that may influence the patient's response to the interventions there is a clear likelihood that the results of the study do not directly measure the interventions only. This is further compounded by the lack of blinding of the researcher and participants as well as patient naivety in this study, that may influence the outcome measures obtained. A RCT needs to be carried out that addresses the pitfalls of this study in order to identify a relationship between the intervention used and the outcomes measured. (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022).
CONCLUSION:	Given in the outcomes table (Table 4.8) the internal validity of the study is moderate, shown as 7/11 with a high percentage agreement between reviewers of 93.8%. The moderate methodological rigour may have influenced the results of this study along with the discussed limitations and therefore the outcomes obtained should be used with caution in clinical practice. Due to the limitations in this study, the outcomes noted in this study are not necessarily as a direct result of the interventions used but may have been affected by lack of homogeneity between participants and groups, lack of blinding and other limitations discussed above. Thus, this study provides limited evidence for the use of the AAI technique in treating acute facet syndrome of the lumbar spine.

Table 4. 10: Tabulated Feedback Data for RCT: Article 5

AUTHOR(S):	Gorrell, Beath, Engel					
YEAR:	2016					
TITLE:	Manual and Instrument Applied Cervical Manipulation for Mechanical Neck Pain: A Randomized Controlled Trial					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	Yes	Yes	Yes	Yes	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Yes	Yes	Yes	Yes	100%
3	Allocation was concealed	Yes	Yes	Yes	Yes	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	Yes	Yes	Yes	Yes	100%
5	There was blinding of all subjects	No	No	No	No	100%
6	There was blinding of all therapists who administered the therapy	No	No	No	No	100%
7	There was blinding of all assessors who measured at least one key outcome	No	No	No	No	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Yes	Yes	Yes	Yes	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	No	Yes	Yes	Yes	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Yes	Yes	Yes	Yes	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Yes	Yes	Yes	Yes	100%
	TOTAL SCORE	**7**	**8**	**8**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**96.9%**

Table 4. 11: Analysis of RCT: Article 5

AUTHOR(S):	Gorrell, Beath, Engel
YEAR:	2016
TITLE:	Manual and Instrument Applied Cervical Manipulation for Mechanical Neck Pain: A Randomized 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**
VAS, NPRS, pressure pain threshold, cervical range of motion, hand grip-strength and wrist blood pressure. Follow up subjective pain scores were obtained via telephone text message seven days post-intervention.	All outcome measures were taken immediately before and after the intervention was applied to the participant. Subjective pain levels (NPRS) were also measured seven days post intervention.	Two months.	65 participants.	Not stated.	Participants allocated into three groups. Group one (control group): stretching. Group two: stretching plus MAM. Group three: stretching plus IAM.	Computed generated random number sequence.	8	96.9%

LIMITATIONS:	This study was carried out Macquarie University's Chiropractic Outpatient and Research Clinic in Sydney. The average age of participants in this study was low, possibly due to the location of where this studied was carried out and therefore the data and evidence in this study is limited to this age group and cannot be applied to the older population. (Corfman 1995; Kabisch *et al.* 2011; Columb and Atkinson 2015). Calculation of the minimum sample size was based on detecting a difference of 0.4 units in pain pressure threshold levels, a standard deviation of 0.4, comparison of two means, an alpha of 0.05 and a power of 80%. These assumptions generated a minimum sample size of twenty-one participants per group and a total cohort size of sixty-three. This study was therefore sufficiently powered. (Columb and Atkinson 2015; Ebrahim Valojerdi, Tanha and Janani 2017). In terms of group homogeneity, previous pregnancies were considered, however factors including but not limited to gender, ethnicity, history of trauma (only recent neck trauma was considered and the presence of a radiculopathy (as exclusions)), onset of neck pain or headaches were not reported in this study. This directly affects the homogeneity of the participants between the groups. There is no reported baseline comparing the groups in the publication, with respect to patient or condition parameters, therefore the impact of non-homogeneity cannot be determined. (Corfman 1995; Kabisch *et al.* 2011). Anyone having had chiropractic treatment within one month prior to this study was excluded. Patients may have a lack of naivety if they have had previous chiropractic care. This, along with a lack of blinding may influence and allow for bias within the outcomes of this study. (Moustgaard *et al.* 2020). The level of blinding in this study is compromised as participants may have known

	what form of treatment they received, there is a lack of a control group, and the practitioners know which intervention they are delivering. (Deaton and Cartwright 2018). These factors include the risk of perception bias, natural history bias and researcher bias (Mazor *et al.* 2002; Krauss 2018). The participants were not merely treated with a manual or instrument assisted adjustment, stretches were also given to participants in each group (i.e. a programme of intervention), therefore the results of the study would not have been able to measure the activator technique directly as there is a lack of a control group and there is a programme of intervention which does not allow a single intervention to be directly related to any of the outcomes. (Kaiser *et al.* 2018). The participants were all given a stretching routine to carry out during this study which has perceived benefit in patient care (Hurwitz *et al.* 2009; Kay *et al.* 2012; Snodgrass *et al.* 2014) and therefore one cannot conclude that the outcomes of this study are directly related to any one single intervention used. To the credit of the study, an administrative officer created the allocation sequence for participants allowing for randomisation and concealed allocation. All assessments were performed by a single assessor which may have resulted in an incorrect initial diagnosis of the participants as there was no inter-examiner r validation conducted (Gorrell, Beath and Engel 2016). In addition, the study had one practitioner treating the MAM group and another treating the IAM group. It is unclear whether these practitioners knew about the other treatment arm in the study and whether or not they knew the comparator treatment. Additionally, it is unclear as to whether there was any training regarding the research protocol to keep variables like doctor-patient interaction similar, so as to highlight treatment outcomes in the results. Notwithstanding this, each practitioner's subjective views in clinical practice (viz. where to adjust, static palpation techniques and demeanour with the participants) may still be an influencing set of variables that may have affected the outcomes. (Nyberg and Russell Smith 2013). It is noted in this study that due to numerous multiple comparisons were performed, a type one error may have occurred (Akobeng 2016; Gorrell, Beath and Engel 2016). There was partial practitioner blinding, no patient blinding, no report on patient naivety and Hawthorne and Observer effects cannot be excluded (McCarney *et al.* 2007; Moustgaard *et al.* 2020; Elston 2021). The control group was not blinded in this study. This, coupled with a lack of patient naivety, may have impacted the outcomes noted. Whilst there is a balance of subjective and objective outcome measurement tools used in this study, the VAS and NPRS were used in this study and not all patients can "accurately" identify their pain levels, patients may note"0" on the scale as being "normal" or "manageable pain", thus affecting results in this study. (Moustgaard *et al.* 2014; Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020). This study also had a low baseline pain level which is a limitation in this study (viz floor effect). (Bruce *et al.* 2013). As a result of the above, it is suggested that the study outcomes may measure a component of the impact of each intervention as compared to the impact of the entire intervention programme (Kaiser *et al.* 2018).
OUTCOME:	Subjective pain scores decreased at seven-day follow-up in the MAM group compared to the control group ($p = 0.015$). There were no other between-group differences for subjective pain levels at seven-day follow-up: IAM to control ($p= 0.235$) and MAM to IAM ($p = 0.367$). There were no between-group differences for pain pressure threshold ($p = 0.195$). Cervical rotation bilaterally (ipsilateral: $p = 0.002$; contralateral $p = 0.015$) and lateral flexion on the contralateral side to manipulation ($p = 0.001$) increased following MAM. Hand grip-strength on the contralateral side to manipulation ($p = 0.013$) increased following IAM when compared to the IAM group. There was no difference in lateral flexion between the MAM and IAM groups on the ipsilateral side to manipulation. There were no changes in wrist blood pressure reported in this study ($p= 0.096$). There was a between group difference in reported hand grip-strength on the contralateral side to manipulation ($p= 0.013$). this difference was an increase of 4.43kg ($p= 0.013$) in the IAM group compared to the MAM group. There was no difference noted on the ipsilateral side to manipulation. ($p = 0.357$). Since none of the changes noted in this study were above the minimum clinically importance difference for either VAS or NPRS, the results are not clinically significant. Also, since a programme of intervention was used (even within the 'control group'), one cannot determine the direct impact of each intervention on the outcomes noted in this study.
DISCUSSION:	In this study, the lack of documented comparability between participant groups at baseline (patient characteristics and outcome measures), which reduces he ability to confirm that the outcomes are due to the intervention and it makes it impossible to determine which patient group would benefit from a similar intervention in clinical practice (external validity).This is further compounded by the programme of interventions, which limits the ability to draw a conclusion about one particular modality included in the programme. The outcomes of this study need to be considered with caution and further investigations, with greater compliance to RCT protocols are needed that address the pitfalls of this study. (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022).
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.10) the internal validity of the study is shown as 8/11 with a 96.9% agreement between reviewers, indicating a good level of internal validity. However, with the limitations that presented in the study, there is a significant argument that the outcomes were not necessarily only as a result of the intervention programme used and were affected by issues homogeneity of the sample groups. This needs to be considered in addition to the intervention programme, which results in no evidence for or against the use of AAI technique in treating mechanical neck pain in the younger population. Further research is required ensuring that the intervention is actually tested for in the study rather than an intervention programme, as used in this study.

Table 4. 12: Tabulated Feedback Data for RCT: Article 6

AUTHOR(S):	Hardas, Murrell					
YEAR:	2018					
TITLE:	Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Trial Assessing the Effects of Applying a Force to C5 by a Mechanically Assisted Instrument on Referred Pain to the Shoulder					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	Yes	Yes	Yes	Yes	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Yes	Yes	Yes	Yes	100%
3	Allocation was concealed	Yes	Yes	Yes	Yes	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	No	Yes	Yes	Yes	66%
5	There was blinding of all subjects	Yes	Yes	Yes	Yes	100%
6	There was blinding of all therapists who administered the therapy	Yes	No	Yes	Yes	66%
7	There was blinding of all assessors who measured at least one key outcome	Yes	Yes	Yes	Yes	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Yes	Yes	Yes	Yes	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	Yes	Yes	Yes	Yes	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Yes	Yes	Yes	Yes	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Yes	Yes	Yes	Yes	100%
	TOTAL SCORE	**10**	**10**	**11**	**11**	
		OVERALL PERCENTAGE AGREEMENT:				**93.8%**

Table 4. 13: Analysis of RCT: Article 6

AUTHOR(S):	Hardas, Murrell
YEAR:	2018
TITLE:	Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Trial Assessing the Effects of Applying a Force to C5 by a Mechanically Assisted Instrument on Referred Pain to the Shoulder

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
Frequency and severity of extreme shoulder pain (patient reported questionnaire), muscle strength for internal rotation of the shoulder and the supraspinatus muscles (via a hand-held dynamometer), cervical range of motion for stiffness and pain in flexion, extension, rotation, lateral flexion, extension/rotation/lateral flexion (quadrant/Kemp's); shoulder impingement on internal rotation.	Pre-treatment assessment with reassessments at 1, 3, 6, 9, 12 and 24 weeks post treatment. The participants received treatment twice per week for six weeks, then once per week for three weeks. At 12 and 24 weeks, there was no intervention, just an assessment done.	24-week assessment period of participants.	125 participants. 65 participants in the treatment cohort and 60 in the placebo cohort.	This was a double blinded study.	Placebo group: MAI applied to C5 but only a click was produced, no force was delivered through the device. Treatment group: MAI applied to C5, the click was produced as well as a force delivered.	Envelopes drawn out of a box to randomise the allocation of participants.	11	93.8%

LIMITATIONS:	Participants were recruited through newspaper advertisements, doctor mail-outs and referrals from other health care professionals. The average age of participants was quite high and as a result, the findings of this study are only applicable to this age group and cannot be generalised to the entire population. (Corfman 1995; Kabisch *et al.* 2011). With an alpha of 0.05, a beta of 0.20 and the power at 0.8, level of significance at p = 0.05 and the difference in means set at 2.39, expected standard deviation of 3.6, the analysis indicated a sample size of thirty-six per group. This study was therefore adequately powered. (Columb and Atkinson 2015; Ebrahim Valojerdi, Tanha and Janani 2017). Given the above population, the study considered the impact of age, gender, side of shoulder pain, duration of symptoms and controlled for these, however many factors (viz. ethnicity, onset of pain, previous trauma, dominant side vs side presenting with pain, occupation, level of activity, occupation) were not

	considered. This impacts the ability to confirm group likeness and thus ensuring that the outcome measures were as a result of the interventions and not due to patient or condition characteristics that were dissimilar. (Corfman 1995; Kabisch *et al.* 2011). Patient naivety should also have been considered (Hariton and Locascio 2018) in that the placebo group received treatment that was merely the MAI producing a clicking sound but no force. In patients with prior experience of chiropractic care, they may well identify the treatment as placebo and respond to outcomes measures accordingly. Since the adjustment was delivered to C5 specifically to the participants in this study, there may have been inaccuracy in locating this vertebral level specifically by using surface anatomy as subjective involvement of the treating physician would be involved. (Nyberg and Russell Smith 2013). To counter naivety in part, there was blinding of participants as well as the assessor blinding. (Moustgaard *et al.* 2020). These help to negate therapist influence that may occur between the groups (Krauss 2018). The Hawthorne and Observer effects may however have been equally present if the participants were unaware of group allocation, with the inverse being true if they were aware of group allocation. At this juncture this cannot be excluded as an influence on the outcomes as there was no mention of a post intervention question determining if participants knew which group they were in during the study. (McCarney *et al.* 2007; Moustgaard *et al.* 2020; Elston 2021). The saving grace of the study is the lack of subjective measures that would have been influenced by many of the confounders above (Moustgaard *et al.* 2014; Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020) , but it does have a limitation in that the outcome measures assume that the placement of the AAI would have been identical for all patients (viz. direction and placement) thus affecting the range of motion parameters equally (Nyberg and Russell Smith 2013).
OUTCOME:	The frequency of extreme shoulder pain in both cohorts experienced a significant improvement at 24 weeks when being compared to preintervention levels. In the treatment group, $p < 0.05$ using Wilcoxon signed-rank test, between pre-treatment and twenty-four weeks; however Mann-Whitney unpaired test showed no significant difference between the two groups at twenty-four weeks and its suggested that time was the significant factor in the reduction of the frequency of pain. (Hardas and Murrell 2018). The level of shoulder pain at rest improved in both groups between the pre-treatment level and the twenty-four weeks levels. In the treatment group, $p < 0.01$ using Wilcoxon signed-rank test, between pre-treatment and twenty-four weeks. Mann Whitney unpaired test showed no significant difference between the two groups at twenty-four weeks and its suggested that time was the significant factor in the reduction of pain severity. (Hardas and Murrell 2018). Cervical range of motion for stiffness and pain in flexion, extension, rotation, lateral flexion, extension/rotation/lateral flexion improved in both groups in this study however there was no statistical significance favouring the treatment group over the sham groups' results. The only outcome measure that was statistically significant was shoulder strength in internal rotation, which was better in the treatment group ($p < 0.04$). Thus, since both groups showed similar improvements with regards to severity and frequency of pain, it is said to be as a result of elapsed time/natural history (24 weeks) rather than as a result of any treatment.
DISCUSSION:	In this study, there is a lack of external validity due to variables that were not accounted for (viz. pain possibility emanating from the intervertebral disc, duration or cause of symptoms, dominant side vs side presenting with pain, ethnicity, occupation). As a result of this, there is high probability that there was a lack of homogeneity between the groups at the baseline which may have had an effect on the outcome measures in this study (given that there may be ceiling or floor effects in some of the outcome measures (Bruce *et al.* 2013)). This may have lead the study to attain an incorrect conclusion about the results (viz. the intervention is no better than placebo or potentially natural history) (type two error (Akobeng 2016)). Thus, this study requires better external validity control with maintenance of the internal validity in order to confirm or refute the findings.
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.12) the internal validity of this study is shown as 11/11 with a high percentage agreement between reviewers of 93.8%, indicating an excellent level of internal validity. However, due to the limitations of this study, there is a possibility that the outcomes of this study may have been influenced and affected by factors that limited external validity. The level of evidence that this study produces in favour of the AAI technique in treating referred pain to the shoulder is limited.

Table 4. 14: Tabulated Feedback Data for RCT: Article 7

AUTHOR(S):	Kendall, French, Hartvigsen, Azari					
YEAR:	2018					
TITLE:	Chiropractic treatment including instrument-assisted manipulation for non-specific dizziness and neck pain in community-dwelling older people: A feasibility randomised sham-controlled trial					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	Yes	Yes	Yes	Yes	
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Yes	Yes	Yes	Yes	100%
3	Allocation was concealed	Yes	Yes	Yes	Yes	100%
4	The groups were similar at baseline regarding the most important prognostic indicators	Yes	Yes	Yes	Yes	100%
5	There was blinding of all subjects	No	Yes	Yes	Yes	66%
6	There was blinding of all therapists who administered the therapy	No	Yes	Yes	Yes	66%
7	There was blinding of all assessors who measured at least one key outcome	Yes	Yes	Yes	Yes	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Yes	Yes	Yes	Yes	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	No	Yes	Yes	Yes	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	No	Yes	Yes	Yes	66%
11	The study provides both point measures and measures of variability for at least one key outcome	Yes	Yes	Yes	Yes	100%
	TOTAL SCORE	**7**	**11**	**11**	**11**	
		OVERALL PERCENTAGE AGREEMENT:				**78.5%**

Table 4. 15: Analysis of RCT: Article 7

AUTHOR(S):	Kendall, French, Hartvigsen, Azari
YEAR:	2018
TITLE:	Chiropractic treatment including instrument-assisted manipulation for non-specific dizziness and neck pain in community-dwelling older people: A feasibility randomised sham-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
Self-reported questionnaires were used, reporting on dizziness (NRS11 and DHI), neck pain (NRS11 and NDI), self-reported concerns of falling (FES-I), quality of life (SF12), mood (DASS21), physical function (step test, TUG, functional reach, four-square step test), cognitive function (MoCA) treatment satisfaction. Physical function and mobility assessments were carried out.	Clinical outcomes were assessed at the baseline visit (one week pre-intervention) and follow-up visit (one-week post-intervention).	Intervention delivered weekly for four weeks. Assessment conducted one week pre- and post-intervention. The study ran for a total of nine months (inclusive of the recruitment period).	Initially 24 participants (Chiropractic n = 13; sham n = 11). Ended with 22 participants (Chiropractic n = 12, sham n = 10).	The researcher performing the outcome assessments was blinded to group allocation, the chiropractors involved in performing the interventions were blinded to the results of the outcome assessments at pre- and post-intervention assessments.	Chiropractic group received AAI assisted cervical and thoracic spine manipulation plus a combination of light massage, mobilisation, range of motion exercises, and home advice about the application of heat. Sham group received AAI assisted manipulation (set to zero impulse) plus gentle touch of cervical and thoracic spinal regions.	Randomisation using a permuted block method.	11	78.5%

LIMITATIONS:	This study was conducted in Melbourne, Australia in a single location at an outer-suburban university. This created limitations for this study as many participants wanted to participate in the study and met the inclusion criteria, however, were unable to travel to the location. (Kendall *et al.* 2018). This limited this number of participants able to participate in this study and resulted in a small, under powered sample size. (Columb and Atkinson 2015; Ebrahim Valojerdi, Tanha and Janani 2017). Participants were recruited through advertisements in the local community newspapers, flyers at RMIT University and via Facebook. The homogeneity between the groups was not favourable and thus lacking in this study. This statement is underpinned by the lack of consideration of medication (acute and chronic), no washout period was noted and patient characteristics (viz. patient occupation, lifestyle, activity level, history of trauma, frequency of previous neck pain occurrences, most recent episode of onset) were not consistently controlled for. (Corfman 1995; Kabisch *et al.* 2011). This is especially true of older adults experiencing neck pain and dizziness who often have co-morbidities (Davis, Chung and Juarez 2011; Divo, Martinez and Mannino 2014) which may contraindicate the interventions (Roberts and Wolfe 2012; Chung and Mior 2015) and should have possibly been excluded. Participants were excluded if they had received any SMT or neck massage three months prior to this study. Since some participants may have experienced chiropractic treatment prior to involvement in this study, there is a risk of a lack of patient naivety in this study (Hariton and Locascio 2018). Participants were blinded to group allocation. The researcher performing the outcome assessments was also blinded to group allocation. There were two treating practitioners, each with at least 20 years of clinical experience. Both of these practitioners were blinded to the results of the outcome assessments at pre- and post-intervention. Participants were not assigned a specific practitioner depending on which group they were allocated to. The practitioner that delivered the intervention was based depending on availability. The treatment times were standardised to fifteen minutes each in both groups. This study did assess the overall blinding in the study by conducting a post intervention survey and the blinding appeared similar between the two groups. (Kendall *et al.* 2018; Moustgaard *et al.* 2020). Without an *a priori* description of the power analysis, it suggests that the small sample size was inadequate to make this a fully powered trial, that was likely to detect significant differences (Columb and Atkinson 2015; Ebrahim Valojerdi, Tanha and Janani 2017; Kendall *et al.* 2018). This implies that trends need to be considered with caution and final conclusions may be underpinned by a type two error (Akobeng 2016). A sample size for a fully powered trial (derived from data in this feasibility trial with an effect size of d= 0.38), using the DHI as the primary outcome measure would require a group size of one hundred and fifty participants (seventy-five per group). Using the NDI as the primary outcome measure (with an effect size of d= 0.46) would require a group size of two hundred and twenty-two (one hundred and eleven per group). Since this was a feasibility study, no statistical analyses were done to determine the effectiveness of the chiropractic intervention. (Kendall *et al.* 2018). In addition to the small numbers there were noted dropouts (not as a result of worsening results, which aids the study in not skewing the outcomes (Bell *et al.* 2013)), which means that the impact of the lack of homogeneity is much greater than a study with larger sample sizes where the aggregation to the mean is closer to the norm in the general population (reference). There were two dropouts noted in this study, one from each group. The dropout from the sham control group left the study due to a spontaneous low back pain complaint unrelated to intervention and the participant from the intervention group dropped out due to an inability in making the travel commitment. Neither of these participants were assessed from post-intervention outcomes. The participants in the intervention group were not merely treated with an adjustment, myofascial complaints were also treated with joint mobilisation, massage, range of motion neck exercises or advice to apply heat at home – therefore an intervention programme was used in this study and any one intervention cannot be associated with the outcomes that were measured (Kaiser *et al.* 2018). Additionally, the interaction between the therapist and patient may be put down to touch therapy (Wright 1987), the Hawthorne effect, patient perception driven by past experience or naivety, or a combination of these (McCarney *et al.* 2007; Hariton and Locascio 2018; Krauss 2018; Elston 2021). The sham group received an adjustment from the AAI set to “zero” and no massage, mobilisation or home advice was given to these participants. The practitioner used the AAI set to zero and placed their hands on the cervical and thoracic spinal regions. This would have required the AAI being calibrated correctly to ensure that no force was actually delivered by the AAI in the sham group. (Deaton and Cartwright 2018). The effect of touch therapy may have influenced the findings in this group too. (Kaiser *et al.* 2018). The preponderance of self-reported questionnaires puts the study at greater risk of patient characteristics, skewed baseline demographics, patient perception, and the influence of all of these factors on accurate reporting of clinical outcomes by patients. The few objective measures may have assisted in balancing this subjective outcome measures skew. (Moustgaard *et al.* 2014; Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020). A fully powered RCT needs to be conducted. (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022).

OUTCOME:	Participants had moderate dizziness at baseline mean in both groups. DHI scores were also similar at baseline and improved in both groups post-intervention (chiropractic 28.33 (14.37) to 40.77 (12.48); sham 44.00 (16.97) to 36.40 (20.11)). Similarly, NDI scores were educed post-intervention (chiropractic 24.94 (12.87) to 19.07 (12.50); sham 24.18 (8.22) to 22.8 (6.2)). 58% of the chiropractic group showed a clinically significant improvement (of at least 19%) in NDI scores compared to 30% in the sham group. The DHI scores improved by the clinically significant amount (of at least 18%) in 67%of the chiropractic group versus 50% of the sham group. Fear of falling was high in both groups at baseline (chiropractic 26.00 (5.61); sham 29.00 (5.71)). This fear reduced slightly in both groups post-intervention (chiropractic 24.42 (5.21); sham 26.7 (6.29)).
DISCUSSION:	In this study, the use of an intervention programme has eliminated the possibility of the outcome measures being able to measure the AAI technique as outlined in this study. Further to this, the small sample size, possible lack of patient naivety, the lack of homogeneity of the groups further compromises the external validity of this study. Based on this study, it is inappropriate for chiropractors in clinical practice to advocate for the use of the AAI technique in treating neck pain and non-specific dizziness as expressed in this study. For this clinical conundrum to be resolved, it is advised that further studies of a similar design (addressing the limitations and pitfalls in this study) would assist in providing better and more structured evidence to contribute to the clinical agenda and improve the evidence base for clinical practice. (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022).
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.14) the internal validity of the study is shown as 11/11 with a percentage agreement between reviewers of 78.5%. Whilst methodological rigour is excellent, apparent and well rated in this study, larger scale research of this type needs to be completed whilst addressing the limitations and pitfalls in this study in order to generate treatment guidelines. In the context of the limitations that presented in this study, there is a significant argument that the outcomes were not a direct result of the AAI technique, and an intervention programme was used. The external validity of this study is poor. This study produces no evidence in favour or against the use of the AAI technique in treating neck pain and non-specific dizziness. Further research is required ensuring that the intervention is actually tested for in the study rather than an intervention programme, as used in this study.

Table 4. 16: Tabulated Feedback Data for RCT: Article 8

AUTHOR(S):	Shearar					
YEAR:	2003					
TITLE:	The Relative Effectiveness of Manual Manipulation versus Manipulation using the "Activator Adjusting Instrument" in the Management of Acute on Chronic Sacroiliac Syndrome					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	Yes	Yes	Yes	Yes	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Yes	Yes	Yes	Yes	100%
3	Allocation was concealed	No	Yes	Yes	Yes	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	No	Yes	Yes	Yes	66%
5	There was blinding of all subjects	No	No	No	No	100%
6	There was blinding of all therapists who administered the therapy	No	No	No	No	100%
7	There was blinding of all assessors who measured at least one key outcome	No	No	No	No	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	No	Yes	Yes	Yes	66%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	No	Yes	Yes	Yes	66%
10	The results of between-group statistical comparisons are reported for at least one key outcome	No	Yes	Yes	Yes	66%
11	The study provides both point measures and measures of variability for at least one key outcome	No	No	No	No	100%
	TOTAL SCORE	**2**	**7**	**7**	**7**	
		OVERALL PERCENTAGE AGREEMENT:				**84.5%**

Table 4. 17: Analysis of RCT: Article 8

AUTHOR(S):	Shearar
YEAR:	2003
TITLE:	The Relative Effectiveness of Manual Manipulation versus Manipulation using the "Activator Adjusting Instrument" in the Management of Acute on Chronic Sacroiliac Syndrome

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 Revised Oswestry Disability Questionnaire, NPRS-101, ORS and the algometer.	Data was collected at the beginning of the first, third and follow-up consultations. If the patient became asymptomatic, in terms of subjective clinical findings, before the final consultation, the patient continued to be evaluated for the remainder of the treatment period but received no further treatment.	Four consultations over a two-week period, and then a follow-up consultation within one week following the fourth treatment.	60 patients, two groups of 30 patients.	The examiner knew which group was being assessed and viewed the previous treatment readings.	Group one (control group): received side posture manipulation of the symptomatic sacroiliac joint using the Diversified Technique of manipulation. Group two: received mechanical force, manually assisted instrument manipulation of the symptomatic sacroiliac joint using a handheld instrument, the AAI.	Randomisation without the use of stratification, depending on a number drawn from a box.	7	84.5%

LIMITATIONS:	This study was located at the DUT Chiropractic Clinic in South Africa. The participants were recruited by means of advertising in local newspapers, pamphlets in local sports clubs, gyms and shopping centres, and advertising by word of mouth. In favour of the homogeneity of the groups, participants were excluded if they used medication for their low back pain or did not comply with a three day wash out period prior to entering the study. Participants with contraindications to manipulation, a history of lumbar surgery, history of participation in research at the facility, pregnant females – were all excluded. Participants had to have a history of low back pain longer than two weeks in durations with a total of more than four weeks of low back pain in the preceding year were accepted into the study, limiting the use of the findings of this study to patients with acute on chronic low back pain. In contrast, the homogeneity was affected negatively as chronic medications were not considered. Any mechanical conditions associated with but secondary to sacroiliac syndrome were assessed and noted in the low back regional exam, but no treatment for these conditions was administered. This affects the baseline homogeneity of condition characteristics between participants in this study. Ethnicity, occupation, previous pregnancies, level of activity and other lifestyle factors were not considered or taken into account in

	this study, therefore affecting the baseline homogeneity of patient characteristics between groups, this compromises the outcomes as a direct measure of the intervention (Corfman 1995; Kabisch *et al.* 2011). Participants needed to be between the ages of eighteen and fifty-nine in this study. The study also lacked homogeneity between the two treatment groups as a result of not including stratification when doing group allocation. The meaning and trends behind the outcomes noted in this study are difficult to process and detect as a result of this (Hill 2000). The sample size was 30 participants per group, with no reporting of dropout or intention to treat analysis. It is therefore assumed that dropouts were replaced to attain the required number of participants. As a result, the reporting may only reflect those patients that benefitted and were not excluded due to worsening symptoms (Bell *et al.* 2013). Due to this sample size and use of non-parametric statistics with certain outcomes, there is a risk of a type two error in this study in drawing conclusions in addition to the study having a limited ability to discuss differences in trends as opposed to statistically significant differences. (Vickers 2005; Columb and Atkinson 2015; Akobeng 2016; Ebrahim Valojerdi, Tanha and Janani 2017). Data was analysed using a 5% significance level in this study. Both parametric and non-parametric testing was used in order to analyse the data obtained. A larger sample size would increase the validity of the study and minimise the risk of a type two error. (Shearar 2003). There may possibly be trends and significant findings in the outcomes should the study be completed with a larger sample size. (Akobeng 2016; Mascha and Vetter 2018).The study was not defined by an *a priori* analysis – there is no mention in this study noting if it was adequately powered or not. There is a lack of diagnostic criteria for sacroiliac joint syndrome. Considering the researcher was a novice researcher, the researcher was also the assessor in the study and there was no inter-examiner validation conducted, there is a risk that the initial diagnosis of participants may have been incorrect, and outcomes of this study would therefore be affected. (Nyberg and Russell Smith 2013; Chu *et al.* 2017). However, the stated criteria for admission were clear and would have mitigated some of these concerns. By contrast the fact that the researcher was the assessor for entry into the study, the person that applied the activator (or treatment) and took measurements, the level of blinding in this study is potentially compromised. As a result, the bias introduced by this lack of blinding questions whether the outcomes do indeed measure the actual intervention or only a component of it. (Moustgaard *et al.* 2020). There is no documented control of patient naivety in this study and therefore subjective findings may have been subjected to bias. (Moustgaard *et al.* 2014; Tempelaar, Rienties and Nguyen 2020). Whilst the Hawthorne and Observer effects may have influenced the subjective findings, there is a balance between subjective and objective findings in this study which reduces the risk of bias as a result of these effects. (McCarney *et al.* 2007; Moustgaard *et al.* 2014; Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020; Elston 2021). There is no placebo control group or group receiving no treatment, which hinders the ability of the study to determine whether the outcomes are actually better than placebo and how they may impact the patient clinically (Deaton and Cartwright 2018). This study and its results were limited to measuring outcomes over a period of two weeks due to the duration of the study (Nair 2019). Long term treatment and measurement may have altered or amplified the findings in this study and given a clearer picture of clinical outcomes when treating patients over an extended period of time. There was irregularity with the booking of the follow-up visits, they were not booked or spaced uniformly, this was noted as a limitation in this study (Shearar 2003). The algometer provides a limitation in that its validity as an objective measure is questionable due to the reproducibility of results and hence accuracy of each reading. This is due to the use of the algometer differing between various practitioners, differences in how the instrument is placed and used will affect the readings. Since one assessor did all the readings in this study, it reduces the influence of this limitation on this study. should many assessors have been involved in this study, this would have served as a larger limitation. (Mutlu and Ozdincler 2015).
OUTCOME:	The purpose of this study was to determine the level of effectiveness of manual manipulation versus manipulation using the AAI technique in the management of acute on chronic sacroiliac syndrome. Two groups were randomly allocated, with group one receiving manual manipulation and group two receiving manipulation using the AAI. The Revised Oswestry Disability Questionnaire, NPRS-101 and Orthopaedic Rating Scale noted pain reduction and improvement between visits one and three and one and five and therefore one and five (p= 0.000) in both groups. The algometer readings noted improvement on the symptomatic side of both groups (p= 0.000) whilst no improvement was noted on the asymptomatic side in either group (p= 0.000). The Revised Oswestry Disability Questionnaire and NPRS-101 both revealed no difference between the two groups at the initial consultation (5% significance level) or at the final consultation (5% significance level), therefore suggesting that subjective pain intensity and disability were improved equally in both groups with no statistically significant differences between the two groups. The Orthopaedic Rating Scale and algometer indicated that both treatment protocols were equally effective and there were no differences between the groups. A decrease in pain was evident in as well as decreased disability scores, in both treatment groups. Neither treatment proved to be more effective than the other in the treatment of acute on chronic sacroiliac syndrome. Some differences did occur between the two groups, favouring instrument manipulation in most cases. These differences were too minor and insufficient to conclude that one treatment was more effective

	than the other. This was the first study to compare these two interventions for the treatment of sacroiliac joint syndrome, and it therefore acts as a baseline for further research in this field, possibly of a larger scale (Shearar 2003). This study implies that the AAI technique may be used with equal confidence as manual manipulation when treating low back pain caused by sacroiliac syndrome. The AAI technique produced outcomes that were equivalent to manual manipulation in this study. Since previous studies have revealed that manual manipulation is better than placebo, the AAI technique could also be considered better than placebo. (Hoiriis *et al.* 2004; Santilli, Beghi and Finucci 2006).
DISCUSSION:	In this study, the lack of comparability between participants at baseline (with regards to patient characteristics as well as conditions characteristics) and the many factors listed within the limitations of this study that were not included in the criteria for this study, reduces the external validity. The potentially disproportionate representation of the variables within the already small sample size, compromises the external validity (ability to extrapolate the results to patients in practice given the unclear composition of the groups). Thus, the patient to whom the intervention can be applied successfully as suggested by the author of the study is limited. This is compounded by the lack of blinding and lack of patient naivety in this study as well as a lack of a control group. The outcomes noted in this study need to be considered with caution and further investigations, with greater compliance to RCT protocols need to be carried out. A larger scale RCT should be carried out whilst addressing the pitfalls of this study. (Andrew *et al.* 1994). Long term follow-up consultation should be included in future studies of similar design as there is no evidence in this study of the long-term effects of each treatment intervention.
CONCLUSION:	Given in the outcomes of the reviewers table (Table 4.16) the internal validity of this study is shown as 7/11 with an 84.5% agreement between the reviewers implying that this study has good internal validity however the external validity is poor which is as a result of the limitations that are present in this study. Outcomes in this study are not necessarily as a direct result of the interventions used, other external factors may have influenced the outcomes, such as lack of homogeneity between the groups at baseline, small sample size, type two error acceptance and lack of a control group. The external validity of this study is poor. Thus, as a result, the level of evidence produced by this study in favour of the use of the AAI technique in the management of Acute on Chronic Sacroiliac Syndrome is limited.

Table 4. 18: Tabulated Feedback Data for RCT: Article 9

AUTHOR(S):	Wood, Colloca, Matthews					
YEAR:	2001					
TITLE:	A pilot randomized clinical trial on the relative effect of instrumental (MFMA) versus manual (HVLA) manipulation in the treatment of cervical spine dysfunction					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	Yes	Yes	Yes	Yes	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Yes	Yes	Yes	Yes	100%
3	Allocation was concealed	No	Yes	Yes	Yes	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	No	Yes	Yes	Yes	66%
5	There was blinding of all subjects	No	Yes	No	No	66%
6	There was blinding of all therapists who administered the therapy	No	No	No	No	100%
7	There was blinding of all assessors who measured at least one key outcome	No	No	No	No	100%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Yes	Yes	Yes	Yes	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	Yes	Yes	Yes	Yes	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Yes	Yes	Yes	Yes	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Yes	Yes	Yes	Yes	100%
	TOTAL SCORE	**6**	**9**	**8**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**90.7%**

Table 4. 19: Analysis of RCT: Article 9

AUTHOR(S):	Wood, Colloca, Matthews
YEAR:	2001
TITLE:	A pilot randomized clinical trial on the relative effect of instrumental (MFMA) versus manual (HVLA) manipulation in the treatment of cervical spine dysfunction

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
Numerical Pain Rating Scale – 101, McGill Short-Form Pain Questionnaire and NDI), Goniometer cervical range of motion.	Subjective and objective assessments were completed in this study at specific time intervals during the treatment period and at a 1-month follow-up.	Patients were treated until an asymptomatic status was achieved or a maximum of eight treatments were completed over a period of approximately four weeks.	30 participants.	The examiner was not blinded in this study.	Group one: received mechanical force, manually assisted manipulation (MFMA) to the cervical spine, delivered by the AAI. Group two (control group): received specific contact HVLA manipulation consisting of standard Diversified rotary/lateral break techniques to the cervical spine.	Each participant pulled a piece of paper from an envelope.	8	90.7%

LIMITATIONS:	This study was conducted at the Technikon Natal Chiropractic Day Clinic in South Africa. Participants were recruited through the use of advertising in local newspapers, on the radio and others were outpatients presenting to the clinic. Although this study was conducted at a Technikon, the age of participants was spread out between age groups and was not predominantly young participants. The age of participants was between 23 and 59 years old, hence results in this study are limited to apply to patients within this age group. The participants in this study were selected through the use of consecutive sampling, where age, sex, occupation and previous manipulative treatment were not taken into account. Whilst participants were not allowed to take medication for the duration of this study, there was no mention of a wash out period prior to the study, there was no medication diary during the study (measuring dosage, frequency or

	other changes) and there was also no information if participants continued with chronic medication (and whether these were homogenous between the groups). Whilst the groups were homogenous in factors such as age and sex; many other factors that were accounted for may have hindered the homogeneity of the groups in this study and therefore reduced the external validity of the study. (Corfman 1995; Kabisch *et al.* 2011). Trends within the participants (age, race, duration of pain, sex, level of dysfunction) could not be drawn on due to the small sample size. (Columb and Atkinson 2015; Ebrahim Valojerdi, Tanha and Janani 2017). In terms of the presenting condition amongst participants, there were many factors unaccounted for which is a limitation in this study as the homogeneity between participants in this study is poor and may have introduced bias into the outcomes noted. Systemic disease, cause of recent onset of pain or previous episodes of pain were not considered. Contributing factors that may have been impacting the participants and their presentation and symptoms were not accounted for, resulting in a group of participants which lacked homogeneity at baseline and therefore the outcomes may have been influenced and subjected to bias by these limitations. (Corfman 1995). Participants were not able to have had any manipulative therapy for one month prior to entering this study, this may result in a lack of patient naivety as some of the participants may have had exposure to chiropractic care and the different forms of interventions used. Patients as a result may have entered the study with a level of expectation which may have influenced the subjective findings. (Hariton and Locascio 2018). There is a balance of subjective and objective outcome measures used in this study. (Moustgaard *et al.* 2014; Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020). However, according to the authors (Wood, Colloca and Matthews 2001), the questionnaires used in this study may not have had the necessary sensitivity to detect subtle changes in the participants' pain and disability. According to the authors of this study, the goniometer also has concerns and limitations with sensitivity and may not have been sensitive enough to detect subtle changes in this study, as it is calibrated at increments of 2 degrees (Wood, Colloca and Matthews 2001). Randomisation of participants into two groups occurred, participants drew a slip of paper from an envelope which determined which group they were in. The examiner wasn't blinded in this study and performed the assessment, delivered the intervention, and took the measurement of outcomes. The level of blinding in this study is therefore compromised and bias is introduced into this study as a result of this. (Moustgaard *et al.* 2020). The outcomes noted in this study therefore need to be considered with caution as the outcomes may not only have measured the outcome of the intervention due to being influenced by biases such as the lack of blinding. (Krauss 2018; Moustgaard *et al.* 2020). The fact that the researcher was also a master's student at the time of the research, implying that he was a relative novice in patient assessment, re-enforces the concerns around the homogeneity of the participants with respect to the homogeneity of the cervical spine dysfunction that each participant presented with. (Corfman 1995; Nyberg and Russell Smith 2013; Chu *et al.* 2017). Palpation and examination for restrictions in the participants was conducted by the treating practitioner and no inter-examiner validation was conducted to confirm the diagnosis of each participant. Therefore, there is a risk that the initial diagnosis of participants may have been incorrect, and outcomes of this study would therefore be affected. (Nyberg and Russell Smith 2013; Chu *et al.* 2017). Statistical analysis was conducted in a two-tailed format with a 95% CI; the power of the test was then assessed at the 80% level (beta = 0.2). Intragroup data were analysed through the use of nonparametric Wilcoxon signed rank test and descriptive statistics for each test. (Vickers 2005). Inter group data were assessed through the use of nonparametric Mann-Whitney U test and descriptive statistics. According to the authors of this study, this study was underpowered and may have been subjected to a type two error which could be reduced by an increase in the sample size. (Wood, Colloca and Matthews 2001; Akobeng 2016; Mascha and Vetter 2018). This study had no control group, (Deaton and Cartwright 2018), there was no patient or practitioner blinding (Moustgaard *et al.* 2020), no documented control of naivety (Hariton and Locascio 2018), no indication if patients knew which group they were in (i.e. post intervention question) (Chaibi, Šaltytė Benth and Bjørn Russell 2015) and Hawthorne and Observer effects cannot be excluded (McCarney *et al.* 2007; Elston 2021). Therefore, it is suggested that the study outcomes may measure a component of this impact as compared to the impact of the intervention alone. It is important to note that the AMCT protocol was used, and it was not purely the AAI being used as an adjustment tool with a Diversified technique in this study. The use of the AMCT was mentioned briefly in this study but no information was given on how it was applied to this patient or incorporated into the assessment, measurement, and treatment.

OUTCOME:	The subjective data from all the questionnaires showed statistically significant changes from the initial to final consultations as well as from the initial consultation to the one month follow up and that both treatment methods acted with equal effectiveness ($p < 0.025$). The data from the NPRS-101 showed a 30% improvement from the initial to the final consultation for the MFMA group and 17.5% for the HVLA group. The results from the McGill questionnaires showed an improvement after the course of treatment of 24.4% for the MFMA group and 26% for the HVLA group. These median values were the same at the one-month follow-up. Power analysis of these subjective data showed a high statistical power for the intratreatment results, whereas the intertreatment results revealed a low statistical power. The objective ranges of motion that were measured in this study showed statistically significant changes in the MFMA group for left and right rotation and left and right lateral flexion from initial consultation to final consultation and for right rotation and right lateral flexion from initial consultation to one month follow-up. In comparison, the HVLA group showed only the change in left rotation from initial to final consultations and initial to one month follow-up to be statistically significant. Both groups showed clinically significant improvements however neither group produced outcomes that were more favourable over the other group.
DISCUSSION:	The lack of consideration of the variables within the already small sample size, compromises the external validity (ability to extrapolate the results to patients in practice given the unclear composition of the groups). Thus, the patient to whom the intervention can be applied successfully as suggested by the author of the study is limited. This is compounded by the lack of blinding and lack of patient naivety in this study. Although there is no placebo/sham control group to compare findings and results within this study, previous studies (Hoiriis *et al.* 2004; Santilli, Beghi and Finucci 2006) show that HVLA is more effective than placebo. Since the MFMA and HVLA group produced similar outcomes, it can be suggested than MFMA manipulation is better than placebo. These results still need to be used with caution due to the small sample size and many other limitations that reduce the external validity of this study. This study needs to be done on a larger scale and with a sham group for the results to be more conclusive. The outcomes of this study need to be considered with caution and a larger scale RCT should be carried out that addresses the pitfalls of this study.
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.18) the internal validity of the study is shown as 8/11 with a 90.7% agreement between reviewers. This indicates good internal validity. However, due to the limitations that this study presents with, such as small sample size, lack of blinding, poor consideration of influencing factors amongst participants and type two error acceptance, the external validity of this study is poor. There is a possibility that the outcomes of this study may have been influenced by external factors and may not be a direct result of the intervention used. The external validity of this study is considered as poor and therefore the level of evidence that this study produces in favour of the use of the AAI within the AMCT protocol in treating cervical spine dysfunction is limited.

Table 4. 20: Tabulated Feedback Data for RCT: Article 10

AUTHOR(S):	Yurkiw, Mior					
YEAR:	1996					
TITLE:	Comparison of two chiropractic techniques on pain and lateral flexion in neck pain patients: a pilot study					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	Yes	Yes	Yes	Yes	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	Yes	Yes	Yes	Yes	100%
3	Allocation was concealed	No	Yes	Yes	Yes	66%
4	The groups were similar at baseline regarding the most important prognostic indicators	Yes	Yes	Yes	Yes	100%
5	There was blinding of all subjects	No	Yes	Yes	Yes	66%
6	There was blinding of all therapists who administered the therapy	No	Yes	Yes	Yes	66%
7	There was blinding of all assessors who measured at least one key outcome	No	Yes	Yes	Yes	66%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	Yes	Yes	Yes	Yes	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	Yes	Yes	Yes	Yes	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	Yes	Yes	Yes	Yes	100%
11	The study provides both point measures and measures of variability for at least one key outcome	Yes	Yes	Yes	Yes	100%
	TOTAL SCORE	**7**	**11**	**11**	**11**	
		OVERALL PERCENTAGE AGREEMENT:				**87.6%**

Table 4. 21: Analysis of RCT: Article 10

AUTHOR(S):	Yurkiw, Mior
YEAR:	1996
TITLE:	Comparison of two chiropractic techniques on pain and lateral flexion in neck pain patients: 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**
VAS, cervical range of motion goniometer.	Pre- and post-intervention/treatment.	Subjects were selected from an active chiropractic practice over a period of six months.	14 participants.	Examiner was blinded in this study.	Group one: (control) received a manual adjustment using the diversified technique Group two: received an adjustment using the AAI within the AMCT protocol	A random numbers table was used.	11	87.6%

LIMITATIONS:	This study was carried out in Canada. There were fourteen participants included in this study between the age of twenty-one and fifty-five. The participants were selected from an active chiropractic practice, hence bias may have been introduced into the study and there is a risk that patients may have falsely reported on their reduction in pain in order to please the researcher which may have resulted in inflated outcomes noted in subjective outcomes in this study as a result of response bias or participation bias. (Mazor *et al.* 2002). The researcher assessed participants prior to inclusion into the study and also delivered the intervention to the participants. There was an examiner who recorded the outcome measurements in this study, however there is still a risk of the bias mentioned above. (Moustgaard *et al.* 2020). Whilst participants were excluded if they had received any SMT within ninety days prior to entering the study, these participants were existing patients of the treating practitioner resulting in a lack of patient naivety, and the outcomes may be influenced by this due to patient perception of prior care (Mazor *et al.* 2002; Thornton *et al.* 2017; Hariton and Locascio 2018). There is limited information given about the participants therefore the homogeneity between the participants and the two groups in this study is questionable. (Corfman 1995; Kabisch *et al.* 2011). Due to these limitations and the small sample size, the results cannot be generalised to the general population (Columb and Atkinson 2015). There is a possibility of the Hawthorne and Observer effects in this study which may have influenced the outcomes noted and therefore the outcomes may not be directly related to the intervention used in each group (McCarney *et al.* 2007; Elston 2021). Only unilateral subacute pain in the lower cervical spine was included in this study, from the level of C3 to C7, limiting the use of the outcomes from this study to this region of the spine with this complaint. There has been no consideration for ethnicity, age, gender, occupation, history of trauma, medication use, previous occurrences, factors associated with the presenting complaint or cause of recent onset of the pain. These factors reduce the homogeneity because

	of increased uncontrolled factors resulting in variance between the groups. The baseline homogeneity of patient characteristics and condition characteristics is lacking and therefore factors other than the interventions being used in this study may influence the outcomes noted. (Corfman 1995; Kabisch *et al.* 2011). This study was a pilot study to compare the effects of two different adjustment techniques commonly used by chiropractors. The sample size was small and the results were statistically insignificant (power less than 80% (Yurkiw and Mior 1996)), hence this pilot study should be used to guide future research studies with a larger sample size. There was a noted pre-test difference between the two groups in this study. According to the authors of this study, quasi-randomisation would have probably lowered the pre-test differences between the treatment groups in this study due to the small sample size. It is suggested in this study that a type two error is apparent. This could be eliminated by increasing the sample size in future studies. There is no placebo group or group receiving no treatment, which hinders the ability of the study to determine whether the outcomes are actually better than placebo and how they may impact the patient clinically (Deaton and Cartwright 2018). Objective and subjective outcome measures were recorded in this study, however due to the lack of patient naivety discussed above, the subjective outcomes may have been subjected to a level of bias (Moustgaard *et al.* 2014; Thornton *et al.* 2017; Hariton and Locascio 2018; Tempelaar, Rienties and Nguyen 2020). The adjustment was only delivered to the patients using the AAI in the prone position. Two types of diversified SMT procedures were used in this study for the group receiving manual adjustments - the seated cervical and the supine rotary cervical adjustments. This is not always the way a practitioner would treat a patient in clinical practice and therefore the results and outcomes of this study cannot be generalised to all patients. No other soft tissue work or home care was given to participants, it was merely the delivery of an adjustment – no intervention programme was utilised (Kaiser *et al.* 2018). It is important to note that the AMCT protocol was used, and it was not purely the AAI being used as an adjustment tool with a Diversified technique in this study. The use of the AMCT was mentioned briefly in this study but no information was given on how it was applied to this patient or incorporated into the assessment, measurement, and treatment.
OUTCOME:	No statistically significant differences were noted between the two group before and after the interventions. ANCOVA was performed and the probability (p value) with the ANCOVA of left lateral flexion is p= 0.835 and right lateral flexion p= 0.702. The pre-treatment VAS data were similar between the two groups, the unpaired t test comparing the pre/post changes between treatment groups was used and the difference between the groups was not statistically significant (p= 0.775). Both Diversified treatment as well as treatment with the AAI (within the AMCT protocol) reduced pain in the participants of each group and improved their cervical spine range of motion. The findings show a trend towards clinical improvement using either of the techniques in this study, however the differences between the results of each of the interventions used in this study, was not statistically significant. Since manual adjustments have been proven to be better than placebo (Hoiriis *et al.* 2004; Santilli, Beghi and Finucci 2006), this study shows that the use of the AAI within the AMCT protocol is also better than placebo since both groups had comparable outcomes in this study.
DISCUSSION:	In this study the extremely small sample size, the lack of comparability between participants at baseline and other limitations discussed above, reduces the external validity. The potentially disproportionate representation of the variables within the already small sample size, compromises the external validity (ability to extrapolate the results to patients in practice given the unclear composition of the groups). There is also a large amount of bias that is introduced into this study since the participants were existing patients prior to entering this study. Thus, the patient to whom the intervention can be applied successfully as suggested by the author of the study is limited. When considering options for adjustment techniques, when manual adjustment may not be suitable for the patient, the AAI seems to be an effective alternative to consider using for patients with cervical spine pain and reduced range of motion. Both groups in this study experienced pain reduction and improved range of motion in the cervical spine after treatment. Caution does need to be made when using this evidence as the sample size contained only 14 participants... Further research needs to be completed that contains a larger sample size and consideration to the limitations is given. (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022).

CONCLUSION:	Given the outcomes of the reviewers in the previous table (Table 4.20) the internal validity of the study is shown as 11/11 with a percentage agreement between reviewers of 87.6%. Whilst methodological rigour and internal validity is excellent and apparent in this study, the external validity is poor. Therefore, the level of evidence that this study produces in favour of the use of the AAI within the AMCT protocol in treating neck pain is limited. Larger scale research of this type needs to be completed in order to base treatment guidelines on it and be able to reliably draw conclusions from the results.

4.4.1.2 Summary of RCTs

Table 4. 22: Outcome and Methodological Ranking of Randomised Controlled Trials

Study Type:		**Randomised Controlled Trials**				
Author(s)	**Year:**	**Title:**	**Reviewer's Methodological Ranking**	**Internal Validity**	**External validity**	**Level of Evidence**
Coetzee	2013	The effect of the activator adjusting instrument in the treatment of chronic sacroiliac joint syndrome	9	Good	Poor	Limited
Gemmell, Jacobson	1995	The immediate effect of activator vs. meric adjustment on acute low back pain: a randomised controlled trial	8	Good	Poor	Limited
Gemmell, Miller	2010	Relative effectiveness and adverse effects of cervical manipulation, mobilisation and the activator instrument in patients with sub-acute non-specific neck pain: results from a stopped randomised trial	8	Good	Poor	No evidence
Gillespie	2003	The Effectiveness of Manual Manipulation versus the Activator Adjusting Instrument in the Management of Acute Facet Syndrome of the Lumbar Spine	7	Moderate	Poor	Limited
Gorrell, Beath, Engel	2016	Manual and Instrument Applied Cervical Manipulation for Mechanical Neck Pain: A Randomized Controlled Trial	8	Good	Poor	No evidence
Hardas, Murrell	2018	Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Trial Assessing the Effects of Applying a Force to C5 by a Mechanically Assisted Instrument on Referred Pain to the Shoulder	11	Excellent	Poor	Limited
Kendall, French, Hartvigsen , Azari	2018	Chiropractic treatment including instrument-assisted manipulation for non-specific dizziness and neck pain in community-dwelling older people: A feasibility randomised sham-controlled trial	11	Excellent	Poor	No evidence
Shearar	2003	The Relative Effectiveness of Manual Manipulation versus Manipulation using the "Activator Adjusting Instrument" in the Management of Acute on Chronic Sacroiliac Syndrome	7	Moderate	Poor	Limited
Wood, Colloca. Matthews	2001	A pilot randomized clinical trial on the relative effect of instrumental (MFMA) versus manual (HVLA) manipulation in the treatment of cervical spine dysfunction	8	Good	Poor	Limited
Yurkiw, Mior	1996	Comparison of two chiropractic techniques on pain and lateral flexion in neck pain patients: a pilot study	11	Excellent	Poor	Limited

4.4.2 Non-Randomised Controlled Trials

4.4.2.1 Tabulated feedback data and analysis of NRCTs

The Newcastle-Ottawa Scale (Wells *et al.* 2000) (Appendix F) was used to review the NRCTs in this systematic review. This scale is divided into three independent sections:

- Selection
- Comparability
- Exposure

Each of these sections has a particular number of criteria, for which a single star may be awarded. The exception is the comparability section where two stars may be awarded.

The maximum number of stars that may be awarded are:

- four stars for selection,
- two for comparability and
- three for exposure.

Therefore, a maximum of nine stars can be awarded per study.

For ease of reference and for data capturing:

- when two stars were awarded by a reviewer, it was recorded with a “2”.
- when one star was awarded by a reviewer, it was recorded with a “1”.
- when no star was awarded by a reviewer, it was recorded with a “0”.

The total for each reviewer was listed within the total score row. A mean score was then calculated for each criterion based on the majority ranking of the reviewers. The final total score calculated for each study, is derived from the majority score of the three reviewers, and not a mean calculation of the three individual reviewer total scores.

As with the RCTs, the percentage agreement was calculated for each individual criterion, to determine the degree of agreement between reviewers. Studies with a total percentage agreement of 100% indicates that the reviewers were all in total agreement regarding that specific criterion. A percentage agreement of 66% indicated that one of the three reviewers was not in agreement, and a percentage agreement of 33% indicated that none of the three reviewers agreed.

To complete the data for each study, the total percentage agreement for the NRCT indicates the overall level of agreement between reviewers for an individual study.

Table 4. 23: List of the table numbers for NRCTs

Tabulated feedback data:	**Analysis of article:**	**Author(s):**	**Year:**	**Title:**
Table 4.24	Table 4.25	Schneider, Brach, Irrgang, Abbott, Wisniewski, Delitto	2010	Mechanical vs Manual Manipulation for Low Back Pain: An Observational Cohort Study
Table 4.26	Table 4.27	Keller, Colloca	2000	Mechanical force spinal manipulation increases trunk muscle strength assessed by electromyography: A comparative clinical trial

Table 4. 24: Tabulated Feedback Data for NRCT: Article 1

AUTHOR(S):	Schneider, Brach, Irrgang, Abbott, Wisniewski, Delitto					
YEAR:	2010					
TITLE:	Mechanical vs Manual Manipulation for Low Back Pain: An Observational Cohort Study					
CRITERIA:[1]		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
Selection:	1. Is the case definition adequate?	1	1	1	1	100%
	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:[2]	5. Comparability of cohorts on the basis of design or analysis	1	1	1	1	100%
Exposure:	6. Ascertainment of exposure	0	1	1	1	66%
	7. Same method of ascertainment for cases and controls	1	1	1	1	100%
	8. Non-response rate	1	1	1	1	100%
	TOTAL SCORE	**4**	**5**	**5**	**5**	
		OVERALL PERCENTAGE AGREEMENT:				**95.8**

[1] For ease of reference, the eight criteria have been labelled one to eight in Section 4.4.2. This contrasts with the Newcastle-Ottawa Scale (Wells *et al.* 2000) which delineates the questions per criterion (viz. selection, comparability and exposure).

[2] This is the only criterion which has a two-point allocation.

Table 4. 25: Analysis of NRCT: Article 1

AUTHOR(S):	Schneider, Brach, Irrgang, Abbott, Wisniewski, Delitto
YEAR:	2010
TITLE:	Mechanical vs Manual Manipulation for Low Back Pain: An Observational Cohort 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**
NPRS and ODI scores. Treatment expectancy questionnaires were also completed by participants at baseline.	From baseline to four weeks.	Eight visits or four weeks.	92 participants.	No blinding.	Group one: manual manipulation. Group two: AAI manipulation.	No randomisation of participants. Participants self-selected their treatment and clinic of choice.	5	95.8%

LIMITATIONS:	Patients were recruited from three private chiropractic offices, two of which used manual lumbar manipulation and one used mechanical instrument manipulation (AAI) as their primary modes of treatment. The chiropractors used their 'treatment as usual" protocols for a maximum of eight visits or four weeks, whichever occurred first. Participants decided which treatment intervention they would like to receive based on personal preference. Each practitioner assessed, treated and assessed outcomes in participants that they had treated. There is a lack of control of variables and a lack of blinding of both the participants and the practitioners in this study. (Karanicolas, Farrokhyar and Bhandari 2010). There were four treating practitioners in this study. This study involves subjective input from each practitioner as well as clinical judgement and skillset of each practitioner that is involved in this study, due to the practitioner assessing the participant and then delivering the treatment to the level, he/she identified. (Nyberg and Russell Smith 2013). A level of standardisation or training prior to beginning this study would have limited variability between each practitioner's technique and methods and would allow for more standardisation between the clinics and less impact of variables on the outcomes. Subjective outcomes would have been influenced in this study due to patient perception, patient expectation and patient satisfaction with the treatment and its anticipated outcome. (Thornton *et al.* 2017). Comparison of baseline patient characteristics between groups showed a difference in age and treatment expectancy between the groups. Whilst many factors were considered, some factors that were not considered include parity, occupation, previous trauma, level of activity, previous occurrences, cause of recent onset on pain, sleeping positions and ergonomics that may affect low back pain were not considered in this study, all of which could have been relevant in acute low back pain patients. This reduces the homogeneity between the treatment groups and exposes the outcomes to bias, this compromises the outcomes as a direct measure of the intervention. (Corfman 1995). The inclusion criteria in this study specified a range for the NPRS and ODI scores at the beginning of the study, this was to exclude patients with extremely high or low NPRS or ODI scores to avoid ceiling of floor effects in this study, thus improving the homogeneity between participants and improving the ability to compare groups. (Bruce *et al.* 2013; Lim *et al.* 2015).

	Whilst this study had ninety-two participants included, the power analysis revealed that fifty participants per group were required to achieve an 80% power at an alpha level of 0.05. Since the sample size used in this study was smaller than suggested through the power analysis, this study may have a type two error which has been accepted. A fully powered study should be carried out with a larger sample size in order to improve the strength of the statistical analysis and produce reliable findings. (Columb and Atkinson 2015). The participants were not merely treated with an adjustment, myofascial complaints were also treated, and home care advice was given to participants (i.e. a programme of intervention), therefore the results of the study would not have been able to measure the activator treatment directly. (Kaiser *et al.* 2018). The design had limitations in this study as no external constraints were placed on the clinicians in terms of their treatment protocols; this resulted in big variations in treatment frequency, application of adjunctive therapies and other clinical activities. The time spent during doctor-patient interaction or total time spent during each office visit was not documented and therefore attention bias may be a confounder in the results of this study. It is noted in this study that without having a good estimate of treatment effect size in advance, it was hard to power this study appropriately. (Schneider *et al.* 2010) Since there was no blinding whatsoever in this study, a risk of the Hawthorne and Observer effects was introduced into the study (McCarney *et al.* 2007; Elston 2021). The outcome measures were only subjective, therefore the impact of a lack of naivety as well as a lack of blinding and patient perception of care / treatment expectancy would have potentially played significant roles in the outcomes of the study. (Thornton *et al.* 2017). It is important to note that the AMCT protocol was used, and it was not purely the AAI being used as an adjustment tool with a Diversified technique in this study. The use of the AMCT was mentioned briefly in this study but no information was given on how it was applied to this patient or incorporated into the assessment, measurement, and treatment.
OUTCOME:	The Activator patients had more application of electrical muscle stimulation, laser therapy, intersegmental traction (roller) table, and posture education. The manual manipulation patients had significantly more applications of heat/ice packs. There was a significant difference between the 2 cohorts with respect to the number of patients in each group that required the maximum number of treatment sessions (8 visits): 70% in the Activator group compared with only 15% in the manual manipulation group. 78% of the Activator patients continued with additional chiropractic care after study termination, whereas only 18% in the manual manipulation groups received additional chiropractic treatment. The mean number of visits at 4 weeks also was significantly different between the 2 cohorts, with the Activator group having a mean of 9.2 visits as compared with the manual manipulation group mean of 4.5 visits. Comparison of baseline characteristics did not show any significant differences between the groups except for age (38.4 vs 49.7 years, $p< 0.001$) and treatment expectancy (5.7 vs 6.3, $p= 0.003$). Linear regression revealed significantly lower NPRS scores in the manual manipulation group at 4 weeks ($\beta = -1.2$; 95% confidence interval, −2.1 to −.28) but no significant difference in ODI scores between the two groups at 4 weeks ($\beta = 1.5$; 95% confidence interval, −8.3 to 2.4). Treatment expectancy, but not age, was found to have a significant main effect on both NPRS and ODI scores at 4 weeks. Exploratory analysis of the clinical patterns of care between the clinicians revealed significant differences in treatment frequency, duration, modality, and radiograph use between the two cohorts.
DISCUSSION:	In this study, the lack of comparability between participants at baseline reduces the external validity. The sample size used was not large enough when considering the power analysis that was conducted and the risk of a type two error is accepted in this study. The potentially disproportionate representation of the variables within the already small sample size, compromises the external validity (ability to extrapolate the results to patients in practice given the unclear composition of the groups). Since a programme of intervention was used in this study, one cannot link outcomes to a particular intervention. Thus, the patient to whom the intervention can be applied successfully as suggested by the author of the study is limited. This study also has no form of blinding of any of the individuals involved, resulting in possible biases and therefore influences on the outcomes of this study. The outcomes of this study need to be considered with caution due to the poor external validity of this study. A fully powered RCT should be carried out that addresses the pitfalls and limitations of this study (Andrew *et al.* 1994).
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.24) the internal validity of the study is shown as 5/9 with a 95.8% agreement between reviewers, which indicates a moderate level of internal validity. However, in the context of the limitations that presented in the study, there is a significant argument that the outcomes were not necessarily only as a result of the intervention and were affected by issues of sample size, type two error acceptance, the use of a programme of intervention and then also the lack of homogeneity of the sample groups. Therefore, the external validity is considered poor. Thus, there is no evidence in favour or against the use of the AAI within the AMCT protocol in treating low back pain, indicating that further research is required.

Table 4. 26: Tabulated Feedback Data for NRCT: Article 2

AUTHOR(S):	Keller, Colloca					
YEAR:	2000					
TITLE:	Mechanical force spinal manipulation increases trunk muscle strength assessed by electromyography: A comparative clinical trial					
CRITERIA:[3]		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
Selection:	1. Is the case definition adequate?	0	0	0	0	100%
	2. Representativeness of the cases	1	1	1	1	100%
	3. Selection of controls	1	1	1	1	100%
	4. Definition of controls	1	1	1	1	100%
Comparability:[4]	5. Comparability of cohorts on the basis of design or analysis	2	1	2	2	66%
Exposure:	6. Ascertainment of exposure	1	1	1	1	100%
	7. Same method of ascertainment for cases and controls	1	1	1	1	100%
	8. Non-response rate	1	1	1	1	100%
	TOTAL SCORE	**8**	**7**	**8**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**95.8%**

[3] For ease of reference, the eight criteria have been labelled one to eight in Section 4.4.2. This contrasts with the Newcastle-Ottawa Scale (Wells *et al.* 2000) which delineates the questions per criterion (viz. selection, comparability and exposure).
[4] This is the only criterion which has a two-point allocation.

Table 4. 27: Analysis of NRCT: Article 2

AUTHOR(S):	Keller, Colloca
YEAR:	2000
TITLE:	Mechanical force spinal manipulation increases trunk muscle strength assessed by electromyography: A comparative 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**
History and health status questionnaire, sEMG, MVC, AMCT assessment and adjustment, stiffness assessment, algometry assessment.	Pre-treatment and post-treatment.	Not stated.	40 participants.	No blinding.	One active treatment group (n = 20, MFMA SMT) and two control groups (one receiving sham-MFMA SMT n = 10, and one receiving no SMT treatment n = 10).	No. Subjects were assigned to the sham-SMT and control groups in such a way that age and sex were uniformly stratified with respect to the active SMT treatment group.	8	95.8%

LIMITATIONS:	This study was conducted at an outpatient clinic in Phoenix, Arizona. Since participants who had previously had SMT were excluded from this study, it is likely that these participants were not existing patients. The subjective findings that were reported on in this study, are at risk of response or participation bias (Mazor *et al.* 2002). Since many objective outcomes were measured in this study, any biases (related to patient expectation, patient satisfaction with the treatment and its anticipated outcome, response or participation bias, Hawthorne or Observer effect) that would have been introduced to subjective outcomes were balanced by the objective findings. (McCarney *et al.* 2007; Thornton *et al.* 2017; Elston 2021). The sample size consisted of a total of forty participants. Patients were excluded if they were pregnant, had previous surgery to the lumbar spinal region, presented with any contraindication to SMT, presented with any significant symptoms unrelated to lumbar complaints. Patients with combined low back and referred or radicular pain in the buttock, thigh or leg were included in this study, affecting the homogeneity between the groups as not all patients had the same baseline characteristics with regards to their presenting condition. The activity levels of daily life of each participant were not considered in the participants in this study. Considering the participants had active involvement (through contracting muscle group), this should have been an important consideration in this study (due to stiffness, muscle gain, change in muscle activity due to other causes). Other factors such as ethnicity, occupation, medication use, previous pregnancy, previous occurrences, cause of recent onset of pain and previous trauma were not considered, affecting the homogeneity between groups which may influence the outcomes measured in this study due to an increase in uncontrolled factors resulting in variance between the groups. This compromises the outcomes as a direct measure of the intervention. The baseline homogeneity of patient characteristics and condition characteristics is lacking and therefore factors other than the interventions being used in this study may influence the outcomes noted. (Corfman 1995; Kabisch *et al.* 2011). In favour of the homogeneity between the groups, age and sex were

	uniformly stratified across the groups. (Hill 2000). All participants in this study presented with low back pain, had not consulted a physician or therapist in the six months prior to the study for low back or leg pain and had not received SMT prior to participation in this study, therefore participants in this study were naïve to treatment. The outcomes of this study cannot be applied to the general population and can only be considered with similar patients. (Corfman 1995). The sample size was small in this study and there is no mention of a power analysis. The authors did suggest that a larger sample size is required in future research studies similar in nature. The possibility of a type two error cannot be eliminated indicating that the results may have an error in conclusion and this therefore effects the external validity of the study. (Akobeng 2016). There is also a lack of blinding which introduces a level of bias into the study. The researcher was the assessor for entry into the study, the person that completed the assessment and applied the intervention and took measurements. Therefore, the level of blinding in this study is compromised with respect to the assessor, therapist and measurements assessor being blinded (Moustgaard *et al.* 2020). The outcomes noted in this study therefore need to be considered with caution as the outcomes may not only have measured the outcome of the intervention due to being influenced by biases such as the lack of blinding. (Krauss 2018; Moustgaard *et al.* 2020). The SMT treatment group received chiropractic adjustments to the thoracolumbar spine, sacrum and pelvis through MFMA SMT after being assessed using the AMCT protocol. The sham-SMT group received the same protocol as the SMT treatment group however a sham-MT thrust was delivered during the AMCT protocol (the AAI was set to zero). The control group was assessed using the AMCT protocol however no SMT intervention or sham-SMT intervention was given. The sham-SMT and control groups were examined approximately eighteen months after the SMT treatment group, however it is noted in this study that identical procedures were still followed and in the same clinical setting. The AMCT protocol was used, and it was not purely the AAI being used as an adjustment tool with a Diversified technique in this study.
OUTCOME:	Nineteen of the twenty participants in the SMT treatment group showed a positive increase in sEMG output during MVC after the active MFMA SMT treatment and stiffness assessment. This study demonstrated that MFMA SMT results in a significant increase in the sEMG of the erector spinae isometric MVC muscle output. The SMT treatment group had a significant ($p < 0.001$) increase in the erector spinae muscle sEMG output (21% increase in comparison with pre-SMT levels) during MVC isometric trunk extension trials. There were no significant changes in pre-SMT vs post-SMT MVC sEMG output in the sham-SMT group (5.8%) or control group (3.9%) in this study. The sEMG output ratio in the treatment group was significantly greater than the sham-SMT group or the control group. These findings indicate that altered muscle function may be a potential short-term therapeutic effect of MFMA SMT.
DISCUSSION:	The lack of comparability and homogeneity between participants' condition and characteristics, the lack of blinding of the examiner, the small sample size, reduces the external validity of the results of this study and the relationship between the intervention and the outcomes of this study may have been influenced by many factors. The outcomes may not be a direct result of the interventions used in this study. Thus, although this study reports to have achieved statistically and clinically significant findings, these need to be considered with caution and further investigations and a large scale RCT should be carried out whilst addressing the pitfalls of this study (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022).
CONCLUSION:	Given that the outcomes of the reviewers in the previous table (Table 4.26) the internal validity of this study is shown as 8/9 with a percentage agreement between reviewers of 95.8%. The internal validity of this study is moderate. However, due to the limitations of this study discussed above, the external validity is poor. Therefore, the level of evidence that this study produces in favour of the AAI within the AMCT technique to increase trunk muscle strength is limited.

4.4.2.2 Summary of NRCTs

Table 4. 28: Outcome and Methodological Ranking of Non-Randomised Controlled Trials

Study Type:	**Non-Randomised Controlled Trials**					
Author(s)	**Year:**	**Title:**	**Reviewer's Methodological Ranking**	**Internal Validity**	**External Validity**	**Level of Evidence**
Schneider, Brach, Irrgang, Abbott, Wisniewski, Delitto	2010	Mechanical vs Manual Manipulation for Low Back Pain: An Observational Cohort Study	5	Moderate	Poor	No evidence
Keller, Colloca	2000	Mechanical force spinal manipulation increases trunk muscle strength assessed by electromyography: A comparative clinical trial	8	Good	Poor	Limited

4.4.3 Observational studies and case studies/case reports

4.4.3.1 Tabulated feedback data and analysis of Observational studies and case studies/case reports

Observational studies and case studies/case reports in this systematic review were reviewed using the Liddle Scale (Liddle, Williamson and Irwig 1996) (Appendix G). This scale has eleven criteria which each can be given one of five different responses by the reviewer (viz. “A”, “B1”, “B2” and “C” or “I”). These responses are outlined below for ease of reference when reviewing the reviewer tables. Additionally, “n/a” could be chosen, or in the event that the criterion was not applicable, or the criterion was not adequately described to classify as “A”, “B1”, “B2” or “C”, then “I” could be selected.

Table 4. 29: List of table numbers for Observational studies and case studies/case reports

Tabulated feedback data:	**Analysis of article:**	**Author(s):**	**Year:**	**Title:**
Table 4.30	Table 4.31	DeVocht, Pickar, Wilder	2004	Spinal Manipulation Alters Electromyographic Activity of Paraspinal Muscles: A Descriptive Study
Table 4.32	Table 4.33	Norton, Callanan	2013	Reduction in Symptoms Associated with Parkinsons Disease Subsequent to Subluxation-Based Chiropractic Care: A Case Study
Table 4.34	Table 4.35	Osterbauer, De Boer, Widmaier, Petermann, Fuhr	1993	Treatment and biomechanical assessment of patients with chronic sacroiliac joint syndrome
Table 4.36	Table 4.37	Polkinghorn	1998	Treatment of cervical disc protrusions via instrumental chiropractic adjustment
Table 4.38	Table 4.39	Polkinghorn	1998	Treatment of symptomatic lumbar disc herniation using activator methods chiropractic technique
Table 4.40	Table 4.41	Polkinghorn	1999	Chiropractic treatment of coccygodynia via instrumental adjusting procedures using activator methods chiropractic technique
Table 4.42	Table 4.43	Polkinghorn	2001	Chiropractic treatment of postsurgical neck syndrome with mechanical force, manually assisted short-lever spinal adjustments
Table 4.44	Table 4.45	Roberts, Wolfe	2009	Chiropractic care of a 6-year-old girl with neck pain; headaches; hand, leg, and foot pain; and other nonmusculoskeletal symptoms
Table 4.46	Table 4.47	Roberts, Wolfe	2012	Chiropractic spinal manipulative therapy for a geriatric patient with low back pain and comorbidities of cancer, compression fractures, and osteoporosis
Table 4.48	Table 4.49	Roberts, Wolfe	2012	Chiropractic management of a veteran with lower back pain associated with diffuse idiopathic skeletal hypertrophy and degenerative disk disease
Table 4.50	Table 4.51	Russell, Kimura, Cowie, de Groot, McMinn, Sherson	2016	Changes in Quality of Life in 7 Older Adult Patients Receiving Activator Methods Chiropractic Technique

Given the above list of case studies and case series, it is important to consider generic limitations for these studies before the details of each of the studies are specifically scrutinised. Many case studies tend to lack in one or more of the following:

1. Patient specific data may be lacking, which makes it difficult for the reader to be able to identify the population group best matched to the outcomes obtained or the data is limited to a highly specific occupation, leisure activity or age group (Crowe *et al.* 2011).
2. Clarity of treatment intervention may be poor as they tend to include a multitude of treatments or a treatment programme (usually reflecting clinical practice) that does not allow for the identification of one particular intervention as being the catalyst for patient improvement or regression (Winters *et al.* 2013).
3. Reported measurements of outcome measures tend to be done on an ad hoc basis and not with regular consistency as would be expected in a higher level structured study (Tierney and Stewart 2004).
4. Documentation of the clinical interaction between the patient and the doctor may be absent yet would be required in a clinical trial (NRCT and RCT).
5. Reports on issues of researcher/practitioner bias, patient naivety and other related biases may be lacking (Onwuegbuzie and Frels 2016).

The above generic limitations result in the lack of ability to accurately replicate these studies to confirm the attained outcomes. Having stated the above, case reports and case series may present interesting outcomes, ideas or trends that warrant further investigation (Winters *et al.* 2013), particularly in areas where little research has been done in the form of RCTs or NRCTs which are usually the basis for developing guidelines for practice and health care payment schemes (Andrews *et al.* 2013).

Table 4. 30: Tabulated Feedback Data for Observational Studies and case studies/case reports: Article 1

AUTHOR(S):	DeVocht, Pickar, Wilder					
YEAR:	2004					
TITLE:	Spinal Manipulation Alters Electromyographic Activity of Paraspinal Muscles: A Descriptive Study					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Are the study participants well-defined in terms of time, place and person?	A	B1	B1	B1	66%
2	What percentage of individuals refused to participate?	A	A	A	A	100%
3	Are outcomes measured in a standard, valid and reliable way?	A	B1	A	A	66%
4	Are outcomes measured in the same way for both intervention and control groups?	A	n/a	A	A	66%
5	Are factors other than intervention comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?	B2	n/a	B2	B2	66%
6	What percentage of individuals recruited into the study are not included in the analysis?	A	A	A	A	100%
7	Is the analysis by intention to intervene (treat)?	n/a	n/a	n/a	n/a	100%
8	Are results homogenous between sites?	A	A	A	A	100%
9	How well was the study done to minimise bias?	B1	B1	B1	B1	100%
10	Is the overall effect of the study due to the study intervention?	B1	B1	B1	B1	100%
11	Explain if there is any practical/ethical reason why an RCT cannot be done?	n/a	B1	n/a	n/a	66%
	TOTAL SCORE	A:6 B1:2 B2:1 C:0 I:0 n/a:2	A:3 B1:5 B2:0 C:0 I:0 n/a:3	A:5 B1:3 B2:1 C:0 I:0 n/a:2	**A:5** **B1:3** **B2:1** **C:0** **I:0** **n/a:2**	
		OVERALL PERCENTAGE AGREEMENT:				**84.5%**

Table 4. 31: Analysis of Observational Studies and case studies/case reports: Article 1

AUTHOR(S):	DeVocht, Pickar, Wilder
YEAR:	2004
TITLE:	Spinal Manipulation Alters Electromyographic Activity of Paraspinal Muscles: A Descriptive 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
sEMG	During the five to ten minutes of the treatment protocol.	One treatment session with each participant.	16 participants.	No blinding.	No control.	No randomisation.	A: 5 B1: 3 B2: 1 C: 0 I: 0 n/a: 2	84.5%

LIMITATIONS:	Participants in this study were recruited from existing chiropractic offices of two local chiropractors who served as the treating clinicians in this study. Participants with low back pain were identified for this study as they would most likely have tight paraspinal muscles in either the lumbar or lower thoracic region. (DeVocht, Pickar and Wilder 2004). Since participants in this study were approached by the treating practitioner directly, no advertising was done, this introduces a level of selection bias into the study. (Boutron *et al.* 2019). It is unclear if both chiropractic offices had access to similar patients. The two groups in this study may lack homogeneity as factors within each group's participants were not considered. There was no mention of ethnicity, age, medication use, occupation, daily activity level, pain level, parity, previous treatment or previous trauma. With these factors not being considered, there is a lack of baseline homogeneity between the two groups at the starting point of this study and therefore the outcomes of the groups cannot reliably be compared. Manual palpation was done by the treating practitioner of each group to determine where the greatest paraspinal tension was in the participants and this is where the electrodes were placed. This may have affected the results in this study and may affect the reproducibility and reliability of the results in this study due to subjective involvement of the treating practitioner in this study. (Nyberg and Russell Smith 2013). In this study, participants were treated at two chiropractic offices, this introduces variable between offices and between the treating practitioners. Factors such as demeanour, patient contact time, and patient naivety may differ between the groups due to different interactions between the two groups and offices. (Hariton and Locascio 2018). Additionally, there is a possibility of the Hawthorne and Observer effects in this study which may have influenced the outcomes noted and therefore the outcomes may not be directly related to the intervention used in each group (McCarney *et al.* 2007; Elston 2021). Since this was an observation-based study, participants in this study were treated by the clinicians in a "normal manner of treatment", no effort was made to control or standardise the adjustments or treatments in any way. (DeVocht, Pickar and Wilder 2004). The sample size was small and there was no power analysis completed. There was no control group in this study, therefore one cannot solely ascribe the observed changes and results to treatment response as they could be due to other factors such as patient relaxation due to prone positioning (Campanini *et al.* 2020). Due to the abrupt nature of the decreases in

	the sEMG readings it is suggested that at least some of the changes were in direct response to treatment. With a control group, this could be verified. Since only sEMG was used as an outcome measure in this study, there is no measurement or consideration of pain levels or other objective measurements in this study. whilst there is a lack of patient naivety in this study, there are no subjective outcome measures utilised in this study, therefore the bias introduced by this lack of patient naivety is negated. (Thornton *et al.* 2017). Due to this study design, there is a lack of a control group and lack of control of many variables which may influence the outcomes. The fact that the researcher was the assessor for entry into the study, the person that applied the activator (or treatment) and took measurements, the level of blinding in this study is potentially compromised. As a result, the bias introduced by this lack of blinding questions whether the outcomes do indeed measure the actual intervention or only a component of it. (Moustgaard *et al.* 2020). There was an inability to compare across participants in this study as a result of two separate issues: two methods were used to collect EMG data (raw and RMS) and EMG levels were not normalised to some constant standard. The recording system used in this study had memory limitations and was only capable of recording raw EMG for short periods of time. (DeVocht, Pickar and Wilder 2004). Therefore, the ability to compare outcomes between the two groups is limited. It is important to note that the AMCT protocol has been used. The use of AMCT was mentioned briefly in this case study but no information was given on how it was applied to the patients or incorporated into the assessment, measurement, and treatment. This does mean that the AAI was used within the AMCT protocol in this study and not just as an adjusting tool/instrument.
OUTCOME:	Amongst the participants, sEMG activity decreased by at least 25% after treatment was received in twenty-four of the thirty-one sites that were monitored in this study. There was less than 25% change at three sites and more than 25% increase at four sites. Data collected from the eight participants receiving AAI adjustments showed that out of the fifteen sites monitored by sEMG, eleven decreased 25% or more, three increased by less than 25% and one increased more than 25%. In the diversified group, of the sixteen sites monitored by sEMG, thirteen decreased 25% or more and three increased by more than 25%. Multiple distinct increases and decreases were observed in many data plots. In some cases, the sEMG activity increased during the treatment protocol and then usually, but not always, decreased to a level lower than the pre-treatment level, in both groups. Where the paraspinal muscles are tight to palpation, the surface sEMG tends to be higher than other muscles that are not tight. It is suggested that the presence of a tight muscle bundle is functionally associated with a spinal dysfunction that needs to be adjusted and corrected through SMT, therefore the tight muscle bundle and the associated higher sEMG level would diminish after SMT is given to the patient. The results of this study show that there is an initial rise in the sEMG level as treatment is delivered, this is thought to be reflexive in nature. The sEMG levels then tend to decrease to be lower than pre-treatment levels in the paraspinal muscles in both groups, at rest. Adjustments induce a virtually immediate change, usually a reduction in resting sEMG level in at least some patients with low back pain and tight paraspinal muscle bundles. Both activator and diversified adjustments reduced the resting sEMG activity in most of the participants in this study. Tight muscle bundles are associated with low back pain and this study supports the suggestion that they can be alleviated through SMT, either using the diversified technique or using the AAI within the AMCT protocol however further research is needed.
DISCUSSION:	Given that this is an observational study, it is more pragmatic and reflective of clinical practice. In this study, the lack of comparability between participants at baseline reduces the external validity. There are a small number of participants involved in this study and the lack of baseline homogeneity between the two groups reduces the reliability of the results of this study. Since two practitioners treated participants in this study, there was no control group, there was a lack of blinding of participants and lack of control of variables in this study – the external validity of this study is poor which maybe factors possibly influencing the outcomes of this study. The relationship between sEMG, adjustments and back pain also needs further investigation through powered RCTs (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022).

CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.30), this study was able to fulfil a majority of the applicable criteria in the Liddle Scale (Liddle, Williamson and Irwig 1996). Whilst the internal validity of this study was good and with a low-risk of bias, the external validity of this study was poor as a result of the limitations noted. Therefore, the results of this study are subject to a degree of bias and this study has poor external validity. This implies that the outcomes are not necessarily reproducible. As a result, the study conclusions must be seen with caution regarding the influence of bias. Therefore, at best, this particular study provides limited evidence in support of the AAI being used within the AMCT protocol in clinical practice and that further studies in this particular area are warranted to validate the outcomes and provide further information regarding the relationship between sEMG, adjustments and back pain whilst comparing the two forms of adjustments used in this study (AAI within the AMCT and Diversified).

Table 4. 32: Tabulated Feedback Data for Observational Studies and case studies/case reports: Article 2

AUTHOR(S):	Norton, Callanan					
YEAR:	2013					
TITLE:	Reduction in Symptoms Associated with Parkinsons Disease Subsequent to Subluxation-Based Chiropractic Care: A Case Study					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Are the study participants well-defined in terms of time, place and person?	B1	B1	B1	B1	100%
2	What percentage of individuals refused to participate?	A	n/a	n/a	n/a	66%
3	Are outcomes measured in a standard, valid and reliable way?	B1	B2	B2	B2	66%
4	Are outcomes measured in the same way for both intervention and control groups?	n/a	n/a	n/a	n/a	100%
5	Are factors other than intervention comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?	n/a	C	n/a	n/a	66%
6	What percentage of individuals recruited into the study are not included in the analysis?	A	n/a	n/a	n/a	66%
7	Is the analysis by intention to intervene (treat)?	n/a	n/a	n/a	n/a	100%
8	Are results homogenous between sites?	n/a	n/a	n/a	n/a	100%
9	How well was the study done to minimise bias?	B2	C	C	C	66%
10	Is the overall effect of the study due to the study intervention?	C	C	C	C	100%
11	Explain if there is any practical/ethical reason why an RCT cannot be done?	C	C	n/a	C	66%
	TOTAL SCORE	A:2 B1:2 B2:1 C:2 I:0 n/a:4	A:0 B1:1 B2:1 C:4 I:0 n/a:5	A:0 B1:1 B2:1 C:2 I:0 n/a:7	**A:0** **B1:1** **B2:1** **C:3** **I:0** **n/a:6**	
		OVERALL PERCENTAGE AGREEMENT:				**81.5%**

Table 4. 33: Analysis of Observational Studies and case studies/case reports: Article 2

AUTHOR(S):	Norton, Callanan
YEAR:	2013
TITLE:	Reduction in Symptoms Associated with Parkinson's Disease Subsequent to Subluxation-Based Chiropractic Care: A Case 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
Range of motion, thermography, sEMG, subjective report from the patient of improvement in tremors, fatigue, mobility, rigidity, and neck pain/stiffness and low back pain.	Initial examination and again after sixty days.	Four months.	1 participant.	No blinding.	No control.	No randomisation.	A: 0 B1: 1 B2: 1 C: 3 I: 0 n/a: 6	81.5%

LIMITATIONS:	This study included a single participant (n = 1), therefore the sample size in this study was small. Sample size and therefore the use of inferential statistics is limited in a case study, as there is only one participant. This also results in the lack of generalisable data as the outcomes are only likely to be similar to the case study patient. (Columb and Atkinson 2015). The participant presented to a private practice for chiropractic care. This study treated a single, 68-year-old, female participant with Parkinson's disease, neck stiffness/pain radiating into the left arm and low back pain which began 3 years prior, after a motor-vehicle accident. The results of this study are therefore limited to in clinical practice to apply to patients with this diagnosis of Parkinson's disease and with a similar case history and presentation of symptoms in clinical practice. It does not allow for generalisation to a larger population and limits the interferential statistics that could have been applied. A radiograph was taken of the cervical spine of the patient prior to any intervention was given. The findings revealed degenerative joint disease at certain levels as well as disc narrowing and intervertebral osteochondrosis. These findings and diagnoses may have had an impact on the results in this study. The patient in this study was seen twice per week for sixty days and thereafter was reassessed and adjustments to the care plan were made. This study does have a balance of subjective and objective measurements therefore providing a balance of outcome measures. (Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020). The AMCT protocol was used in this study, not just the AAI adjustment technique. Prone leg length observation, stress, pressure, and isolation tests were conducted on the participant in order to detect all subluxations. The patient started using Sinemet, the concurrent treatments utilizing prescription drugs and chiropractic care is a limitation to this study as one cannot determine if the outcomes noted are as a direct result of the intervention or if they have been influenced by the use of medication. The participant did relay that she noted a decrease in the frequency of tremors prior to beginning the medication though, thus not negating the effectiveness of chiropractic care in reducing the motor symptoms associated with Parkinson's disease, however the outcomes need to be considered with caution as the medication may have influenced the findings noted.

	Postural exercises were given to the participant to improve neck mobility, no specificity, or details of what was given to the participant for home care or additional care were given. This introduces variables that were uncontrolled in this study. A programme of intervention was used in this study; therefore, the results of this study would not have been able to measure the use of the AAI within the AMCT protocol directly as the participant was performing exercises at home that would have impacted the outcomes of this study. (Kaiser *et al.* 2018). Due to this study design, with it being an observational study, there is a lack of a control group, lack of patient naivety and lack of control of many variables which may influence the outcomes (Deaton and Cartwright 2018; Hariton and Locascio 2018). There is a lack of blinding of the examiner and assessor which may influence the outcomes noted, as the treating practitioner performed these tasks too (Karanicolas, Farrokhyar and Bhandari 2010).
OUTCOME:	The participant noted a decrease in hand tremors and improved flexibility in her cervical spine. She reported a reduction in her low back pain and an increase in energy levels. Range of motion improved significantly in cervical extension, right and left lateral flexion and right rotation. Lumbar range of motion also increased significantly in flexion, extension and left lateral flexion. Thermal asymmetry (thermography) was reduced as well as muscle hypertonicity (sEMG).
DISCUSSION:	Given that this is an observational study, it is more pragmatic and reflective of clinical practice. There are factors and limitations in this study that affect the validity and reliability of the outcomes of this study, and it cannot be concluded that the results and outcomes of this study can be applied similarly to all people who are diagnosed with Parkinson's disease. Although this study, with all its limitations, showed a good, favourable outcome for the use of the AAI within the AMCT protocol for reducing symptoms associated with Parkinson's disease, it cannot be used to determine the efficacy of this intervention as this intervention was not used alone in this study. A programme of intervention was used, and the study structure was poor. If there was a better understanding of the parameters that were used in this study, it would be beneficial to conduct a RCT with a bigger sample size and with the use of a control group (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022).
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.32), this study was not able to fulfil or describe a majority of the applicable criteria in the Liddle Scale (Liddle, Williamson and Irwig 1996). The internal validity of this study was poor and with a high risk of bias, the external validity of this study was poor as a result of the limitations noted. Therefore, the results of this study are subject to a degree of bias and this study has poor external validity. This implies that the outcomes are not necessarily reproducible. As a result, the study conclusions must be seen with caution regarding the influence of bias. Therefore, this particular study provides no evidence in support of the AAI being used within the AMCT protocol to reduce symptoms associated with Parkinson's disease in clinical practice. Further studies in this particular area are needed in order to validate the outcomes and provide further information regarding the relationship between adjustments using the AAI within the AMCT protocol and reduction of symptoms associated with Parkinson's disease. The findings in this study need to be accepted with caution and further testing in the form of a RCT designed study. It needs to be considered that this treatment may not be beneficial when this study is reproduced with a bigger sample size that has an increased homogenous group.

Table 4. 34: Tabulated Feedback Data for Observational Studies and case studies/case reports: Article 3

AUTHOR(S):	Osterbauer, De Boer, Widmaier, Petermann, Fuhr					
YEAR:	1993					
TITLE:	Treatment and biomechanical assessment of patients with chronic sacroiliac joint syndrome					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Are the study participants well-defined in terms of time, place and person?	B1	B2	B1	B1	66%
2	What percentage of individuals refused to participate?	A	A	A	A	100%
3	Are outcomes measured in a standard, valid and reliable way?	B2	B2	B2	B2	100%
4	Are outcomes measured in the same way for both intervention and control groups?	n/a	n/a	n/a	n/a	100%
5	Are factors other than intervention comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?	n/a	n/a	n/a	n/a	100%
6	What percentage of individuals recruited into the study are not included in the analysis?	B1	B2	B2	B2	66%
7	Is the analysis by intention to intervene (treat)?	n/a	n/a	n/a	n/a	100%
8	Are results homogenous between sites?	n/a	n/a	n/a	n/a	100%
9	How well was the study done to minimise bias?	B2	B2	B2	B2	100%
10	Is the overall effect of the study due to the study intervention?	C	C	C	C	100%
11	Explain if there is any practical/ethical reason why an RCT cannot be done?	C	n/a	n/a	n/a	66%
	TOTAL SCORE	A:1 B1:2 B2:2 C:2 I:0 n/a:4	A:1 B1:0 B2:4 C:1 I:0 n/a:5	A:1 B1:1 B2:3 C:1 I:0 n/a:5	**A:1** **B1:1** **B2:3** **C:1** **I:0** **n/a:5**	
		OVERALL PERCENTAGE AGREEMENT:				**90.7%**

Table 4. 35: Analysis of Observational Studies and case studies/case reports: Article 3

AUTHOR(S):	Osterbauer, De Boer, Widmaier, Petermann, Fuhr
YEAR:	1993
TITLE:	Treatment and biomechanical assessment of patients with chronic sacroiliac joint syndrome

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, Oswestry disability index, lumbar provocation tests, biomechanical measures of gait and postural sway.	Prior to intervention, end of treatment, one year follow up.	One week baseline, five weeks of intervention, with a one year follow up.	10 participants.	No blinding.	No control.	No randomisation.	A: 1 B1: 1 B2: 3 C: 1 I: 0 n/a: 5	90.7%

LIMITATIONS:	The participants were selected in a private practice. Ten out of one hundred and fifty-three consecutive new patients with “primary”, chronic, uncomplicated sacroiliac joint syndrome were selected over an eleven-month period on the basis of painful SIJ and provocation tests. There is therefore a risk of selection bias in this study as the researcher selected the ten specific participants. (Boutron *et al.* 2019). Participants were paid at the end of the study for their participation. This may have resulted in inflated reporting of outcome measures (subjective). (Mazor *et al.* 2002; Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020). The participants lack homogeneity at baseline, many factors were unaccounted for in this study. Factors such as age, occupation, previous trauma/surgery, medication use, parity, ethnicity, previous occurrences, or previous treatment were not considered, and this affects the baseline homogeneity of the participants involved in this study. As a result, there is difficulty relating the intervention to the outcomes noted as there are many factors that may have influenced the outcomes. (Corfman 1995). The participants in this study were all diagnosed with sacroiliac pain syndrome and were in the dysfunction (phase I) stage according to the classification of Kirkaldy-Willis (Kettler *et al.* 2011; Suri *et al.* 2011). The pain was chronic in nature, persisting for six months or more prior to the study. This restricts the applicability of the evidence produced by this study to patients with a similar description in clinical practice. (Corfman 1995). This also serves as a limitation in this study as there is a risk for an incorrect diagnosis being given to a participant which would affect the outcomes of this study. The risk of this is low as the researchers are experienced and not novice researchers (Chu *et al.* 2017), yet there was no inter-examiner validation completed in this study to ensure validation of correct diagnosis. Participants were also found to have secondary problems, associated or concomitant to the sacroiliac pain syndrome, such as facet syndrome. Finding a participant with “pure” sacroiliac pain syndrome is difficult (Barros, McGrath and Gelfenbeyn 2019; Newman, McLean and Scozzafava 2020). As a result of this, the outcomes noted in this study were influenced as not all participants would have had the same secondary problems

	and the outcomes may be skewed as a result of this as each participant would have responded differently to treatment depending on what secondary complaints they presented with. Therefore, one cannot determine the direct impact of the intervention on chronic sacroiliac joint syndrome. The sample size of this study was only ten participants (n = 10), therefore one cannot apply these outcomes to the general population as there is limited information and outcomes to draw trends from resulting in a lack of power in the estimates and a high variability. When using a larger sample size, the power is improved and the risk of an error is reduced. Due to this study design, with it being an observational study, there is a lack of a control group, lack of patient naivety and lack of control of many variables which may influence the outcomes (Deaton and Cartwright 2018; Hariton and Locascio 2018). There is a lack of blinding of the examiner and assessor which may influence the outcomes noted, as the treating practitioner performed these tasks too (Karanicolas, Farrokhyar and Bhandari 2010). As a result of this there is a risk of the Hawthorne and Observer effects which may have impacted the subjective results noted in this study. (McCarney *et al.* 2007; Moustgaard *et al.* 2014; Thornton *et al.* 2017; Tempelaar, Rienties and Nguyen 2020; Elston 2021). Assessment for the spinal regions or levels to be adjusted and treatment of these areas followed the AMCT protocol. There is not much detail given in this study as to the exact tests performed on the participants in order to locate the spinal regions or levels needing to be adjusted, therefore it is unclear if the exact protocol was followed or if any deviations to the protocol were carried out. The adjustments were delivered using the AAI within the AMCT protocol. A one year follow up questionnaire was done with the participants in this study to assess the long-term results and stability of their symptoms, however only six of the ten participants participated in this questionnaire at the one year follow up period and the information received from this questionnaire may not be reliable due to the elapsed time between intervention and feedback, participants may have problems with memory recall. (Kessels 2003). There is also a risk of natural history influencing these findings. There was no record of use of a diary by participants of medication use or change, stress levels, work habits, trauma or significant incidences within the one-year period.
OUTCOME:	Pain in participants decreased significantly in this study. The VAS score declined more than 40% in seven of the ten participants. The mean pain on the VAS scale reduced from a starting value of twenty-five for the first two visits to an average of twelve at the last two visits. The average disability scores and the number of positive provocation tests also diminished significantly. The Oswestry index decreased by at least 50% in six patients, from an average value of 28% to 13%. Gait and sway parameters were indistinguishable from normal, before and after treatment. At the one year follow up a questionnaire was done, which revealed a low-level stability of symptoms in the participants.
DISCUSSION:	Most chiropractors believe that they can successfully diagnose and treat sacroiliac joint syndrome as a discrete biomechanical category of low back pain. Difficulty stems from the inability to clearly isolate it from other factors, such as facet syndrome or disc lesions in a patient as patients may have a combination of complaints and symptoms and this may influence findings in this study. Orthopaedic tests were done on the participants in this study to diagnose sacroiliac joint syndrome prior to intervention and participation commenced, however the participants may have had secondary diagnoses and complaints. Participants were assessed and treated using the AAI within the AMCT protocol and their pain levels were reduced, and function was improved. The AAI was used to deliver adjustment to these participants and significant reduction in their chronic low back pain has been noted in this study. This study does not describe the AMCT protocol, it purely makes mention that it was used, independent examiners were not used, and pre- and post-intervention measures lacked in reliability and validity and results were mostly based on subjective findings. Pain and disability reduced in the participants in this study suffering from chronic sacroiliac joint syndrome after receiving adjustments with an AAI within the AMCT protocol. The findings in this study need to be accepted with caution and further testing in the form of a RCT designed study (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022). It needs to be considered that this treatment may not be beneficial when this study is reproduced with a bigger sample size that has an increased homogenous group. Given that this is an observational study, it is more pragmatic and reflective of clinical practice. There are factors and limitations in this study that affect the validity and reliability of the outcomes of this study, and it cannot be concluded that the results and outcomes of this study can be applied similarly to all people who are diagnosed with chronic sacroiliac joint syndrome. Although this study, with all its limitations, showed a good, favourable outcome for the use of the AAI within the AMCT protocol for reducing symptoms associated with chronic sacroiliac joint syndrome, it cannot be used to determine the efficacy of this intervention due to limitations of this study such as small sample size, lack of control and lack of blinding in this study.

CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.34), this study was not able to fulfil or describe a majority of the applicable criteria in the Liddle Scale (Liddle, Williamson and Irwig 1996).The internal validity of this study was poor and with a moderate to high- risk of bias. The external validity of this study was poor as a result of the limitations noted. Therefore, the results of this study are subject to a degree of bias due to poor internal and external validity. This implies that the outcomes are not necessarily reproducible. As a result, the study conclusions must be seen with caution regarding the influence of bias and lack of rigour and reliability. Therefore, this particular study provides no evidence in support of the AAI being used within the AMCT protocol to treat chronic sacroiliac joint syndrome in clinical practice. Further studies in this particular area are needed in order to validate the outcomes and provide further information regarding the relationship between adjustments using the AAI within the AMCT protocol and chronic sacroiliac joint syndrome in patients. The findings in this study need to be accepted with caution and further testing in the form of a RCT designed study is needed.

Table 4. 36: Tabulated Feedback Data for Observational Studies and case studies/case reports: Article 4

AUTHOR(S):	Polkinghorn					
YEAR:	1998					
TITLE:	Treatment of cervical disc protrusions via instrumental chiropractic adjustment					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Are the study participants well-defined in terms of time, place and person?	A	B1	A	A	66%
2	What percentage of individuals refused to participate?	n/a	A	n/a	n/a	66%
3	Are outcomes measured in a standard, valid and reliable way?	C	B2	C	C	66%
4	Are outcomes measured in the same way for both intervention and control groups?	n/a	n/a	n/a	n/a	100%
5	Are factors other than intervention comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?	C	n/a	n/a	n/a	66%
6	What percentage of individuals recruited into the study are not included in the analysis?	n/a	A	n/a	n/a	66%
7	Is the analysis by intention to intervene (treat)?	n/a	n/a	n/a	n/a	100%
8	Are results homogenous between sites?	n/a	n/a	n/a	n/a	100%
9	How well was the study done to minimise bias?	C	B2	C	C	66%
10	Is the overall effect of the study due to the study intervention?	C	C	C	C	100%
11	Explain if there is any practical/ethical reason why an RCT cannot be done?	n/a	C	n/a	n/a	66%
	TOTAL SCORE	A:1 B1:0 B2:0 C:4 I:0 n/a:6	A:2 B1:1 B2:2 C:2 I:0 n/a:4	A:1 B1:0 B2:0 C:3 I:0 n/a:7	**A:1** **B1:0** **B2:0** **C:3** **I:0** **n/a:7**	
		OVERALL PERCENTAGE AGREEMENT:				**78.4%**

Table 4. 37: Analysis of Observational Studies and case studies/case reports: Article 4

AUTHOR(S):	Polkinghorn
YEAR:	1998
TITLE:	Treatment of cervical disc protrusions via instrumental chiropractic adjustment

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**
AMCT (neurological isolation testing), pain reduction (no form of measurement mentioned).	Not stated.	Not stated.	1 participant.	No blinding.	No control.	No randomisation.	A: 1 B1: 0 B2: 0 C: 3 I: 0 n/a: 7	78.4%

LIMITATIONS:	This study included a single participant (n = 1), therefore the sample size in this study was small. Sample size and therefore the use of inferential statistics is limited in a case study, as there is only one participant. This also results in the lack of generalisable data as the outcomes are only likely to be similar to the case study patient. (Columb and Atkinson 2015). This is a case study discussed a single patient who suffered from post-traumatic cervical syndrome with multiple protrusions of cervical intervertebral discs after an automobile accident. The participant was a forty-two-year-old woman and suffered with acute neck and arm pain after traumatic injury sustained in an automobile accident. Radiological examination revealed a complete reversal of the cervical lordosis and magnetic resonance imaging of the cervical spine revealed intervertebral disc protrusions, ranging in size from one to four millimetres and four sperate segmental levels in the cervical spine. This limits the use of this evidence in clinical practice to patients with a similar complaint and injury, therefore the results of this study cannot be applied to the general population. (Corfman 1995; Columb and Atkinson 2015). The mechanism of injury is not described in this study in terms of force and vectors involved in the automobile accident. Factors that may have influenced the outcomes of this study were not considered such as medication use and natural progression and reduction of pain with elapsed time. One therefore cannot determine if the outcomes measures were in fact as a direct result of the intervention used. Along with this, it was not a standalone intervention used with this participant. The researcher does not give much information of how the adjunctive therapeutic procedures (cervical support, hot pack, electric stimulation, active range of motion exercises) were used and incorporated into this patient's rehabilitation and treatment in the form of a programme of intervention. This affects reproducibility and validity of this study, and one cannot conclude that the outcomes are directly related to the adjustments delivered with the AAI within the AMCT protocol as there were others forms of intervention incorporated in the care of this participant. (Kaiser *et al.* 2018).

	Subjective and objective measurements were incorporated into this study however, there is no clarity in this study of the exact assessment used or forms of measurement used, making this study hard to reproduce. The participant had previous chiropractic care and therefore there is a lack of patient naivety. Subjective outcomes may have been influenced by this as well as patient perception, patient expectation and patient satisfaction with the treatment and its anticipated outcome. (Thornton *et al.* 2017). The participant received manual adjustments within the first two weeks after the automobile accident. Her symptoms were aggravated by the manual adjustments within the first two weeks. However, she changed practitioners, starting treatment with the practitioner who completed this case report and it is reported her symptoms improved with instrument assisted manipulation. (Polkinghorn 1998). This may not have been directly related to the technique used (manual vs instrument). This may have been due to the acute nature of the injury initially (at the time when she received manual adjustments) that it did not improve but rather was aggravated initially with the manual treatment. By the time she started treatment with this practitioner providing adjustments with the AAI within the AMCT protocol, the acute nature of the injury had possibly subsided, and improvements were noted. Therefore, the improvement may be related to natural progression and improvement of symptoms over time. The causal relationships in this study need to be considered as her improvement in symptoms may perhaps be due to duration post-accident versus type of adjustment given (manual vs instrument assisted (AAI within the AMCT protocol)). (Galer *et al.* 2000). No consideration was given to the psychological state of the patient either, this may have also improved over time after the accident and influenced the subjective outcomes. The use of the AMCT protocol was mentioned briefly in this study but no information was given on how it was applied to this patient or incorporated into the assessment, measurement, and treatment or if any deviations from the protocol were made. This does mean that the AAI was used within the AMCT protocol in this study and not just as an adjusting tool/instrument. Only the neck and upper back was adjusted in this study using the AAI within the AMCT protocol. Due to this study design, with it being an observational study, there is a lack of a control group and lack of control of many variables which may influence the outcomes. Since there is no control, there is no comparison to analyse in this case report and there are no comparative intervention groups to compare findings and outcomes with. Therefore, it is unclear if the outcomes would be the same when carried out with a larger sample size. (Deaton and Cartwright 2018). There is a lack of blinding of examiners and assessors which may influence the outcomes noted as the treated practitioner performed these tasks too. (Karanicolas, Farrokhyar and Bhandari 2010).
OUTCOME:	The participant was treated three times per week, with a gradual reduction in frequency of treatment as her condition improved. Improvement was seen within the first week of AAI adjusting. Improvement in neck and arm pain was exhibited in the participant since starting treatment with an AAI within the AMCT protocol.
DISCUSSION:	The participant initially received manual chiropractic adjustments which resulted in an increase in her symptoms. Thereafter she started receiving treatment from a chiropractor using the AAI within the AMCT protocol to adjust the neck and upper back and she experienced a complete reduction in her presenting symptoms. This needs to be considered with caution as the improvement in her symptoms may have been related to elapsed time after the injury rather than the type of intervention used (as discussed in the limitations above). (Galer *et al.* 2000). Given that this is an observational study, it is more pragmatic and reflective of clinical practice. There are factors and limitations in this study that affect the validity and reliability of the outcomes of this study, and it cannot be concluded that the results and outcomes of this study can be applied similarly to all people with similar presentation to the participant in this study. The findings suggest that the use of the AAI within the AMCT protocol provides an alternative method to deliver adjustments when a manual adjustment is not relieving symptoms or is contraindicated. The relationship between the improvement of the participant's symptoms and the type of intervention used is unclear as natural history may have influenced the findings considering the acute nature of her injury with the initial treating practitioner using manual adjustments. One cannot conclude that the AAI within the AMCT protocol was more effective than manual adjustments with this participant in this study due to the many limitations noted, such as small sample size, programme of intervention, lack of control and lack of blinding in this study. There are many factors that may have influenced the outcomes and therefore one cannot conclude that the intervention alone was responsible for the outcomes noted in this study and therefore the findings are not reproducible and need to be considered with caution.

	The findings in this study need to be accepted with caution and further testing in the form of a RCT designed study needs to be carried out. (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022). It needs to be considered that this treatment may not be beneficial when this study is reproduced with a bigger sample size that has an increased homogenous group.
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.36), few of the applicable criteria in the Liddle Scale (Liddle, Williamson and Irwig 1996) were fulfilled resulting in a high-risk of bias in this study. As a result of the limitations noted above, the external validity of this study is poor and therefore this study provides no evidence in support of the used of the AAI within the AMCT protocol for the treatment of cervical disc protrusions in patients. The outcomes are not necessarily reproducible or reliable or as a direct result of the intervention used, therefore the conclusions of this study must be considered with caution. Further studies in this particular area are needed in order to validate the outcomes and provide further information regarding the relationship between adjustments using the AAI within the AMCT protocol and reduction of symptoms associated with cervical disc protrusions.

Table 4. 38: Tabulated Feedback Data for Observational Studies and case studies/case reports: Article 5

AUTHOR(S):	Polkinghorn					
YEAR:	1998					
TITLE:	Treatment of symptomatic lumbar disc herniation using activator methods chiropractic technique					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Are the study participants well-defined in terms of time, place and person?	B1	A	A	A	66%
2	What percentage of individuals refused to participate?	A	n/a	n/a	n/a	66%
3	Are outcomes measured in a standard, valid and reliable way?	B2	B1	B2	B2	66%
4	Are outcomes measured in the same way for both intervention and control groups?	n/a	n/a	n/a	n/a	100%
5	Are factors other than intervention comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?	n/a	C	n/a	n/a	66%
6	What percentage of individuals recruited into the study are not included in the analysis?	A	n/a	n/a	n/a	66%
7	Is the analysis by intention to intervene (treat)?	n/a	n/a	n/a	n/a	100%
8	Are results homogenous between sites?	n/a	n/a	n/a	n/a	100%
9	How well was the study done to minimise bias?	B2	C	C	C	66%
10	Is the overall effect of the study due to the study intervention?	C	C	C	C	100%
11	Explain if there is any practical/ethical reason why an RCT cannot be done?	C	n/a	n/a	n/a	66%
	TOTAL SCORE	A:2 B1:1 B2:2 C:2 I:0 n/a:4	A:1 B1:1 B2:0 C:3 I:0 n/a:6	A:1 B1:0 B2:1 C:2 I:0 n/a:7	**A:1** **B1:0** **B2:1** **C:2** **I:0** **n/a:7**	
		OVERALL PERCENTAGE AGREEMENT:				**78.4%**

Table 4. 39: Analysis of Observational Studies and case studies/case reports: Article 5

AUTHOR(S):	Polkinghorn
YEAR:	1998
TITLE:	Treatment of symptomatic lumbar disc herniation using activator methods chiropractic technique

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
AMCT, Pain levels reported by patient, muscle strength testing	Pre-treatment, after four weeks of treatment and after a further eight weeks of treatment. A one year follow up was done.	Twelve weeks of treatment and a one-year follow-up.	One.	No blinding	No control.	No randomisation.	A: 1 B1: 0 B2: 1 C: 2 I: 0 n/a: 7	78.4%

LIMITATIONS:	This study included a single participant (n = 1), therefore the sample size in this study was small. Sample size and therefore the use of inferential statistics is limited in a case study, as there is only one participant. This also results in the lack of generalisable data as the outcomes are only likely to be similar to the case study patient. (Columb and Atkinson 2015). This study discussed the case of a twenty-six-year-old male patient with a posttraumatic athletic injury resulting in symptomatic lumbar disc herniation of 2 years duration. He suffered from a multi-symptom complex composed of low back pain, left groin pain, left leg pain, left foot drop, and associated muscle weakness and atrophy. This limits the use of intervention in clinical practice to patients with a similar complaints and injuries. The results of this study cannot be applied to the general population due to the fact that this study observed a single participant. (Corfman 1995; Columb and Atkinson 2015). Since there is no control or other participants in this study, there is no comparison to analyse in this case report and no intervention to compare between groups as you would see in a clinical trial. This is purely a report based on a patient treated, stating observations and procedures used. Factors that may have influenced the outcomes of this study were not considered such as mechanism of injury in terms of force and vectors, medication use, level of activity, aggravating or relieving factors. No therapeutic intervention other than MFMA spinal adjustments with an AAI according to AMCT protocol were utilised in the management of this case. Subjective outcomes may have been influenced by patient perception, patient expectation and patient satisfaction with the treatment and its anticipated outcome. Subjective and objective measurements were both incorporated into this study, balancing the risk of bias introduced by only utilising only subjective outcomes. (Thornton *et al.* 2017). No medical or diagnostic imaging, tests or scans were completed at the end of this patient's treatment to assess the discs and the low back (in order to compare findings with imaging done prior to this study). One year after this study was completed, the participant returned for chiropractic care for a different complaint. He noted positive changes and outcomes of his previous care. This may be unreliable outcome measures as the patient may not accurately recall the pain and symptoms he was experiencing an entire year prior to this (Kessels 2003).

	The AAI was used within the AMCT protocol in this study with the evaluation of the participant utilizing isolation testing procedures. It was noted that no deviations to the AMCT protocol were carried out in this study. (Osterbauer, Fuhr and Keller 1995). Due to this study design, with it being an observational study, there is a lack of a control group and a lack of control of many variables which may influence the outcomes. (Deaton and Cartwright 2018). There is a lack of blinding of the examiner and assessor which may influence the outcomes noted as the treating practitioner performed these tasks too.
OUTCOME:	The patient received adjustments with an AAI within the AMCT protocol and responded favourably, with his multi-symptom complex being resolved within ninety days of beginning treatment. Four weeks into treatment the patient noted reduction in chronic symptoms in all areas, left leg pain and paraesthesia had completely resolved and the ipsilateral foot drop was much improved. The low back pain was mild and a dull ache in nature, no sharp pain was noted. The left groin pain had subsided and had become intermittent and mild and there was no "twitching" or "catching" in the groin anymore. Twelve weeks into treatment the patient had essentially recovered. He noted no low back pain, left groin pain or left leg pain. All positive objective findings had diminished. There was still slight residual weakness in the left foot but no apparent foot drop as experienced previously at the beginning of treatment. Muscle strength had returned to the left leg and slight residual atrophy was noted in left thigh and calf at this point. No residuals or recurrences of his low back problems were noted at the one-year follow-up, there was complete resolution of the residual atrophy of the left leg.
DISCUSSION:	A manual adjustment of the lumbar spine often involves a torsional stress onto the discs of the lumbar spine whereas adjusting with an AAI avoids this stress on the discs. Therefore, in patients with disc injuries or pathologies, the use of the AAI in delivering adjustments is often used in clinical practice. Using the AAI to deliver an adjustment allows for a controlled force to be delivered to a very specific location/joint. It cannot be concluded that the results and outcomes of this study can be applied similarly to all people with similar presentation to the participant in this study. The findings suggest that the use of the AAI within the AMCT protocol provides an alternative method to deliver adjustments when a manual adjustment is not relieving symptoms or is contraindicated. However, since this study only includes a single participant, the mechanism of injury is poorly described, there is a lack of a control group and blinding in this type of study, the efficacy of the intervention cannot be determined. Although this study, with all its limitations, showed a good, favourable outcome for the use of the AAI within the AMCT protocol for reducing symptoms associated with lumbar disc herniations, these findings cannot be applied to the general population and a larger scale study needs to be conducted. (Andrew *et al.* 1994). It needs to be considered that this treatment may not be beneficial when this study is reproduced with a bigger sample size that has an increased homogenous group. The findings in this study also need to be used with caution as there are many variables that were not controlled in this study. it is important to note that the AAI was used within the AMCT protocol in this study and not just as an adjusting tool/instrument.
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.38), few of the applicable criteria in the Liddle Scale (Liddle, Williamson and Irwig 1996) were fulfilled resulting in a moderate to high-risk of bias in this study. As a result of the limitations noted above, the external validity of this study is poor and therefore this study provides no evidence in support of the used of the AAI within the AMCT protocol for the treatment of lumbar disc herniations in patients. The outcomes are not necessarily reproducible or reliable, therefore the conclusions of this study must be considered with caution. Further studies in this particular area are needed in order to validate the outcomes and provide further information regarding the relationship between adjustments using the AAI within the AMCT protocol and reduction of symptoms associated with lumbar disc herniations.

Table 4. 40: Tabulated Feedback Data for Observational Studies and case studies/case reports: Article 6

AUTHOR(S):	Polkinghorn					
YEAR:	1999					
TITLE:	Chiropractic treatment of coccygodynia via instrumental adjusting procedures using activator methods chiropractic technique					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Are the study participants well-defined in terms of time, place and person?	A	B1	A	A	66%
2	What percentage of individuals refused to participate?	n/a	A	n/a	n/a	66%
3	Are outcomes measured in a standard, valid and reliable way?	B2	B2	B2	B2	100%
4	Are outcomes measured in the same way for both intervention and control groups?	n/a	n/a	n/a	n/a	100%
5	Are factors other than intervention comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?	C	n/a	n/a	n/a	66%
6	What percentage of individuals recruited into the study are not included in the analysis?	n/a	A	n/a	n/a	66%
7	Is the analysis by intention to intervene (treat)?	n/a	n/a	n/a	n/a	100%
8	Are results homogenous between sites?	n/a	n/a	n/a	n/a	100%
9	How well was the study done to minimise bias?	B2	B2	B2	B2	100%
10	Is the overall effect of the study due to the study intervention?	B2	C	B2	B2	66%
11	Explain if there is any practical/ethical reason why an RCT cannot be done?	n/a	C	n/a	n/a	66%
	TOTAL SCORE	A:1 B1:0 B2:3 C:1 I:0 n/a:6	A:2 B1:1 B2:2 C:2 I:0 n/a:4	A:1 B1:0 B2:3 C:0 I:0 n/a:7	**A:1** **B1:0** **B2:3** **C:0** **I:0** **n/a:7**	
		OVERALL PERCENTAGE AGREEMENT:				**81.5%**

Table 4. 41: Analysis of Observational Studies and case studies/case reports: Article 6

AUTHOR(S):	Polkinghorn
YEAR:	1999
TITLE:	Chiropractic treatment of coccygodynia via instrumental adjusting procedures using activator methods chiropractic technique

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
AMCT, pain levels reported by patient.	Patient was reassessed at each consult.	3.5 weeks with a follow up at three months.	One participant.	No blinding.	No control.	No randomisation.	A: 1 B1: 0 B2: 3 C: 0 I: 0 n/a: 7	81.5%

LIMITATIONS:	This study included a single participant (n = 1), who suffered from acute coccygodynia. This study discussed a twenty-nine-year-old female who was referred by her supervisor for chiropractic evaluation and treatment regarding coccygeal pain that had begun three weeks prior after moving heavy boxes during the course of her employment. The participant is an administrator and is not used to heavy lifting. Several days after moving boxes she experienced a dull ache in her 'tailbone', punctuated by episodes of intermittent sharp pain. The pain was aggravated whilst sitting and was worse when rising from a seated position to a standing position. The pain was worsening and was rated a seven to eight out of ten by the participant. The participant had no previous occurrences of this pain. She had taken medication for the pain, without any relief. Sample size and therefore the use of inferential statistics is limited in a case study, as there is only one participant. This also results in the lack of generalisable data as the outcomes are only likely to be similar to the case study patient. (Columb and Atkinson 2015). This limits the use of this evidence in clinical practice to patients with a similar presentation whilst the findings of this study cannot be applied to the general population. Since there is no control or other participants in this study, there is no comparison to analyse in this case report and no intervention to compare between groups as you would see in a clinical trial. This is purely a report based on a patient treated, stating observations and procedures used. Factors that may have influenced the outcomes of this study were not considered such as medication use, previous pregnancy, previous injuries, level of activity, secondary complaints, natural progression, and reduction of pain with elapsed time. One therefore cannot determine if the outcomes measures were in fact as a direct result of the intervention used. No therapeutic intervention other than spinal adjustments with an AAI according to AMCT protocol were utilised in the management of this case. (Kaiser *et al.* 2018). The use of the AMCT protocol is mentioned in this case study and was used in the evaluation of the patient to determine where adjustments needed to be delivered and in what direction. This means the AAI was used within the AMCT protocol in this study and not just as an adjusting tool/ instrument and it was used without any deviation from the protocol. (Fuhr, Colloca and Green 1997). The AMCT protocol was used in this case study to determine the areas needing

	to be adjusted and how to direct these adjustments. Prone leg length observation, stress, pressure, and isolation tests were conducted on the participant in order to detect all spinal regions and levels needing to be adjusted. The AMCT protocol was also used as a measurement tool in this study to assess outcome measures. Whilst both subjective and objective measurement tools were included in this study, only leg length and pain intensity were considered. Subjective outcomes may have been influenced by this as well as patient perception, patient expectation and patient satisfaction with the treatment and its anticipated outcome. (Thornton *et al.* 2017). Due to this study design, with it being an observational study, there is a lack of a control group and lack of control of many variables which may influence the outcomes. (Deaton and Cartwright 2018)There is a lack of blinding of examiners and assessors which may influence the outcomes noted as the treated practitioner performed these tasks too.
OUTCOME:	The patient presented with pain that was a continual dull ache in the coccygeal region. It has been present for three weeks in duration, beginning after lifting heavy boxes. There is acute intermittent sharp pain rated a seven or eight out of ten by the participant, particularly when sitting or rising from a seated position. After one single treatment session, the patient had complete resolution of her pain after being adjusted using the AAI in the coccygeal region after being assessed with the AMCT protocol. She continued with chiropractic care and was seen eight more times over a three-and-a-half-week period, with neuromechanical evidence of coccygeal involvement noted at each visit, although her subjectively she was asymptomatic. On the eleventh visit she was asymptomatic with no objective findings. Three months after treatment, a follow-up revealed that she had no coccygeal pain since the treatment.
DISCUSSION:	Delivering an adjustment to the coccygeal region of an individual can be done internally or externally. The AAI is an option to use when considering an external coccygeal adjustment and it is well tolerated over internal adjustments (Patel, Appannagari and Whang 2008). Although this study, with all its limitations, showed a good, favourable outcome for the use of the AAI within the AMCT protocol for reducing symptoms associated with coccygodynia, it cannot be used to determine the efficacy of this intervention due to limitations of this study such as small sample size, lack of control and lack of blinding in this study (Karanicolas, Farrokhyar and Bhandari 2010; Columb and Atkinson 2015). These limitations may have influenced the outcomes of this study which reduces the external validity of this study and therefore one cannot conclude that the intervention alone was responsible for the outcomes noted in this study and therefore the findings need to be considered with caution. Further testing in the form of a RCT designed study needs to be carried out. (Andrew *et al.* 1994; Qureshi, Gough and Loudon 2022). It needs to be considered that this treatment may not be beneficial when this study is reproduced with a bigger sample size that has an increased homogenous group.
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.40), this study was not able to fulfil or describe majority of the applicable criteria in the Liddle Scale (Liddle, Williamson and Irwig 1996). The internal validity of this study was poor and with a moderate to high- risk of bias. The external validity of this study was poor as a result of the limitations noted. Therefore, the results of this study are subject to a degree of bias due to poor internal and external validity. This implies that the outcomes are not necessarily reproducible. As a result, the study conclusions must be seen with caution regarding the influence of bias. Therefore, this particular study provides no evidence in support of the AAI being used within the AMCT protocol to treat coccygodynia in clinical practice. Further studies in this particular area are needed in order to validate the outcomes and provide further information regarding the relationship between adjustments using the AAI within the AMCT protocol and coccygodynia. The findings in this study need to be accepted with caution and further testing in the form of a RCT designed study is needed.

Table 4. 42: Tabulated Feedback Data for Observational Studies and case studies/case reports: Article 7

AUTHOR(S):	Polkinghorn					
YEAR:	2001					
TITLE:	Chiropractic treatment of postsurgical neck syndrome with mechanical force, manually assisted short-lever spinal adjustments					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Are the study participants well-defined in terms of time, place and person?	B1	A	B1	B1	66%
2	What percentage of individuals refused to participate?	A	n/a	n/a	n/a	66%
3	Are outcomes measured in a standard, valid and reliable way?	B2	C	C	C	66%
4	Are outcomes measured in the same way for both intervention and control groups?	n/a	n/a	n/a	n/a	100%
5	Are factors other than intervention comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?	n/a	C	n/a	n/a	66%
6	What percentage of individuals recruited into the study are not included in the analysis?	A	n/a	n/a	n/a	66%
7	Is the analysis by intention to intervene (treat)?	n/a	n/a	n/a	n/a	100%
8	Are results homogenous between sites?	n/a	n/a	n/a	n/a	100%
9	How well was the study done to minimise bias?	B2	C	C	C	66%
10	Is the overall effect of the study due to the study intervention?	C	C	C	C	100%
11	Explain if there is any practical/ethical reason why an RCT cannot be done?	C	n/a	n/a	n/a	66%
	TOTAL SCORE	A:2 B1:1 B2:2 C:2 I:0 n/a:4	A:1 B1:0 B2:0 C:4 I:0 n/a:6	A:0 B1:1 B2:0 C:3 I:0 n/a:7	**A:0** **B1:1** **B2:0** **C:3** **I:0** **n/a:7**	
		OVERALL PERCENTAGE AGREEMENT:				**78.4%**

Table 4. 43: Analysis of Observational Studies and case studies/case reports: Article 7

AUTHOR(S):	Polkinghorn
YEAR:	2001
TITLE:	Chiropractic treatment of postsurgical neck syndrome with mechanical force, manually assisted short-lever spinal 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**
AMCT, pain levels reported by patient.	Each follow up.	Eight months.	One participant.	No blinding.	No control.	No randomisation.	A: 0 B1: 1 B2: 0 C: 3 I: 0 n/a: 7	78.4%

LIMITATIONS:	This study included a single participant (n = 1), therefore the sample size in this study was small. Sample size and therefore the use of inferential statistics is limited in a case study, as there is only one participant. With a larger sample size, this study could have produced more reliable and valid results to use in practice when deciding on treatment options for a patient. (Columb and Atkinson 2015). The patient in this case study is a 35-year-old woman who had post-surgical neck pain for over 5 years after multiple spinal surgeries. The pain was aggravated by sudden movements of her neck as well as prior to damp or wet weather. The flare-ups of pain were severe enough to confine her to bed. The participant reported severe pain, burning in character, affecting both sides of the neck, more so on the left and extending down the left side of the upper back. This does not allow for the generalisation of the findings other than those suffering with post-surgical neck syndrome (i.e. they conform to the parameters to the single participant in this study). The patient has a history of medication use to ease her pain, there is no information in this study as to how her medication use changed, reduced, or stopped during this study. There is no mention of a wash out period either. Further information is needed as this may have influenced the findings of this study, either exacerbating or reducing the outcomes noted (pain levels) and therefore it cannot be determined if the outcomes are a direct measure of the intervention used or not. The psychological state of the participant was poor when entering treatment, she was upset about the possibility of a third spinal surgery There is a possibility that the psychological state of the participant affected the findings. Coming into chiropractic care and being offered non-surgical treatment may have improved her psychological state, and as a result may have influenced the subjective outcome in this study. There was no comparison of her psychological state upon entering treatment to the end of treatment. (McGrath 1994; Thornton *et al.* 2017).. Radiographic imaging of the patient was completed however magnetic resonance imaging was not carried out. The participant and the practitioner agreed to a trial period of care before completing further imaging studies. The AMCT protocol was used in this study (Fuhr, Colloca and Green 1997), not just the AAI adjustment. Prone leg length observation, stress, pressure, and isolation tests were conducted on the participant in order to detect all spinal regions and levels needing to be adjusted. The AMCT protocol was also used as a measurement tool in this study. Isolation testing was used after the adjustment in order to measure the benefit delivered to the patient. Both objective and

	subjective measurements were utilised in this study as outcome measures. Subjective outcomes may have been influenced by patient perception, patient expectation and patient satisfaction with the treatment and its anticipated outcomes. (Thornton *et al.* 2017). No programme of intervention was used in this study, it was purely the AAI being used within the AMCT protocol (Fuhr, Colloca and Green 1997; Kaiser *et al.* 2018). Since this is an observational study, many factors were unaccounted for or controlled which affects the reliability of the results of this study. Due to this study design, there is a lack of a control group and lack of control of many variables which may influence the outcomes (Deaton and Cartwright 2018).There is a lack of blinding of examiners and assessors which may influence the outcomes noted as the treated practitioner performed these tasks too (Karanicolas, Farrokhyar and Bhandari 2010).
OUTCOME:	The woman suffered with chronic neck pain for 5 years after two separate neck surgeries: a discectomy at C3/4 and a fusion at C5/6. Surgeries were performed six months apart in an attempt to resolve persistent neck pain and spasm of the cervical musculature. Neither surgery was effective in relieving the patient's pain. Now, 5 years after the surgery, a third surgery was suggested to the patient to alleviate the chronic pain. The patient then sought chiropractic care to avoid another surgical intervention. The patient was assessed using AMCT protocol and was treated using the AAI to deliver the adjustments. She comfortably tolerated treatment and responded favourable to this therapy with all chronic symptoms resolving within thirty days of starting chiropractic care with the AAI. After one week of chiropractic care, the acute exacerbation had resolved. After one month of chiropractic care virtually all of the previous chronic neck pain had resolved. On re-examination at two months, the patient was pain free and cervical range of motion had improved to near normal. She was treated over an eight-month period, during which she had several slight episodes of pain, usually as a result of strenuous physical activity. There was long-term relief of the patient pain, with a longitudinal examination over the next 2 years, it showed that the patient experienced no residual effects or further recurrences of her previous chronic pain after her initial course of chiropractic care receiving treatment with the AAI. (Polkinghorn and Colloca 2001).
DISCUSSION:	The use of the AAI to deliver an adjustment provides an option to chiropractors to use this instrument instead of a manual adjustment, especially in cases in which the patient's surgical history or presenting symptoms make forceful manipulation of the spine, particularly performed at the end range, inappropriate (Taylor *et al.* 2004). The patient in this study was unable to tolerate any forceful rotary manipulation in the cervical spine in her presenting condition, hence the AAI was used to adjust her. The AAI provides a controlled means to deliver a high velocity thrust to the cervical spine without having to rotate the spine in treatment delivery. Often patients experience severe pain upon range of motion and by eliminating the need to rotate the cervical spine to deliver the adjustment, it makes the patient experience less pain and discomfort when receiving the adjustment with the AAI. Whilst the findings of this study are favourable and from the discussion above the AAI may be considered to be more appropriate to use in certain cases, the results of this study need to be considered with caution as there are limitations in this study which have affected the outcomes noted. The participants medication use, past experiences with practitioners and surgeons, her psychological state along with uncontrolled variables, small sample size, and a lack of blinding, may have all influenced the outcomes noted in this study. (McGrath 1994; Corfman 1995; Karanicolas, Farrokhyar and Bhandari 2010; Columb and Atkinson 2015) This study only reported findings from a single participant. Results may vary when using a larger sample size (Columb and Atkinson 2015). These limitations result in poor external validity. This study is an observational study, and it reflects clinical practice. The findings need to be considered with caution. There are many factors that may have influenced the outcomes and therefore one cannot conclude that the intervention alone was responsible for the outcomes noted in this study and therefore the findings are not reproducible. A well-structured RCT would be difficult to carry out due to the fact that patient presentation and individual factors may differ and vary a lot between participants with post-surgical neck syndrome. Therefore, homogeneity of groups in an RCT would be difficult to achieve. (Corfman 1995; Kabisch *et al.* 2011).
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.42), this study only fulfilled few of the applicable criteria in the Liddle Scale (Liddle, Williamson and Irwig 1996). The internal validity of this study was poor and with a high- risk of bias, the external validity of this study was poor as a result of the limitations noted. Therefore, the results of this study are subject to a degree of bias and this study has poor external validity. This implies that the outcomes are not necessarily reproducible. As a result, the study conclusions must be seen with caution regarding the influence of bias. Therefore, this particular study provides no evidence in support of the AAI being used within the AMCT protocol to reduce symptoms associated with post-surgical neck syndrome in clinical practice.

Table 4. 44: Tabulated Feedback Data for Observational Studies and case studies/case reports: Article 8

AUTHOR(S):	Roberts, Wolfe					
YEAR:	2009					
TITLE:	Chiropractic care of a 6-year-old girl with neck pain; headaches; hand, leg, and foot pain; and other nonmusculoskeletal symptoms					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Are the study participants well-defined in terms of time, place and person?	B2	B1	B1	B1	66%
2	What percentage of individuals refused to participate?	n/a	n/a	n/a	n/a	100%
3	Are outcomes measured in a standard, valid and reliable way?	A	C	A	A	66%
4	Are outcomes measured in the same way for both intervention and control groups?	n/a	n/a	n/a	n/a	100%
5	Are factors other than intervention comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?	n/a	n/a	n/a	n/a	100%
6	What percentage of individuals recruited into the study are not included in the analysis?	n/a	n/a	n/a	n/a	100%
7	Is the analysis by intention to intervene (treat)?	n/a	n/a	n/a	n/a	100%
8	Are results homogenous between sites?	n/a	n/a	n/a	n/a	100%
9	How well was the study done to minimise bias?	B2	C	B2	B2	66%
10	Is the overall effect of the study due to the study intervention?	B2	B1	B2	B2	66%
11	Explain if there is any practical/ethical reason why an RCT cannot be done?	A	n/a	n/a	n/a	66%
	TOTAL SCORE	A:2 B1:0 B2:3 C:0 I:0 n/a:6	A:0 B1:2 B2:0 C:2 I:0 n/a:7	A:1 B1:1 B2:2 C:0 I:0 n/a:7	**A:1** **B1:1** **B2:2** **C:0** **I:0** **n/a:7**	
		OVERALL PERCENTAGE AGREEMENT:				**84.5%**

Table 4. 45: Analysis of Observational Studies and case studies/case reports: Article 8

AUTHOR(S):	Roberts, Wolfe
YEAR:	2009
TITLE:	Chiropractic care of a 6-year-old girl with neck pain; headaches; hand, leg, and foot pain; and other nonmusculoskeletal symptoms

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**
AMCT, NDI, VAS.	Not stated.	19 weeks.	One participant.	No blinding.	No control.	No randomisation.	A: 1 B1: 1 B2: 2 C: 0 I: 0 n/a: 7	84.5%

LIMITATIONS:	This study included a single participant (n = 1), therefore the sample size in this study was small. Sample size and therefore the use of inferential statistics is limited in a case study, as there is only one participant. This also results in the lack of generalisable data as the outcomes are only likely to be similar to the case study patient. (Columb and Atkinson 2015). This study was of a particular individual, a six-year-old female paediatric patient, with very specific presentation and history making the results and findings in study applicable to a very specific, limited amount of people meeting the same criteria as the participant in this study. The findings of this study cannot be applied to the general population. It may not be feasible to conduct a RCT to expand on this study as this case report presents a unique case history along with chronic symptoms (several-year history of unexplained fatigue, vomiting and couching spells). The unique constellation of symptoms and clinical course would be difficult to identify in a large number of patients in order to conduct a valuable, reliable and fully powered RCT. (Andrew *et al.* 1994; Columb and Atkinson 2015; Ebrahim Valojerdi, Tanha and Janani 2017). Ethical consideration is needed too, as this study involves a paediatric participant (Sammons and Starkey 2012). The mechanism of injury is not detailed in this study, it is stated that there was trauma from hitting her head on a slide, but no further information is noted. The participant had chiropractic care prior to this study, after her injury and there is limited information given on this. There is therefore a lack of patient naivety in this study however due to the participants age, this may possibly be negated. (Sammons and Starkey 2012). The causative factor of the patient's improvement and resolution of symptoms in this case report is not clear, whilst it may be related to her treatment, it may also be as a result of her relocation or psychological factors, it could have been spontaneous or as a natural course of the disorder. (McGrath 1994). There is mention that the participant used ice and ibuprofen at home, with no results. There is no discussion of a wash-out period or continued use of these adjunctive therapies. There is no information in this study as to how her medication use changed, reduced, or stopped during this study. There is no mention of a wash out period either. Further information is needed as this may have influenced the findings of this study, either exacerbating or reducing the outcomes

	noted. The participant was also advised to rest for the initial two weeks of this study. With this, one cannot conclude if the outcomes may have been affected by this and if the outcomes measured were directly related to the intervention used or if they were influenced by these factors. The AMCT protocol was used in this study, not just the AAI adjustment. The same levels were adjusted at each consult. The AMCT protocol was also used as a measurement tool in this study. Outcome measures in this study are limited to AMCT protocol and pain intensity, with the use of NDI and VAS. Whilst there is therefore both objective and subjective outcome measures in this study, these measurements of pain intensity may not have recorded accurate findings as the participant was of a young age and these measurement tools may have been misinterpreted by her (Shields *et al.* 2003) or may have been influenced by the practitioner as the practitioner was the assessor and examiner too in this study which speaks to a lack of blinding in this study (Karanicolas, Farrokhyar and Bhandari 2010). The patient in this study is only 6 years old, her reports on pain and subjective findings may be unreliable in this study due to her age and comprehension of certain questions or pain rating scales (Shields *et al.* 2003). Since this is an observational study, many factors were unaccounted for or controlled which affects the outcomes of this study. Due to this study design, with it being an observational study, there is a lack of a control group and lack of control of many variables which may influence the outcomes. Since there is no control, there is no comparison to analyse in this case report and there are no comparative intervention groups to compare findings and outcomes with. Therefore, it is unclear if the outcomes would be the same when carried out with a larger sample size. (Deaton and Cartwright 2018).
OUTCOME:	There was reported trauma where the patient hit her head and has acute pain, described by the patient as her "neck and brain hurting" and hand, foot and occasional leg pain. She also has a several year history of unexplained fatigue, vomiting and coughing spells. She had a neck disability index of 17.8%, left lateral and rotational head tilt, cervical antalgic lean, loss of cervical range of motion, anterior cervical translation, and spasm, tenderness, trigger points and oedema along the cervical and thoracic spine. The patient received manual adjustments initially (two weeks post injury) and there was minimal change in the patient's pain and symptoms. The patient was hesitant and would not lie prone for the manual adjustments to be delivered, the treating chiropractor adjusted the patient in a seated position. Shortly after this the family relocated and the patient's pain and symptoms persisted. Three and a half months post injury she presented to a new chiropractor (the practitioner who formed this study) with the same symptom's presentation. This chiropractor used AMCT and adjusted her using the AAI within the AMCT protocol. Adjustments were given using the AAI within the AMCT protocol to C5, C7, T1 and T6 throughout her treatment. After her third treatment, she experienced improvement in her symptoms, a reduction in the intensity and frequency of her coughing and vomiting. After the fourth treatment her neck pain was reduced. After the fifth treatment, all the patient's symptoms dissipated with a complete return to normal activity and spinal stability after nine treatments. At nineteen weeks her spine continued to be asymptomatic, and her neck disability index was 0%. When the patient initially entered treatment, she was nervous and apprehensive, after ten weeks of treatment she was relaxed and alert in treatments.
DISCUSSION:	Given that this is an observational study, it is more pragmatic and reflective of clinical practice. The participant in this study had an array of symptoms presenting when she started treatment. Many factors may have influenced the outcomes noted in this study, including her relocation, psychological state and medication use. Her improvement may have been related to the natural course of the disorder, rather than the actual intervention There are many limitations of this study that affect the external validity of this study. The causal relationship between the intervention used and her improvement of symptoms is not clear due to the limitations of this study. The lack of control of variables, symptom presentation, lack of blinding, small sample size, young age of participant and limitations with measurement tools used – all influence the findings of this study. The efficacy of the intervention itself is unclear. One cannot conclude that the intervention alone was responsible for the outcomes noted in this study and therefore the findings need to be considered with caution. A well-structured RCT would be difficult to carry out due to the fact that patient presentation was very specific and included various complaints. It would also be difficult to carry out an RCT with paediatric participants, due to ethical concerns. (Andrew *et al.* 1994; Sammons and Starkey 2012).
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.44), this study fulfilled some of the applicable criteria in the Liddle Scale. The internal validity of this study was poor and with a moderate- risk of bias. The external validity of this study was poor as a result of the limitations noted. Therefore, the

	results of this study are subject to a degree of bias due to poor internal and external validity. This implies that the outcomes are not necessarily reproducible or reliable or as a direct result of the intervention being used. As a result, the study conclusions must be seen with caution regarding the influence of bias. Therefore, this particular study provides no evidence in support of the AAI being used within the AMCT protocol to treat paediatric patients with neck pain; headaches; hand, leg, and foot pain; and other nonmusculoskeletal symptoms in clinical practice. This study does show signs that the patient (paediatric) felt more relaxed receiving adjustments with the use of the AAI versus manual adjustments, further RCT studies should be conducted in this area.

Table 4. 46: Tabulated Feedback Data for Observational Studies and case studies/case reports: Article 9

AUTHOR(S):		Roberts, Wolfe				
YEAR:		2012				
TITLE:		Chiropractic spinal manipulative therapy for a geriatric patient with low back pain and comorbidities of cancer, compression fractures, and osteoporosis				
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Are the study participants well-defined in terms of time, place and person?	B1	B1	B1	B1	100%
2	What percentage of individuals refused to participate?	n/a	n/a	n/a	n/a	100%
3	Are outcomes measured in a standard, valid and reliable way?	A	B1	B1	B1	66%
4	Are outcomes measured in the same way for both intervention and control groups?	n/a	n/a	n/a	n/a	100%
5	Are factors other than intervention comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?	n/a	n/a	n/a	n/a	100%
6	What percentage of individuals recruited into the study are not included in the analysis?	n/a	n/a	n/a	n/a	100%
7	Is the analysis by intention to intervene (treat)?	n/a	n/a	n/a	n/a	100%
8	Are results homogenous between sites?	n/a	n/a	n/a	n/a	100%
9	How well was the study done to minimise bias?	B2	C	B2	B2	66%
10	Is the overall effect of the study due to the study intervention?	B1	B1	B1	B1	100%
11	Explain if there is any practical/ethical reason why an RCT cannot be done?	B2	n/a	n/a	n/a	66%
	TOTAL SCORE	A:1 B1:2 B2:2 C:0 I:0 n/a:6	A:0 B1:3 B2:0 C:1 I:0 n/a:7	A:0 B1:3 B2:1 C:0 I:0 n/a:7	**A:0** **B1:3** **B2:1** **C:0** **I:0** **n/a:7**	
		OVERALL PERCENTAGE AGREEMENT:				**90.7%**

Table 4. 47: Analysis of Observational Studies and case studies/case reports: Article 9

AUTHOR(S):	Roberts, Wolfe
YEAR:	2012
TITLE:	Chiropractic spinal manipulative therapy for a geriatric patient with low back pain and comorbidities of cancer, compression fractures, and osteoporosis

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
AMCT, Revised Oswestry Low Back Pain Disability Questionnaire, NPRS	Not stated.	33 weeks.	One participant.	No blinding.	No control.	No randomisation.	A: 0 B1: 3 B2: 1 C: 0 I: 0 n/a: 7	90.7%

LIMITATIONS:	This study included a single participant (n = 1), therefore the sample size in this study was small. Sample size and therefore the use of inferential statistics is limited in a case study, as there is only one participant. This also results in the lack of generalisable data as the outcomes are only likely to be similar to the case study patient. (Columb and Atkinson 2015). The participant in this study had reported trauma 4 years prior to this study. Whilst it is noted that he fell nine feet, there is no details about the trauma, injuries sustained, or diagnostic tests or imaging completed after his fall. His history notes depression, osteoarthritis, difficulty breathing, high blood pressure, cardiac complaints, and kidney dysfunction (reportedly due to his prescription medication). The patient was on a significant amount of medication and has leukaemia. The details of medication use, and treatment medically was not noted and may have influenced the findings of this study. Therefore, the findings of this study cannot be applied to the general population. There are ethical considerations that need to be considered with such a case. (Surbone 2008). Whilst this study noted the treatment goals of reducing pain, increasing strength and being able to help his wife by lifting her, no information was given as to if any adjunctive therapies or home care advice was given to the participant to assist in achieving these goals. Since the patient was on medication, it is unclear if this may have influenced the outcomes of this study. (Kaiser *et al.* 2018). The patient was not managed in a controlled environment due to the design of this study (case report) hence there are many variables that need to be considered such as medication use, psychological factors, previous trauma, onset of symptoms, medical history, family history, level of activity and compliance with medical treatment. This case report may be hard to reproduce as a RCT because of the clinical presentation and comorbidities in the patient in this case report. However, due to the lack of a control group in this study, there is no group to compare findings with to provide evidence in support of or against the intervention being investigated. The participant had received prior chiropractic care (seventeen treatments but was non-responsive to the clinical intervention). There is therefore a lack of patient naivety in this study and subjective outcomes may be influenced by patient perception, patient expectation and patient satisfaction with the treatment and its anticipated outcome. (Thornton *et al.* 2017). The spontaneous improvement in the patient's symptoms is possible,

	possibly due to natural history, considering that prior treatment had not helped the patient prior to receiving chiropractic care with the AAI within the AMCT protocol (in this case study). Factors such as improvement in mental health with personalized care (McGrath 1994) and the possible benefits of touch therapy (Wright 1987) could have also played a role in his recovery and symptom reduction. The AAI adjustments were delivered within the AMCT protocol to the same vertebral levels throughout his treatment, this is not often the case in clinical practice as patients usually are reassessed and adjusted at the required levels at each visit. The AMCT protocol was used in this case report to determine the areas needing to be adjusted and how to direct these adjustments. Prone leg length observation, stress, pressure, and isolation tests were conducted on the participant in order to detect all subluxations and areas of dysfunction. The AMCT protocol was also used as a measurement tool in this study. Forms of measurement are limited in this study with the basis being on leg length and pain intensity. The subjective measurements of pain intensity may not have recorded accurate findings as the participant was of an older age and cognitive impairment may have resulted in a lack of understanding and comprehension of the measurement tools. (Schofield 2018). Memory recall, understanding and comprehension may have influenced findings (Kessels 2003). These measurement tools may have been misinterpreted by him or may have been influenced by the practitioner as the practitioner was the assessor and examiner too in this study, resulting in a lack of blinding (Karanicolas, Farrokhyar and Bhandari 2010). Since this is a case report, many factors were unaccounted for or controlled and the relationship between the outcomes and the intervention used is not clear. There is a lack of blinding, lack of a control group, and lack of control of many variables which may influence the outcomes. (Karanicolas, Farrokhyar and Bhandari 2010; Deaton and Cartwright 2018).
OUTCOME:	The geriatric patient presented with low back pain and a history of leukaemia, multiple compression fractures, osteoporosis, and degenerative joint disease. There is a history of trauma in the area, he fell 4 years prior to this and fell 9 feet. His low back pain started recently after lifting his wife into a truck. Thereafter he went to chiropractor for treatment and after seventeen treatments, he had no improvement. He then saw his medical physician who referred him into this office for care roughly four to five weeks after his last visit to the previous chiropractor. The patient began treatment with AMCT, and adjustments were delivered to him using the AAI within the AMCT protocol. Treatment was once per week for four weeks, then once every two weeks for two visits then finally once every three weeks for one visit. This was subject to change based on the progress of the patient and his symptom presentation. The patient entered treatment with his Revised Oswestry Low Back Pain Disability Questionnaire being 26% and his pain rating on the NPRS was 10/10. He presented with a left head tilt, right high shoulder, and right high ilium with anterior translation and flexion of the torso and spasm and tenderness form the lower thoracic spine to lumbar spine. The patient was treated with the AMCT, and adjustment were delivered using the AAI. Eight treatments were done, and the patient was stable and remained stable for four months without spasm or tenderness in the spine. His Revised Oswestry score dropped to 6% and his NPRS pain rating was 4/10. The geriatric patient also noted improved quality of life.
DISCUSSION:	The AAI is said to be a favourable option for adjusting the geriatric population due to many reasons such as their restricted motion and comorbidities that may contraindicate manual HVLA manipulation. The AAI delivers a controlled, specific adjustment to the restricted joint without having to place the patient into positions that require torque and/or rotation. Whilst this study produced favourable results, many factors serve as limitations in this study, reducing the studies external validity. The limitations affect the outcomes, implying that the findings cannot be directly related to the intervention used. Given that this is an observational study, it is more pragmatic and reflective of clinical practice. However, with this, the causal relationship between the intervention used and his improvement of symptoms is not clear due to the limitations of this study. The lack of control of variables (such as medication use, psychological state, cognitive abilities, previous trauma, onset of symptoms, medical history, family history, level of activity and compliance with medical treatment), lack of patient naivety, symptom presentation, lack of blinding, small sample size, and age of participant all influence the findings of this study. (McGrath 1994; Karanicolas, Farrokhyar and Bhandari 2010; Columb and Atkinson 2015; Thornton *et al.* 2017).

	A well-structured RCT would be difficult to carry out due to the fact that patient presentation was very specific and included various comorbidities. It would also be difficult to carry out an RCT with geriatric participants, due to ethical concerns and the presence of numerous comorbidities. (Surbone 2008; Akobeng 2016; Qureshi, Gough and Loudon 2022).
CONCLUSION:	The outcomes of the reviewers in the previous table (Table 4.46), showed that this study fulfilled some of the applicable criteria in the Liddle Scale (Liddle, Williamson and Irwig 1996). The internal validity of this study was good and with a low to moderate risk of bias. The external validity of this study was poor as a result of the limitations noted. Therefore, this particular study provides limited evidence in support of the AAI being used within the AMCT protocol to treat geriatric patients with low back pain and comorbidities of cancer, compression fractures, and osteoporosis in clinical practice.

Table 4. 48: Tabulated Feedback Data for Observational Studies and case studies/case reports: Article 10

AUTHOR(S):		Roberts, Wolfe				
YEAR:		2012				
TITLE:		Chiropractic management of a veteran with lower back pain associated with diffuse idiopathic skeletal hypertrophy and degenerative disk disease				
CRITERION:			**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Are the study participants well-defined in terms of time, place and person?		B2	B2	B2	B2	100%
2	What percentage of individuals refused to participate?		n/a	n/a	n/a	n/a	100%
3	Are outcomes measured in a standard, valid and reliable way?		A	B1	B1	B1	66%
4	Are outcomes measured in the same way for both intervention and control groups?		n/a	n/a	n/a	n/a	100%
5	Are factors other than intervention comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?		n/a	n/a	n/a	n/a	100%
6	What percentage of individuals recruited into the study are not included in the analysis?		n/a	n/a	n/a	n/a	100%
7	Is the analysis by intention to intervene (treat)?		n/a	n/a	n/a	n/a	100%
8	Are results homogenous between sites?		n/a	n/a	n/a	n/a	100%
9	How well was the study done to minimise bias?		C	B2	C	C	66%
10	Is the overall effect of the study due to the study intervention?		B2	B2	B2	B2	100%
11	Explain if there is any practical/ethical reason why an RCT cannot be done?		C	n/a	n/a	n/a	66%
	TOTAL SCORE		A:1 B1:0 B2:2 C:2 I:0 n/a:6	A:0 B1:1 B2:3 C:0 I:0 n/a:7	A:0 B1:1 B2:2 C:1 I:0 n/a:7	**A:0** **B1:1** **B2:2** **C:1** **I:0** **n/a:7**	
			OVERALL PERCENTAGE AGREEMENT:				**90.7%**

Table 4. 49: Analysis of Observational Studies and case studies/case reports: Article 10

AUTHOR(S):	Roberts, Wolfe
YEAR:	2012
TITLE:	Chiropractic management of a veteran with lower back pain associated with diffuse idiopathic skeletal hypertrophy and degenerative disk disease

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
NPS, Oswestry Questionnaire, Health Status Questionnaire, AMCT.	At most, but not all, follow-up appointments.	Seven weeks of treatment, follow up done after one year and nine months.	One participant.	No blinding.	No control.	No randomisation.	A: 0 B1: 1 B2: 2 C: 1 I: 0 n/a: 7	90.7%

LIMITATIONS:	This study included a single participant (n = 1), therefore the sample size in this study was small. Sample size and therefore the use of inferential statistics is limited in a case study, as there is only one participant. This also results in the lack of generalisable data as the outcomes are only likely to be similar to the case study patient. (Columb and Atkinson 2015). The participant was 74 years old, had degenerative disc disease and diffuse idiopathic skeletal hyperostosis. He presented with severe, insidious onset low back pain and a loss of feeling in his lower extremities for a duration of three months. He also has antalgia and severe difficulty with ambulation, hence used a walker. There are ethical considerations that need to be considered with such a case due to his age and comorbidities. (Davis, Chung and Juarez 2011; Divo, Martinez and Mannino 2014). Treatment would have had to consider this participants physical condition and restraints (such as poor ambulation and antalgia) when dealing with the participant. (Surbone 2008). The results of this case report are limited to apply to patients with similar presentation and history to this patient in this study and cannot be applied to the general population. Given that this is a case report and it lacks a control group or sham intervention being used to compare findings with (Deaton and Cartwright 2018). The patient was not managed in a controlled environment hence there were many variables. The participant was hit by a car twice at the age of 5 years. There is a lack of further information about this trauma and injuries sustained as well as the force and vectors associated with this incident. The participant was distressed upon entering treatment, therefore his psychological state may have influenced findings in this study. (McGrath 1994). It is unknown what his prior experiences were with health care providers and if this have been a cause of his distressed state upon beginning treatment (perhaps having had poor prior experiences with other health care providers). This may have also influenced the subjective findings in this study due to patient perception, patient expectation and patient satisfaction with the treatment and its anticipated outcome. (Thornton *et al.* 2017). The patient was on medication for hypertension, but no other medication use was noted in this study. There was no mention of any wash out period and therefore medication use needs to be considered when looking at the outcomes of this study as the outcomes may have been influenced and a result of more than just the intervention being used. The participant had a history of colon cancer and had surgery in 2004. There is no further information given. It is unclear if any further treatment was required or carried out or if regular check-ups were carried out. There is a lack of details with regards to this participants past medical history and therefore the factors that may have influenced the outcomes

	in this study are not described. The participants family history, level of activity, prior occupation and compliance with medical treatment are not noted in this study. These factors need to be considered when looking at this case report and the findings noted in it. This case report may be hard to reproduce or run a RCT based off because of the clinical presentation and comorbidities in the patient in this study. (Andrew *et al.* 1994; Davis, Chung and Juarez 2011; Divo, Martinez and Mannino 2014; Qureshi, Gough and Loudon 2022). Factors such as improvement in mental health with personalized care (McGrath 1994) and the possible benefits of touch therapy (Wright 1987) could have also played a role in his recovery and symptom reduction. The patient was advised to use ice at home on his low back. Since this was included, a programme of intervention was used, and the findings of this study cannot be related to the AAI adjustments within the AMCT protocol. AMCT protocol was used in this case study to determine the areas needing to be adjusted and how to direct these adjustments. The AMCT protocol was also used as a measurement tool in this study The NPS may have been hard for the participant to comprehend due to this age and distressed state. The questionnaires used may have posed the same problems. There is a risk of cognitive impairment and a lack of comprehension and understanding of the scales may have interfered with the findings noted. (Schofield 2018). Memory recall, understanding and comprehension may have all influenced subjective findings. The final follow-up was completed one year and nine months after the initiation of treatment, memory recall may have influenced these findings. (Kessels 2003; Moustgaard *et al.* 2014). These measurement tools may have been misinterpreted by him or may have been influenced by the practitioner as the practitioner was the assessor and examiner too in this study, resulting in a lack of blinding (Karanicolas, Farrokhyar and Bhandari 2010). There is a possibility of bias in this study, favouring the intervention as the author administered the intervention and collected the data for outcomes measures. The author also was limited with time constraints to collect outcome measures at each visit, possibly resulting in rushed patient interaction which the participant may have been able to detect. (Thornton *et al.* 2017) The follow-up completed one year and nine months after treatment is not reliable due to the memory recall limiting the outcomes noted after this period of elapsed time. (Kessels 2003). Since this is an observational study, many factors were unaccounted for or controlled which affects the reliability of the results of this study. There is a lack of blinding, lack of a control group and lack of control of many variables discussed above which may influence the outcomes. (Karanicolas, Farrokhyar and Bhandari 2010; Deaton and Cartwright 2018).
OUTCOME:	The patient had degenerative disc disease and diffuse idiopathic skeletal hyperostosis. He presented with severe, insidious onset low back pain and a loss of feeling in his lower extremities for a duration of three months. He also had antalgia and severe difficulty with ambulation, hence used a walker. He was treated using the AAI within the AMCT protocol. The patient's pain was initially 10/10 in the low back on the NPS at the beginning of this study. His Oswestry Questionnaire was forty-four and Health Status Questionnaire was 52%. He had severe difficulty with ambulation and used a walker. Two weeks into treatment, he reported no back pain, after four treatments. He was able to walk with a cane instead of the walker. After seven weeks of treatment, the NPS reduced from 10/10 to 0/10 and his revised Oswestry score was 13.3% from an initial 44%. His Health Status questionnaire increased from 52% to 77%. A follow up after one year and nine months showed an Oswestry score of 10% and a Health Status Score of 67%, above average for his age.
DISCUSSION:	This study produced favourable results, however these need to be considered with caution as many factors (such as medication use, age, comorbidities, previous trauma, psychological state) have influenced the outcomes in this study; particularly as there is no control group, a lack of blinding, a lack of a control group, a small sample size and a programme of intervention has been used in this study, one cannot contribute the outcomes noted purely to the intervention of the AAI within the AMCT protocol. The numerous limitations in this study result in this study having poor external validity. The causal relationship between the intervention used and his improvement of symptoms is not clear due to the limitations of this study. If this study were to be repeated with a different individual, the results may result in different outcomes. Therefore, the findings of this study are not reliable and further research needs to be carried out, reducing the limitations whilst still considering ethical concerns. (Andrew *et al.* 1994; Sammons and Starkey 2012).
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.48), this study fulfilled few of the applicable criteria in the Liddle Scale (Liddle, Williamson and Irwig 1996). The internal validity of this study was poor and with a high- risk of bias. The external validity of this study was poor as a result of the limitations noted. Therefore, this particular study provides no evidence in support of the AAI being used within the AMCT protocol to manage veterans with low back pain associated with diffuse skeletal hypertrophy and degenerative disc disease in clinical practice.

	The patient improved in this case report however there are too many variables, and only a single participant, to be able to conclude that the improvement and resolution of his symptoms was solely due to his treatment. The results in this study need to be used with caution and the variables and lack of control need to be considered when referring to this study.

Table 4. 50: Tabulated Feedback Data for Observational Studies and case studies/case reports: Article 11

AUTHOR(S):	Russell, Kimura, Cowie, de Groot, McMinn, Sherson					
YEAR:	2016					
TITLE:	Changes in Quality of Life in 7 Older Adult Patients Receiving Activator Methods Chiropractic Technique					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Are the study participants well-defined in terms of time, place and person?	B1	A	B1	B1	66%
2	What percentage of individuals refused to participate?	n/a	n/a	n/a	n/a	100%
3	Are outcomes measured in a standard, valid and reliable way?	A	A	A	A	100%
4	Are outcomes measured in the same way for both intervention and control groups?	n/a	n/a	n/a	n/a	100%
5	Are factors other than intervention comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?	C	C	C	C	100%
6	What percentage of individuals recruited into the study are not included in the analysis?	n/a	A	A	A	66%
7	Is the analysis by intention to intervene (treat)?	n/a	n/a	n/a	n/a	100%
8	Are results homogenous between sites?	A	n/a	A	A	66%
9	How well was the study done to minimise bias?	C	n/a	C	C	66%
10	Is the overall effect of the study due to the study intervention?	B2	A	B2	B2	66%
11	Explain if there is any practical/ethical reason why an RCT cannot be done?	B1	n/a	n/a	n/a	66%
	TOTAL SCORE	A:2 B1:2 B2:1 C:2 I:0 n/a:4	A:4 B1:0 B2:0 C:1 I:0 n/a:6	A:3 B1:1 B2:1 C:2 I:0 n/a:4	**A:3** **B1:1** **B2:1** **C:2** **I:0** **n/a:4**	
		OVERALL PERCENTAGE AGREEMENT:				**81.5%**

Table 4. 51: Analysis of Observational Studies and case studies/case reports: Article 11

AUTHOR(S):	Russell, Kimura, Cowie, de Groot, McMinn, Sherson
YEAR:	2016
TITLE:	Changes in Quality of Life in 7 Older Adult Patients Receiving Activator Methods Chiropractic Technique

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
SF-36, Pain levels reported by patient.	Varied between participants.	Varied between participants.	7 participants.	No blinding.	No control.	No randomisation.	A: 3 B1: 1 B2: 1 C: 2 I: 0 n/a: 4	81.5%

LIMITATIONS:	This study involved seven elderly participants. The findings cannot be generalised to the larger population. There are no clear relationships between symptoms in each participant that were monitored or measured throughout this study, merely changes in quality of life. The patients in this study were aged between 69 and 80 years old, with varying complaints affecting their quality of life. Seven participants were selected from two chiropractic offices in Auckland. Patients were included if they were older adults receiving AMCT care and for whom two quality of life assessments had been performed. There is therefore a risk of selection bias (Boutron *et al.* 2019) and a lack of patient naivety which may have had significant roles in the outcomes of this study. (Hariton and Locascio 2018). The participants were treated for a variety of musculoskeletal complaints. There is a lack of sample homogeneity in this study which is a limitation which may have affected the findings in this study. (Corfman 1995; Kabisch *et al.* 2011). One participant reported using prescription medication (with no reported wash out period). Some participants had a surgical history, history of trauma or comorbidities, whereas others did not. Factors such as alternative intervention, previous occupation, level of activity and psychological state were not considered and as a result there is a lack of homogeneity of patient and condition characteristics between the participants in this study. (Corfman 1995; Kabisch *et al.* 2011). The treatment frequency and duration varied and the time period over which they received care varied. Frequency of measurement also varied between participants as well as the number or location of adjustments delivered. Resulting in lack of homogeneity of care between the participants. A certain treatment plan therefore cannot be linked to the findings of this study as each participant received a different structured treatment plan. No information was given for any adjunctive therapies or home care advice given to the participant. If any other form of intervention was included, then the findings would be influenced by more than just the intervention of the AAI within the AMCT protocol and rather by the intervention programme as a whole (Kaiser *et al.* 2018). This study makes mention of alternative interventions and therefore it is assumed that a programme of intervention was used for some, if not all, of the participants. In addition, the course of care ranged from five-weeks to fifteen months at an initial frequency of one to three visits weekly for four to eight weeks of care. The average

	number of adjustments administered per visit ranged from five point two to seven point seven with an overall average of six point four per patient per visit. It is evident that the treatment for each patient was tailored to their needs and therefore there is a vast difference in each participant's case and response to treatment. The AAI was used within the protocol in this study and not just as an adjusting tool/instrument. Quality of life was the main measure in this study, however subjective pain levels were noted. The subjective measurements may have been influenced by the practitioner as the practitioner was the assessor and examiner too in this study, resulting in a lack of blinding (Karanicolas, Farrokhyar and Bhandari 2010). There is also a risk of response bias, participation bias (Mazor *et al.* 2002) as well as the Hawthorne or Observer effects (McCarney *et al.* 2007; Elston 2021), since the participants knew the researcher prior to participating in this study. Factors such as improvement in mental health with personalized care (McGrath 1994) and the possible benefits of touch therapy (Wright 1987) could have also played a role in his recovery and symptom reduction. This is a case series and therefore lacks a control group or sham intervention being used to compare findings with. The patients were not managed in a controlled environment hence many variables were not controlled. Thus, causal inference cannot be ascertained in this study, it is not possible to definitively identify what specifically contributed to the reported improvements in the participants in this study.
OUTCOME:	All participants reported improvements in their SF-36 questionnaire. The improvement of quality of life was measured with the SF-36 and the average improvement was eight points in the physical component and four point one points in the mental component. Four cases had a second progress evaluation using the SF-36 and showed an overall improvement of five point two in the physical and nine point eight in the mental components from baseline.
DISCUSSION:	Each participant in this study had differing initial symptoms and presentation affecting their quality of life. Each case varied within this case series. They all experienced pain and an affected quality of life. They all had differing histories and comorbidities, and these may not have been adequately considered in this case series. Each patient was assessed using the AMCT protocol and then treated and adjusted according to findings, meaning the treatment of each participant varied. Whilst the results of this study are favourable in improving quality of life and reducing pain in the participants, the limitations reduce the reliability and validity of these findings. This study has a poor external validity and outcomes cannot be directly related to the intervention of the AAI within the AMCT protocol. This study cannot be used to determine the efficacy of this intervention to these participants due to limitations of this study such as small sample size, lack of homogeneity between participants, lack of control over treatment of participants and lack of blinding in this study. These limitations may have influenced the outcomes of this study which reduces the external validity of this study. The findings in this study need to be accepted with caution and further testing in the form of a RCT designed study needs to be carried out addressing the limitations of this study. (Andrew *et al.* 1994; Sammons and Starkey 2012).
CONCLUSION:	Given in the outcomes of the reviewers in the previous table (Table 4.50), this study was able to fulfil and describe some of the applicable criteria in the Liddle Scale (Liddle, Williamson and Irwig 1996). The internal validity of this study was good and with a moderate- risk of bias. The external validity of this study was poor as a result of the limitations noted. Since a programme of intervention was utilised in this study, one cannot relate out comes of this study to the single intervention itself. Therefore, this particular study provides no evidence in support of the AAI being used within the AMCT protocol to improve the quality of life in older adult patients in clinical practice. Further studies in this particular area are needed in order to validate the outcomes and provide further information regarding the relationship between adjustments using the AAI within the AMCT protocol and the improvement of the quality of life in older adult patients. The findings in this study need to be accepted with caution and further testing in the form of a RCT designed study is needed that addresses the limitations noted in this study. (Andrew *et al.* 1994; Sammons and Starkey 2012).

4.4.3.2 Summary of Observational studies and case studies/case reports

Table 4. 52: Outcome and Methodological Ranking of Observational studies and case studies/case reports

Study Type:	**Observational studies and case studies/case reports**					
Author(s)	**Year:**	**Title:**	**Reviewer's Methodological Ranking**	**Internal validity**	**External Validity**	**Level of Evidence**
DeVocht, Pickar, Wilder	2004	Spinal Manipulation Alters Electromyographic Activity of Paraspinal Muscles: A Descriptive Study	A: 5 B1: 3 B2: 1 C: 0 I: 0 n/a: 2	Good	Poor	Limited
Norton, Callanan	2013	Reduction in Symptoms Associated with Parkinsons Disease Subsequent to Subluxation-Based Chiropractic Care: A Case Study	A: 0 B1: 1 B2: 1 C: 3 I: 0 n/a: 6	Moderate to poor	Poor	No evidence
Osterbauer, De Boer, Widmaier, Petermann, Fuhr	1993	Treatment and biomechanical assessment of patients with chronic sacroiliac joint syndrome	A: 1 B1: 1 B2: 3 C: 1 I: 0 n/a: 5	Moderate	Poor	No evidence
Polkinghorn	1998	Treatment of cervical disc protrusions via instrumental chiropractic adjustment	A: 1 B1: 0 B2: 0 C: 3 I: 0 n/a: 7	Moderate to poor	Poor	No evidence
Polkinghorn	1998	Treatment of symptomatic lumbar disc herniation using activator methods chiropractic technique	A: 1 B1: 0 B2: 1 C: 2 I: 0 n/a: 7	Moderate to poor	Poor	No evidence
Polkinghorn	1999	Chiropractic treatment of coccygodynia via instrumental adjusting procedures using activator methods chiropractic technique	A: 1 B1: 0 B2: 3 C: 0 I: 0 n/a: 7	Moderate	Poor	No evidence
Polkinghorn	2001	Chiropractic treatment of postsurgical neck	A: 0 B1: 1	Moderate to poor	Poor	No evidence

		syndrome with mechanical force, manually assisted short-lever spinal adjustments	B2: 0 C: 3 I: 0 n/a: 7			
Roberts, Wolfe	2009	Chiropractic care of a 6-year-old girl with neck pain; headaches; hand, leg, and foot pain; and other non-musculoskeletal symptoms	A: 1 B1: 1 B2: 2 C: 0 I: 0 n/a: 7	Moderate	Poor	No evidence
Roberts, Wolfe	2012	Chiropractic spinal manipulative therapy for a geriatric patient with low back pain and comorbidities of cancer, compression fractures, and osteoporosis	A: 0 B1: 3 B2: 1 C: 0 I: 0 n/a: 7	Moderate to good	Poor	Limited
Roberts, Wolfe	2012	Chiropractic management of a veteran with lower back pain associated with diffuse idiopathic skeletal hypertrophy and degenerative disk disease	A: 0 B1: 1 B2: 2 C: 1 I: 0 n/a: 7	Moderate	Poor	No evidence
Russell, Kimura, Cowie, de Groot, McMinn, Sherson	2016	Changes in Quality of Life in 7 Older Adult Patients Receiving Activator Methods Chiropractic Technique	A: 3 B1: 1 B2: 1 C: 2 I: 0 n/a: 4	Moderate to good	Poor	No evidence

4.5 Conclusion

In this chapter the findings of the internal validity of the article by means of the reviewer rating of each article within this review is offered. It has also provided an outline of the external validity factors of each article in terms of its limitations, properties, structure, and outcomes. This permits an understanding of the relationship of the internal and external validity of the articles and how these impact the outcomes of the article and thus the evidence that is available based on the outcomes of the various articles.

To meet the requirements of this study, the following chapter (Chapter Five) introduces a discussion around the AAI technique and the AAI within the AMCT protocol in order to be able to establish the level of evidence that is available for each within each spinal region.

CHAPTER FIVE DISCUSSION OF RESULTS

5.1 Introduction

After reviewing the different study types that were presented in Chapter Four, this chapter contextualises the level of evidence to support the effectiveness of the use of the Activator Adjusting Instrument (AAI) in treating spinal pain, as discussed in Chapter Four.

5.2 A review of the effectiveness of the use of the AAI in treating spinal pain

The 23 articles that met the inclusion criteria were reviewed and discussed (Chapter Four), thereafter the articles were grouped (Chapter Five) in order to determine and summate the level of evidence to support the effectiveness of the use of the AAI in treating spinal pain in various regions of the spine:

- Cervical spine (Neck)
- Thoracic spine (Midback)
- Lumbar spine, sacroiliac, and coccygeal region (Low back)

The articles have also been grouped, separating the articles that used the AAI within the AMCT protocol (Table 5.1) from those that used the AAI technique (the AAI as an adjusting tool) (Table 5.2), outside of the AMCT protocol. Following this are the articles that had no pain measurement done but have measured sEMG response to adjustments with the AAI within the AMCT protocol.

Table 5. 1: Articles using the AMCT protocol

Author(s):	Year:	Title:	Region of the spine:	Study type:
Polkinghorn	1998	Treatment of cervical disc protrusions via instrumental chiropractic adjustment	Cervical spine	CS
Polkinghorn	2001	Chiropractic treatment of postsurgical neck syndrome with mechanical force, manually assisted short-lever spinal adjustments	Cervical region	CS
Roberts, Wolfe	2009	Chiropractic care of a 6-year-old girl with neck pain; headaches; hand, leg, and foot pain; and other nonmusculoskeletal symptoms	Cervical region	CS
Wood, Colloca. Matthews	2001	A pilot randomized clinical trial on the relative effect of instrumental (MFMA) versus manual (HVLA) manipulation in the treatment of cervical spine dysfunction	Cervical spine	RCT
Yurkiw, Mior	1996	Comparison of two chiropractic techniques on pain and lateral flexion in neck pain patients: a pilot study	Cervical spine	RCT
DeVocht, Pickar, Wilder	2004	Spinal Manipulation Alters Electromyographic Activity of Paraspinal Muscles: A Descriptive Study	Low back	CS
Keller, Colloca	2000	Mechanical force spinal manipulation increases trunk muscle strength assessed by electromyography: A comparative clinical trial	Low back	NRCT
Roberts, Wolfe (a)	2012	Chiropractic spinal manipulative therapy for a geriatric patient with low back pain and comorbidities of cancer, compression fractures, and osteoporosis	Low back	CS
Roberts, Wolfe (b)	2012	Chiropractic management of a veteran with lower back pain associated with diffuse idiopathic skeletal hypertrophy and degenerative disk disease	Low back	CS
Schneider, Brach, Irrgang, Abbott, Wisniewski, Delitto	2010	Mechanical vs Manual Manipulation for Low Back Pain: An Observational Cohort Study	Low back	NRCT
Osterbauer, De Boer, Widmaier, Petermann, Fuhr	1993	Treatment and biomechanical assessment of patients with chronic sacroiliac joint syndrome	Low back, Sacroiliac region	CS
Polkinghorn	1998	Treatment of symptomatic lumbar disc herniation using activator methods chiropractic technique	Lumbar spine	CS
Polkinghorn	1999	Chiropractic treatment of coccygodynia via instrumental adjusting procedures using activator methods chiropractic technique	Coccygeal region	CS
Norton, Callanan	2013	Reduction in Symptoms Associated with Parkinson's Disease Subsequent to Subluxation-Based Chiropractic Care: A Case Study	Full spinal	CS
Russell, Kimura, Cowie, de Groot, McMinn, Sherson	2016	Changes in Quality of Life in 7 Older Adult Patients Receiving Activator Methods Chiropractic Technique	Full spinal	CS

Table 5. 2: Articles using the AAI as an adjustment tool (AAI technique) (outside of the AMCT protocol)

Author(s):	Year:	Title:	Region of the spine:	Study type:
Gemmell, Miller	2010	Relative effectiveness and adverse effects of cervical manipulation, mobilisation and the activator instrument in patients with sub-acute non-specific neck pain: results from a stopped randomised trial	Cervical spine	RCT
Gorrell, Beath, Engel	2016	Manual and Instrument Applied Cervical Manipulation for Mechanical Neck Pain: A Randomized Controlled Trial	Cervical spine	RCT
Hardas, Murrell	2018	Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Trial Assessing the Effects of Applying a Force to C5 by a Mechanically Assisted Instrument on Referred Pain to the Shoulder	Cervical spine	RCT
Kendall, French, Hartvigsen, Azari	2018	Chiropractic treatment including instrument-assisted manipulation for non-specific dizziness and neck pain in community-dwelling older people: A feasibility randomised sham-controlled trial	Cervical spine	RCT
Coetzee	2013	The effect of the activator adjusting instrument in the treatment of chronic sacroiliac joint syndrome	Sacroiliac region	RCT
Shearar	2003	The Relative Effectiveness of Manual Manipulation versus Manipulation using the "Activator Adjusting Instrument" in the Management of Acute on Chronic Sacroiliac Syndrome	Sacroiliac region	RCT
Gemmell, Jacobson	1995	The immediate effect of activator vs. meric adjustment on acute low back pain: a randomised controlled trial	Low back	RCT
Gillespie	2003	The Effectiveness of Manual Manipulation versus the Activator Adjusting Instrument in the Management of Acute Facet Syndrome of the Lumbar Spine	Lumbar spine	RCT

5.3 Discussion of the criteria for grading evidence

The articles that were evaluated in this systematic review (see Table 5.1 and 5.2), were individually graded (Chapter Four) based on a review of their methodological rigour (internal validity) and external validity (ability to contextualize results in clinical practice). Relevant scales were utilized by blinded reviewers, as well as the researcher, when reviewing each article in this systematic review in order to critique and determine the level of evidence that each article contributes in its own right.

This systematic review utilizes the criteria defined by Foley et al. (2003) and Dagenais and Haldeman (2011) in order to summate all the evidence gathered and determine the level of evidence there is for the use of the AAI in treating spinal pain in each region of the spine.

According to Foley et al. (2003) and Dagenais and Haldeman (2011), literature considers the following six categories of evidence types:

- The first three categories address the level/quality of the evidence produced.

    1. “Strong evidence”: The findings of articles within one specific area were supported by the results of at least two RCT’s which achieved at least a “fair or moderate” grading.

    2. “Moderate evidence”: The findings of articles within one specific area were supported by the results of one RCT which achieved at least a “fair or moderate” grading.

    3. “Limited evidence”: The findings of articles within one specific area were supported by the results of at least one nonexperimental study (e.g., NRCT, case study or observational study).

    4. “No evidence”: In the event that either a highly graded article reveals that the intervention on trial scores is no higher than the placebo, or a low-grade article produces little to no evidence to support the treatment regimen.

- The following categories describe whether there are any conflicting results among articles within one specific area. These include:

    1. “Consensus of evidence”: If there is a lack of evidence, agreement was reached between reviewers as to whether the AAI could be effective in treating spinal pain. This could also be utilized when the outcome of the intervention (the AAI) is consistent among other articles.

    2. “Conflicting Evidence”: If an incongruity is found between the results of at least two RCTs. In the case where only one RCT in a group of RCTs shows incongruity or disparity, the results of the majority of the articles are considered the platform from which a deduction can be made, unless the incongruity article has a superior quality.

These criteria and gradings were utilized in this systematic review and are based on the levels of evidence employed by the US Agency for Healthcare Policy and Research (Foley *et al.* 2003b). By following this method, it was easy to draw conclusions where various articles were found to be in agreement. However, interpretation of individual article results as a collective proved more challenging when article results conflicted. It is therefore required that the reader(s) be critical in their consumption of the researcher's interpretation.

5.4 Grading of evidence for each spinal region

5.4.1 Cervical spine

5.4.1.1 Articles using the AMCT protocol

Table 5. 3: Spinal region: Cervical spine (AMCT protocol)

Author(s) / Year:	**Study Type:**	**Internal validity ranking:**	**External validity ranking:**	**-Clinical outcome -Level of evidence of each article -Programme of intervention or individual intervention**	**Level of Evidence:**					
					Strong	**Moderate**	**Limited**	**Consensus**	**Conflicting**	**No Evidence**
Wood, Colloca. Matthews, 2001	RCT	8/11 (Good)	Poor	-Positive -Limited -Individual intervention						
Yurkiw, Mior, 1996	RCT	11/11 (Excellent)	Poor	-Positive -Limited -Individual intervention						
Polkinghorn, 1998	CS	A:1 B1:0 B2:0 C:3 I:0 n/a:7	Poor	-Positive -No evidence -Programme of intervention			**X**	**X**		
Polkinghorn, 2001	CS	A:0 B1:1 B2:0 C:3 I:0 n/a:7	Poor	-Positive -No evidence -Individual intervention						
Roberts, Wolfe, 2009	CS	A:1 B1:1 B2:2 C:0 I:0 n/a:7	Poor	-Positive -No evidence -Programme of intervention						

Given the outcomes of these reviews, it would suggest that there is limited evidence (Foley *et al.* 2003b; Dagenais and Haldeman 2011) in favour of the use of the AAI within the AMCT protocol in treating cervical spine pain.

From the five articles that provided clinical outcomes, three were case studies and two were RCTs. Whilst the internal validity of some of these articles was good, which reflects good methodological rigour of the article, external validity of the articles in this category were generally poor. Factors affecting the external validity of articles are not completely factored into the scales used to review the articles despite the fact that these factors and limitations may influence the outcomes of an article through different bias (Mazor *et al.* 2002; Thornton *et al.* 2017; Krauss 2018). The level of evidence is lower than expected once incorporating the external validity of each article.

Wood, Colloca and Matthews (2001) aimed to compare the effect of instrument (within the AMCT protocol) versus manual manipulation in the treatment of cervical spine dysfunction and Yurkiw and Mior (1996) aimed to compare the effect of manual adjusting versus AAI adjusting within the AMCT protocol on neck pain and lateral flexion in patients with neck pain. Both articles concluded that both treatment methods had a positive effect on subjective and objective clinical outcomes, with no significant differences between the two groups. With both these articles, the sample size was small and further RCTs should include a larger sample size and consider the limitations each of these articles have. Whilst both of these articles had good internal validity, the external validity of these articles was poor as a result of the limitations of these articles. There are however articles that suggest that manual adjusting is better than placebo (Hoiriis *et al.* 2004; Santilli, Beghi and Finucci 2006). Therefore, even though these articles showed no significant differences between the groups, AAI within the AMCT may too be better than placebo since there were no differences in the outcomes between the groups. The degree of the improvement beyond that of placebo is then limited to the bias introduced through the external validity discussions.

Polkinghorn (1998) assessed the effect of the AAI adjustment within the AMCT protocol on cervical spine protrusions. The participant had reduction in pain from the initial week of treatment. A programme of intervention was used in this article and as a result, the outcomes of this article cannot be directly related to the intervention of the AAI within the AMCT protocol as the other interventions used may have influenced the outcomes too and this article cannot provide evidence in support of, or against, the use of the AAI within the AMCT protocol. (Kaiser *et al.* 2018). Polkinghorn (2001) assessed the effect of the AAI adjustment within the AMCT protocol on post-surgical neck syndrome. The chronic symptoms the participant presented

with all resolved within thirty days of starting treatment. Since these are case studies, each documenting the findings with only one participant, the results of these articles need to be considered with caution.

Roberts and Wolfe (2009) assessed the effect of the AAI adjustment within the AMCT protocol on a 6-year-old girl with neck pain; headaches; hand, leg, and foot pain; and other non-musculoskeletal symptoms. The participant had improvement in her symptoms and after the fourth treatment her neck pain had reduced in severity and continued to improve over the course of this study. The presentation of the participant in this case study was unique and a RCT may be hard to reproduce with many participants. This article had many limitations which impact the reliability of the findings reported. The causative factor of the participants improvement and resolution of her symptoms remains unclear in this article. A programme of intervention was used in this article and as a result, the outcomes of this article cannot be directly related to the intervention of the AAI within the AMCT protocol as the other interventions used may have influenced the outcomes too and this article cannot provide evidence in support of or against the use of the AAI within the AMCT protocol. (Kaiser *et al.* 2018). Since this is a case study, documenting the findings of only one participant, the results need to be considered with caution.

There is limited evidence supporting the use of the AAI within the AMCT protocol in treating neck pain and cervical spine dysfunction even though there seems to be consensus that the clinical outcome tends to be positive for the patients. Since the RCTs conducted were small in size, larger RCTs should be conducted in future addressing the limitations that have been addressed and discussed for each article. The case studies should have their outcomes confirmed or refuted through a formally structured, fully powered trial. There is limited evidence supporting the use of AAI within the AMCT protocol over manual adjusting. All of the above articles utilized subjective outcome measures that related to pain levels (other outcome measures were also included). The evidence suggests that both treatment methods are equally effective in reducing pain and alleviating symptoms in patients. Since manual adjusting has previously been proved to be better and more effective than placebo (Hoiriis *et al.* 2004; Santilli, Beghi and Finucci 2006), AAI within the AMCT protocol is also better than placebo as both of these interventions produced results and outcomes that were equally as effective when compared in articles.

The datedness of the above articles is a concern and new publications that are compliant with current research practices should be carried out in order to improve the structure of the articles and the level of evidence available. Application and use of the STROBE (Cuschieri 2019),

CONSORT (Turner *et al.* 2012), and CARE (Riley *et al.* 2017) guidelines would be beneficial for future research studies.

Since there is limited evidence supporting the use of the AAI within the AMCT protocol in treating cervical spine complaints, there are challenges that arise in clinical practice:

- the impossibility of providing an evidence informed base of information to patients, which impacts on the ability of the patient to receive adequate information to provide fully informed consent decisions (Allied Health Professions of South Africa 2015; Boucher, Brousseau and Chahine 2016),
- the inability to produce clinical practice guidelines which could steer the informed consent process (Gambrill 2003) and
- the erosion of multi and inter-disciplinary confidence within professions and between professions in relation to the use of mobilisation as a modality (Makaram 1995).

5.4.1.2 Articles using the AAI as an adjustment tool (AAI technique) outside of the AMCT protocol

Table 5. 4: Spinal region: Cervical spine (AAI as an adjustment tool (AAI technique) outside of the AMCT protocol)

Author(s) / Year:	**Study Type:**	**Internal validity ranking:**	**External validity ranking:**	**-Clinical outcome -Level of evidence of each article -Programme of intervention or individual intervention**	**Level of Evidence:**					
					Strong	**Moderate**	**Limited**	**Consensus**	**Conflicting**	**No Evidence**
Gemmell, Miller, 2010	RCT	8/11 (Good)	Poor	-Positive -No evidence -Programme of intervention						
Gorrell, Beath, Engel, 2016	RCT	8/11 (Good)	Poor	-Positive -No evidence -Programme of intervention						
Hardas, Murrell, 2018	RCT	11/11 (Excellent)	Poor	-Positive -Limited -Individual intervention				**X**		**X**
Kendall, French, Hartvigsen, Azari, 2018	RCT	11/11 (Excellent)	Poor	-Positive -No evidence -Programme of intervention						

Given the outcomes of these reviews, it would suggest that there is no evidence (Foley *et al.* 2003b) in favour of the use of the AAI technique in treating pain in the cervical spine of patients. Due consideration of the limitations of these articles is required.

There are four RCTs in this category that all provide positive clinical outcomes and have good to excellent internal validity when being reviewed with the PEDro scale, however each one of these articles has poor external validity which reduces the level of evidence they provide. Three of these articles involve the use of an intervention programme and therefore these three articles provide no level of evidence for or against the use of the AAI technique in treating cervical spine complaints. The outcomes of these three articles that utilize an intervention programme cannot be directly related to the intervention of the AAI technique as the other interventions used may have influenced the outcomes too and therefore these three articles cannot provide any evidence in support of or against the use of the AAI technique. (Kaiser *et al.* 2018).

Gemmell and Miller (2010) assessed the effect of cervical manipulation, mobilisation and the AAI technique in participants with acute non-specific neck pain. This article concluded that all treatment methods used successfully reduced neck pain in the participants. No single method proved to be more favourable than the others. Whilst previous articles have proven manual manipulation to be more effective and better than placebo (Hoiriis *et al.* 2004; Santilli, Beghi and Finucci 2006), the use of mobilisation and AAI technique in this article cannot also be noted as being better than placebo purely because they produced outcomes that were similar to manual manipulation in this article. This is due to the fact that these interventions were not used as single interventions. This article involved the use of an intervention programme, the outcomes of this article cannot be directly related to the intervention of only the AAI technique as the other interventions used may have influenced the outcomes too and this article cannot provide evidence in support of or against the use of the AAI technique. (Kaiser *et al.* 2018). Since the outcome measures were mostly subjective in this article, the patient influencers may have detracted from the ability of the article to report accurate clinical changes. The limitations in this article need to be considered, myofascial complaints were treated in the participants with no controls or standardization across home care advice and stretches advised to participants. This variable impacted the results of this article and therefore this article provides no level of evidence. This RCT was stopped due to poor recruitment.

Gorrell, Beath and Engel (2016) compared the effectiveness of manual and instrument (AAI) applied cervical manipulation in treating mechanical neck pain. A single treatment session was done with each participant in this article, no follow up care or treatment was included. Each

group was treated by a different practitioner which may have impacted the results in this article. This article concluded that manual manipulation provided more pain reduction after a single treatment session in participants with mechanical neck pain than AAI adjustments did. A programme of intervention was used in this article and as a result, the outcomes of this article cannot be directly related to the intervention of the AAI technique as the other interventions used may have influenced the outcomes too and this article cannot provide evidence in support of or against the use of the AAI technique. (Kaiser *et al.* 2018).

Hardas and Murrell (2018) assessed the effect of adjusting C5 with an AAI on referred pain to the shoulder in participants. Since pain reduction was equal in both the intervention group as well as the control group, the causative factor for the pain reduction may purely be elapsed time. This article had excellent internal validity however the external validity of this article was poor. Majority of the outcomes noted were objective which reduces the level of bias that would have occurred if the majority of the outcomes were subjective in nature (Thornton *et al.* 2017). This article did not make use of an intervention programme and provides a limited level of evidence in support of the use of the AAI technique in treating cervical spine complaints.

Kendall *et al.* (2018) assessed the effectiveness of the AAI technique in treating neck pain and non-specific dizziness in participants. The group receiving treatment with the AAI technique had significant improvement in their neck pain as well as their dizziness when compared to the control group. The participants were not merely treated with an AAI adjustment - myofascial complaints were also treated with joint mobilisation, massage, range of motion neck exercises or home advice, therefore this article provides no evidence for or against the use of the AAI technique. A programme of intervention was used in this article and as a result, the outcomes of this article cannot be directly related to the intervention of the AAI technique as the other interventions used may have influenced the outcomes too and this article cannot provide evidence in support of or against the use of the AAI technique. (Kaiser *et al.* 2018).

Three of the above articles provide no level of evidence. Hardas and Murrell (2018) provide limited evidence, however the intervention appeared to be no more effective than placebo in this article. Therefore, there is no evidence in support of or against the use of the AAI technique in treating cervical pain complaints.

Further studies need to be conducted that take into consideration the limitations in these articles and address the numerous pitfalls of each article. Compliance with guidelines and checklists is imperative in future studies in order for valuable and reliable evidence to be collated.

Since there is no evidence supporting the use of the AAI technique in treating cervical spine complaints, there are challenges that arise in clinical practice:

- the impossibility of providing an evidence informed base of information to patients, which impacts on the ability of the patient to receive adequate information to provide fully informed consent decisions (Allied Health Professions of South Africa 2015; Boucher, Brousseau and Chahine 2016),
- the inability to produce clinical practice guidelines which could steer the informed consent process (Gambrill 2003) and
- the erosion of multi- and inter-disciplinary confidence within professions and between professions in relation to the use of mobilisation as a modality (Makaram 1995).

Comparing the outcomes of the evidence for the use of the AAI within the AMCT protocol and the use of the AAI technique in treating cervical spine complaints, the AAI within the AMCT protocol has more evidence behind its use, although limited. The use of the AAI within the AMCT protocol is better than placebo. There is no evidence for or against the use of the AAI technique in treating cervical spine complaints.

5.4.2 Lumbar spine, sacroiliac, and coccygeal region (Low back)

5.4.2.1 Articles using the AMCT protocol

Table 5. 5: Spinal region: Lumbar spine, sacroiliac, and coccygeal region (AMCT protocol)

Author(s) / Year:	Study Type:	Internal validity ranking:	External validity ranking:	-Clinical outcome -Level of evidence of each article -Programme of intervention or individual intervention	Level of Evidence:					
					Strong	Moderate	Limited	Consensus	Conflicting	No Evidence
Schneider, Brach, Irrgang, Abbott, Wisniewski, Delitto, 2010	NRCT	5/9 (Moderate)	Poor	-Positive -No evidence -Programme of intervention						
Osterbauer, De Boer, Widmaier, Petermann, Fuhr, 1993	CS	A:1 B1:1 B2:3 C:1 I:0 n/a:5	Poor	-Positive -No evidence -Individual intervention						
Polkinghorn, 1998	CS	A:1 B1:0 B2:1 C:2 I:0 n/a:7	Poor	-Positive -No evidence -Individual intervention						
Polkinghorn, 1999	CS	A:1 B1:0 B2:3 C:0 I:0 n/a:7	Poor	-Positive -No evidence -Individual intervention				X		X
Roberts, Wolfe, 2012 (a)	CS	A:0 B1:3 B2:1 C:0 I:0 n/a:7	Poor	-Positive -Limited -Individual intervention						
Roberts, Wolfe, 2012 (b)	CS	A:0 B1:1 B2:2 C:1 I:0 n/a:7	Poor	-Positive -No evidence -Programme of intervention						

Given the outcomes of these reviews, it would suggest that there is no evidence (Foley *et al.* 2003b; Dagenais and Haldeman 2011) surrounding the use of the AAI within the AMCT protocol in treating pain in the lumbar spine, sacroiliac, and coccygeal region.

Schneider *et al.* (2010) assessed the effect of manual versus AAI adjustments within the AMCT protocol on low back pain in participants. Whilst both groups reported pain reduction, this article found that manual adjustments reduced the low back pain of participants more than AAI adjustments within the AMCT protocol. A programme of intervention was used in this article and as a result, the outcomes of this article cannot be directly related to the intervention of the AAI within the AMCT protocol as the other interventions used may have influenced the outcomes too and this article cannot provide evidence in support of or against the use of the AAI within the AMCT protocol. (Kaiser *et al.* 2018).

Osterbauer *et al.* (1993) assessed the effect AAI adjustments within the AMCT protocol on participants with chronic SIJ syndrome and found that pain was significantly reduced after a few treatments. Polkinghorn (1998) assessed the effect of AAI adjustments within the AMCT protocol on participants with symptomatic lumbar disc herniations. This case study involved a single participant, and the participants pain was reduced and presenting neurological symptoms resolved within a few weeks of initiating treatment. Polkinghorn (1999) assessed the effect of AAI adjustments within the AMCT protocol on a single participant with coccygodynia. This case study reported pain resolution after a single treatment session. Whilst all of these articles produced favourable results and no programme of intervention was used, the internal and external validity of these articles was poor and therefore there is no level of evidence provided by these articles.

Roberts and Wolfe (2012) (a) assessed the effect of AAI adjustments within the AMCT protocol on a geriatric patient with low back pain and comorbidities of cancer, compression fractures, and osteoporosis. Whilst the patient did report a reduction in pain and objective findings noted improvements in disability, there were many limitations in this article which resulted in poor external validity. This is a case study of a single participant, and the findings are not generalizable to the general population. Specific attention needs to be given to the patient presentation in this case study when considering this evidence. This article provides limited evidence in support of the use of the AAI within the AMCT protocol in treating low back pain.

Roberts and Wolfe (2012) (b) also conducted a case study of a veteran with low back pain associated with diffuse idiopathic skeletal hypertrophy and degenerative disk disease, where

the participant was treated with the AAI within the AMCT protocol. This article involved the use of a programme of intervention and therefore provides no evidence.

It is noted that all of the articles completed prior to the year 2000 (Osterbauer *et al.* 1993; Polkinghorn and Colloca 1998, 1999; Schneider *et al.* 2010) provide no level of evidence. Roberts and Wolfe (2012) (a) provided no level of evidence whereas Roberts and Wolfe (2012) (b) provided limited evidence. Since updated checklists and guidelines (such as STROBE (Cuschieri 2019), CONSORT (Turner *et al.* 2012), and CARE (Riley *et al.* 2017)) have been published since these studies were completed, these should be used and followed in future research studies.

There is evidently no evidence available that is able to guide treatment guidelines and informed consent. As a result of not having any evidence in support of or against the use of the AAI within the AMCT protocol in treating lumbar spine, sacroiliac, and coccygeal complaints, the following challenges arise in clinical practice:

- the impossibility of providing an evidence informed base of information to patients, which impacts on the ability of the patient to receive adequate information to provide fully informed consent decisions (Allied Health Professions of South Africa 2015; Boucher, Brousseau and Chahine 2016),
- the inability to produce clinical practice guidelines which could steer the informed consent process (Gambrill 2003) and
- the erosion of multi and inter-disciplinary confidence within professions and between professions in relation to the use of mobilisation as a modality (Makaram 1995).

5.4.2.2 Articles using the AAI as an adjustment tool (AAI technique) outside of the AMCT protocol

Table 5. 6: Spinal region: Lumbar spine, sacroiliac, and coccygeal region (AAI as an adjustment tool (AAI technique) outside of the AMCT protocol)

Author(s) / Year:	Study Type:	Internal validity ranking:	External validity ranking:	-Clinical outcome -Level of evidence of each article -Programme of intervention or individual intervention	Level of Evidence:					
					Strong	Moderate	Limited	Consensus	Conflicting	No Evidence
Coetzee, 2013	RCT	9/11 (Good)	Poor	-Positive -Limited -Individual intervention						
Gemmell, Jacobson, 1995	RCT	8/11 (Good)	Poor	-Positive -Limited -Individual intervention						
Gillespie, 2003	RCT	7/11 (Moderate)	Poor	-Positive -Limited -Individual intervention			X	X		
Shearar, 2003	RCT	7/11 (Moderate)	Poor	-Positive -Limited -Individual intervention						

Given the outcomes of these reviews, it would suggest that there is limited evidence (Foley *et al.* 2003b; Dagenais and Haldeman 2011) in favour of the use of the AAI technique in treating pain in the lumbar spine, sacroiliac, and coccygeal regions of patients. Due consideration of the limitations of these articles is required.

Coetzee (2013) assessed the effect of the AAI technique in treating chronic SIJ syndrome. This article concluded that the AAI is effective in treating chronic SIJ syndrome with the treatment group having more pain reduction than the control group. This study was conducted by a novice researcher and had poor external validity. The subjective outcome measures in this article may have been influenced by factors such as the Hawthorne or Observer effect and therefore may have detracted from the ability of the article to report accurate clinical changes. The objective findings in this article did also however note improvement in participants. This article provides limited evidence for the use of the AAI technique in treating pain in the lumbar spine, sacroiliac, and coccygeal regions of patients.

Gemmell and Jacobson (1995) compared the immediate effect of AAI technique adjustments and meric adjustments on acute low back pain in participants and Gillespie (2003) compared the same two treatment methods in reducing pain in participants with acute facet syndrome of the lumbar spine. Shearar (2003) also compared the same two treatment methods, assessing their effectiveness in managing acute on chronic sacroiliac syndrome. These articles all concluded that both interventions reduce pain levels, equally. Therefore, one treatment method isn't more effective in reducing the pain in patients with acute low back pain, acute lumbar facet syndrome or acute chronic sacroiliac syndrome pain. Since manual adjustments are more effective and better than placebo (Hoiriis *et al.* 2004; Santilli, Beghi and Finucci 2006), the AAI technique may too be better than placebo in treating lumbar spine, sacroiliac, and coccygeal complaints since there were no differences in the outcomes between the groups. The degree of the improvement beyond that of placebo is then limited to the bias introduced through the external validity discussions.

There are four RCTs that all provide a limited level of evidence in support of the use of the AAI technique in treating lumbar spine, sacroiliac, and coccygeal complaints. This evidence suggests that this treatment is able to reduce pain and improve range of movement in the lumbar spine, sacroiliac, and coccygeal regions of the spine. Application and use of the STROBE (Cuschieri 2019), CONSORT (Turner *et al.* 2012), and CARE (Riley *et al.* 2017) guidelines would be beneficial for future research studies in order to achieve a stronger level of evidence to base treatment guidelines and informed consent on the evidence.

Since there is limited evidence supporting the use of the AAI technique in treating lumbar spine, sacroiliac, and coccygeal complaints, there are challenges that arise in clinical practice:

- the impossibility of providing an evidence informed base of information to patients, which impacts on the ability of the patient to receive adequate information to provide fully informed consent decisions (Allied Health Professions of South Africa 2015; Boucher, Brousseau and Chahine 2016),
- the inability to produce clinical practice guidelines which could steer the informed consent process (Gambrill 2003) and
- the erosion of multi and inter-disciplinary confidence within professions and between professions in relation to the use of mobilisation as a modality (Makaram 1995).

Comparing the outcomes of the evidence for the use of the AAI within the AMCT protocol and the use of the AAI technique in treating lumbar spine, sacroiliac, and coccygeal complaints, the AAI technique has more evidence behind its use, although limited. There is no evidence

for or against the use of the AAI within the AMCT protocol in treating lumbar spine, sacroiliac, and coccygeal complaints.

It is noted that the AAI technique has a greater number of RCTs (the AAI within the AMCT protocol has no RCTs for this spinal region). This is possibly due to the AAI technique possibly being more supported despite the evidence only being marginally better when compared to the AAI within the AMCT protocol. There is also a possibility that RCTs may have been conducted and carried out yet remain inaccessible and unpublished due to achieving unfavourable results.

5.4.3 Full spinal

5.4.3.1 Articles using the AMCT protocol

Table 5. 7: Spinal region: Full spinal (AMCT protocol)

Author(s) / Year:	**Study Type:**	**Internal validity ranking:**	**External validity ranking:**	**-Clinical outcome -Level of evidence of each article -Programme of intervention or individual intervention**	**Level of Evidence:**					
					Strong	**Moderate**	**Limited**	**Consensus**	**Conflicting**	**No Evidence**
Norton, Callanan, 2013	CS	A:0 B1:1 B2:1 C:3 I:0 n/a:6	Poor	-Positive -No evidence -Programme of intervention				**X**		**X**
Russell, Kimura, Cowie, de Groot, McMinn, Sherson, 2016	CS	A:3 B1:1 B2:1 C:2 I:0 n/a:4	Poor	-Positive -No evidence -Programme of intervention						

Given the outcomes of these reviews, it would suggest that there is no evidence (Foley *et al.* 2003b; Dagenais and Haldeman 2011) surrounding the use of the AAI within the AMCT protocol in treating spinal pain (full spinal region). A programme of intervention was used in both of these articles and as a result, the outcomes of these articles cannot be directly related to the intervention of the AAI within the AMCT protocol as the other interventions used may have influenced the outcomes too. Therefore, these articles provide no evidence in support of or against the use of the AAI within the AMCT protocol. (Kaiser *et al.* 2018).

Norton and Callanan (2013) assessed the reduction of symptoms associated with Parkinson's disease as a result of AAI adjustments within the AMCT protocol. This case study suggested that pain reduction was evident in the participant as well as reduction in symptoms associated with Parkinson's disease. Russel *et al.* (2016) assessed the impact AAI adjustments within the AMCT protocol had on the quality of life of older adults. This case study suggested that quality of life was improved in the participants. Whilst both of these articles produced favourable results, there is no evidence produced in support of or against the use of the AAI within the AMCT protocol as the intervention used as part of an intervention programme in both of these articles as not as a standalone treatment. One therefore cannot identify which part of the programme intervention was responsible for the outcomes noted. Future studies need to address this limitation in order for evidence to be collated for this area.

Only case studies are available considering the full spinal region using the AAI within the AMCT protocol (no RCTs or NRCTs) and there are no articles available considering the full spinal region with the AAI technique. It is unclear as to why this is the case. It is again possible that RCTs may have been carried out and possibly produced unfavourable results, and as a result have been kept inaccessible and unpublished. It is also possible that when RCTs are carried out they aim for specificity, and therefore focus on a specific region or area of concern in participants therefore resulting in no RCTs covering the general spinal region.

Since there is no evidence for either AAI technique or AAI within the AMCT protocol in treating the full spinal region, informed consent cannot be utilized as there is no evidence to base it on. There is also no evidence available that is able to guide treatment guidelines. As a result of not having any evidence in support of or against the use of the AAI within the AMCT protocol in treating the full spinal region, the following challenges arise in clinical practice:

- the impossibility of providing an evidence informed base of information to patients, which impacts on the ability of the patient to receive adequate information to provide fully informed consent decisions (Allied Health Professions of South Africa 2015; Boucher, Brousseau and Chahine 2016),
- the inability to produce clinical practice guidelines which could steer the informed consent process (Gambrill 2003) and
- the erosion of multi and inter-disciplinary confidence within professions and between professions in relation to the use of mobilisation as a modality (Makaram 1995).

5.4.4 Articles using the AMCT protocol that assess sEMG response

Table 5. 8: Spinal region: Lumbar spine, sacroiliac, and coccygeal region (AMCT protocol)

Author(s) / Year:	Study Type:	Internal validity ranking:	External validity ranking:	-Clinical outcome -Level of evidence of each article -Programme of intervention or individual intervention	Level of Evidence:					
					Strong	Moderate	Limited	Consensus	Conflicting	No Evidence
Keller, Colloca, 2000	NRCT	8/9 (Good)	Poor	-Positive -Limited -Individual intervention						
DeVocht, Pickar, Wilder, 2004	CS	A: 5 B1: 3 B2: 1 C: 0 I: 0 n/a: 2	Poor	-Positive -Limited -Individual intervention			X	X		

There is very limited evidence surrounding the effect of AAI adjustments on sEMG levels and spinal pain. (Foley *et al.* 2003b; Dagenais and Haldeman 2011).

Keller and Colloca (2000) assessed the effect that AAI adjustments within the AMCT protocol have on trunk muscle strength in participants with low back pain. DeVocht, Pickar and Wilder (2004) assessed the effect of adjustments within the AMCT protocol on the sEMG levels of paraspinal muscles in patient with low back pain and tight paraspinal muscles.

Since this systematic review is focused on spinal pain and pain reduction through treatment with the AAI, the sEMG findings will not be discussed further in the conclusion (5.5). Further research should also be conducted to assess the relationship between sEMG levels and spinal pain in patients as well as the effect AAI adjustments have on sEMG levels when compared to other treatment methods.

5.5 Conclusion

Table 5. 9: Level of evidence supporting pain reduction for each region of the spine (AAI within the AMCT protocol)

Spinal region	Level of Evidence:					
	Strong	Moderate	Limited	Consensus	Conflicting	No Evidence
Cervical spine			X	X		
Lumbar spine, sacroiliac, and coccygeal region				X		X
Full spinal				X		X

Table 5. 10: Level of evidence supporting pain reduction for each region of the spine (AAI as an adjustment tool (AAI technique) outside of the AMCT protocol)

Spinal region	Level of Evidence:					
	Strong	Moderate	Limited	Consensus	Conflicting	No Evidence
Cervical spine				X		X
Lumbar spine, sacroiliac, and coccygeal region			X	X		

Given Table 5.9 and 5.10 above, representing a summary of the review outcomes for the use of the AAI within each spinal region (AAI used within the AMCT protocol and AAI used as an adjustment tool (AAI technique) outside of the AMCT protocol), it is clear that further research is needed.

There is limited evidence supporting the use of the AAI within the AMCT protocol in the cervical region only and no evidence in the remaining spinal regions (lumbar spine, sacroiliac, and coccygeal regions and the full spinal region). The AAI as an adjustment tool (AAI technique),

outside of the protocol has limited evidence supporting its use in the lumbar spine, sacroiliac, and coccygeal regions and no evidence in the cervical spine or for the full spinal region.

Only two RCTs surrounding the use of the AAI within the AMCT protocol in treating the cervical spine and one NRCT surrounding this interventions' use in treating lumbar spine, sacroiliac, and coccygeal regions. The remaining articles for the use of the AAI within the AMCT protocol are all case studies/reports.

There is a possibility that certain studies have not been published and remain inaccessible due to attaining unfavourable outcomes. This systematic review may therefore have been affected by publication bias.

It is noted that a majority of the RCTs completed surrounding the use of the AAI have been assessing the use of the AAI as an adjustment tool (AAI technique) outside of the protocol. There are only two RCTs and one NRCT that assess the effectiveness of the AAI within the AMCT protocol in treating spinal pain, the remainder of the articles are case studies. This is concerning as the AAI is being used within the AMCT in clinical practice, case studies are being completed, yet there is evidently a limitation to the evidence in support of or against its use. It is also evident that there are no articles for either the AAI technique or the AAI within the AMCT protocol that focus on the thoracic region. Further research is needed in the form of large scale, fully powered RCTs that assess the effectiveness of the use of the AAI as an adjustment tool (AAI technique) outside of the AMCT protocol as well as the AAI within the AMCT in treating spinal pain. Future research needs to consider updated checklists and guidelines and must follow these as well as consider the limitations and pitfalls noted in articles in this systematic review, in order to ensure that quality evidence can be collated.

The testing of manual therapies is a difficult enterprise in that there is a limitation of blinding with regards to the patients (unless they are totally naïve about the intervention) in addition to a limitation in blinding the practitioner's treating patients. This requires that the articles consider independent patient screeners, therapists and outcome assessors in order to effectively blind the process in such a manner as to ensure minimal impact on the outcomes of the article. This influenced the external validity in many of the articles included in this systematic review and future studies should consider these factors.

Many of the articles in this systematic review made use of a programme of intervention and this resulted in these articles providing no evidence in support of or against the use of the AAI technique or the AAI within the AMCT protocol. This detracted from many of the articles'

abilities to draw specific conclusions around particular techniques being responsible for certain outcomes. This is possibly also due to a large number of case studies in this systematic review, where the treatment was carried out as usual and there was no effort to isolate and use just the intervention being investigated in this systematic review. Future studies should be mindful of this as a single intervention needs to be used in order to provide any level of evidence in support of or against the intervention.

The clinical presentation of spinal pain does not account for all the variables that patients present with. As a result, the lack of sample group homogeneity provides for a difficult environment within which to test specific interventions. This requires some deliberation in order for articles to show greater consistency in the application of the criteria and delineation of the sample populations. Without this, the results of the articles reviewed now and in the future may remain ambivalent as the manner in which these subsets of patients respond is different and directly impacts on the overall outcome of the group's results. Since many of the articles included in this systematic review did not account for this and did not manage to control homogeneity of participants and/or condition homogeneity between participants, the external validity of many articles was negatively affected and the level of evidence affected by this lack of homogeneity.

Monitoring the changes of outcomes in patients with spinal pain seems to be heavily reliant on subjective outcome measures completed by the patient, with few objective measures that can corroborate these findings. This results in the studies being influenced by patient perception, patient satisfaction and patient expectations, the Hawthorne and Observer effects, which makes it more difficult to conclusively state whether the changes in the patient's clinical presentation is as a direct result of the intervention. Notwithstanding the varying levels of evidence between spinal regions and between the AAI technique and the AAI within the AMCT protocol; more research is required in all fields addressing the concerns highlighted in this discussion in order for the evidence to be improved and better evaluated so that practical recommendations for patients are based on a solid evidence-based foundation (Bronfort *et al.* 2010).

Practitioners need to be aware and mindful of the limited level of evidence (and no evidence in some areas) supporting the use of the AAI technique or the AAI within the AMCT protocol when they are deciding on forms of treatment to use and going through the process of informed consent with patients.

CHAPTER SIX CONCLUSION AND RECOMMENDATIONS

6.1 Introduction

This chapter concludes this dissertation and presents recommendations for future studies as well as recommendations for practitioners utilising the intervention reviewed.

6.2 Conclusions

The aim of this study was to identify and analyse the literature and therefore state the current knowledge of the effectiveness of the use of the Activator Adjusting Instrument in treating spinal pain. Through conducting a systematic search, 23 articles were selected to be reviewed in this systematic review. These articles were selected in a methodological manner and were screened through inclusion and exclusion criteria.

These articles were reviewed by appointed reviewers, as well as the researcher, using the appropriate scales and measurement tools per study type. This allowed for each article to be evaluated and critiqued in order to be ranked according to the level of evidence in support of, or against, the use of the AAI in treating spinal pain. Each article has been discussed in Chapter Four following the evaluation of each article's methodological rigour (internal validity) and external validity.

Based on the outcomes of the above evaluation and analysis of each article, it was determined whether the articles provided evidence in support of, or against, the use of the AAI in treating spinal pain in clinical practice. This was presented in Chapter Five and contextualised utilising the criteria outlined by Foley *et al.* (2003).

Therefore, in the context of the above, this systematic review concluded that the use of the AAI within the AMCT protocol has limited evidence supporting its use in the cervical region and no evidence supporting or against its use in clinical practice for the thoracic, lumbar, sacroiliac, and coccygeal regions of the spine. There are two RCTs, one NRCT and case studies that have been completed measuring its effect on spinal pain..

This systematic review concludes that the AAI being used as an adjustment tool (AAI technique) outside of the AMCT protocol has limited evidence to support its use in the lumbar, sacroiliac, and coccygeal regions of the spine. There is no evidence in support of, or against,

the use of the AAI in the cervical or thoracic regions and this needs to be considered by practitioners as well as researchers.

Whilst the AAI adjustment (both the AAI technique or the AAI within the AMCT protocol) is not more effective at reducing spinal pain when compared to manual adjustment techniques, it is comparable in the spinal areas where there is limited evidence, producing similar pain reduction in patients with spinal pain in these regions.

This systematic review did not focus on the sEMG response to AAI adjustments, however, there were two articles which did measure sEMG responses to adjustments using the AAI within the AMCT protocol. The two articles produced limited evidence supporting the use of the AAI within the AMCT protocol and further research should be conducted assessing the relationship between AAI adjustments (AAI technique and/or the AAI within the AMCT protocol), sEMG responses and spinal pain.

The need for further research, in all the above fields, is evident in order to expand on the limited pool of existing evidence. This would strengthen the available literature and allow for improved clinical decision-making based on evidence that is of high quality and practical value. This will also allow for evidence-based practice to occur as well as informed consent procedures.

6.3 Recommendations

6.3.1 Recommendations to improve this systematic review

In future systematic reviews, it may be advantageous to familiarise the reviewers with the appropriate measurement tools and scales being used, prior to the review process. Familiarity with and understanding of the scales may reduce reviewer variance and may reduce the possibility for interpretation bias in the review process. Future systematic reviews may consider a ‘test’ review prior to the actual review process starting, so that the results of such a ‘test’ review could be discussed, in order to deal with any misunderstandings or confusion.

Reviewers were sent explanations of each of the scales being utilized in this systematic review, however interpretation and understanding of the explanations and scales themselves, may have differed between reviewers. The scales used to evaluate articles need improvement

overall in order to facilitate the evaluation process of articles and reduce the potential for confusion or misunderstanding when being utilized.

The amount of funds utilised for this study could be increased in order to permit the inclusion of non-English articles in the systematic review. This would increase the number of articles included in the systematic review and therefore improve the value of the systematic review, as more evidence would be included in the summation and analysis procedures. This would also limit the risk of language bias in future systematic reviews by including non-English articles, but it would however introduce a translation bias into the systematic review as non-English articles would need to be translated. The fact that multilingual reviewers may need to be appointed with this recommendation would also need to be considered.

It is suggested that future systematic reviews include non-English articles, to ensure that all articles within this particular domain are included and form part of the review process and pool of evidence. Whilst this would limit language bias, it would introduce translation bias, which too would then need to be considered in future systematic reviews. (Bero *et al.* 1998; Stern and Kleijnen 2020; Pieper and Puljak 2021).

6.3.2 Recommendations for future studies

In terms of future studies in this domain, it would be important for authors to follow appropriate publication guidelines for the type of study being published (e.g., RCTs, NRCTs, case studies). STROBE, CONSORT, CARE guidelines (Turner *et al.* 2012; Riley *et al.* 2017; Cuschieri 2019). This will make reviewing these articles easier and more efficient and will also highlight the rigour to any novice reader. By improving the methodological presentation in articles, reviewer agreement may increase when these articles are reviewed resulting in further credibility and validity to the article and the domain in which the publication is published.

RCTs provide the highest level of evidence, this is particularly true in the field of manual therapy, where many studies seem to be pragmatic in nature. To improve the evidence in a certain field, it is necessary for researchers to consider study types that will provide stronger forms of evidence in the domain. However, the purer the RCT design the less able the extrapolation of data to the general population. Therefore, there is a tension between the pragmatic nature of NRCTs that are more applicable to practice settings versus the pure RCT that may not be applicable in clinical practice but most accurately measures the intervention.

With manual therapy, a RCT with a pure design is difficult to achieve and it is recommended that the following factors are incorporated into the methodology to make the article structure more rigorous and reliable:

- Optimal sample size
- Determining the sample size through an *a priori* calculation
- Carefully considering exclusion and inclusion criteria
- Homogeneity between participants and groups
- Thoroughly and systematically documenting all diagnostic/ intervention and/or follow-up procedures
- Allowing for a standardisation of interventions between participants
- Use of a single intervention rather than an intervention programme
- Appropriate use of a control group
- Balance between subjective and objective measurement tools
- Use of appropriate measurement tools
- Appropriate blinding
- Appropriate randomisation

6.3.3 Recommendations for practitioners

Since many patients turn to chiropractic treatment for spinal pain, it is important for practitioners to have access to high quality literature to guide decision-making processes and informed consent procedures – particularly as practitioners are increasingly required to work within an evidence-informed model of practice. (Bronfort *et al.* 2010). Within this evidence-informed model of practice, practitioners are required to utilise appropriate and validated tools to measure their patient progress consistently and accurately through their course of treatment whilst basing their treatment protocol on evidence-based guidelines.

It is evident that many practitioners make use of the AAI in clinical practice both within the AMCT protocol and outside of the AMCT protocol (using the AAI as an adjustment tool - AAI technique)). However, this systematic review has shown that there is no evidence supporting the use of the AAI within the AMCT protocol except for in the cervical spine where there is limited evidence; and there is no evidence supporting the use of the AAI as an adjustment tool (AAI technique), except for in the lumbar spine, sacroiliac and coccygeal regions. There is a concern that the AAI technique and/or the AAI within the AMCT protocol is being used in clinical practice treating pain throughout the spinal regions; many case studies and observational studies have been carried out (confirming that these interventions are being

used in clinical practice with patients), whilst there is no supporting evidence in support of, or against, the use in certain areas; and in the areas where there is evidence supporting each intervention, the evidence is limited. There is limited evidence that practitioners can use when providing evidence-based care and obtaining informed consent from patients.

No evidence available to support the use of the AAI within the AMCT protocol:

- Thoracic spine
- Lumbar spine, sacroiliac, and coccygeal region
- Full spinal region

Limited evidence available to support the use of the AAI within the AMCT protocol:

- Cervical spine

No evidence available to support the use of the AAI outside of the AMCT protocol:

- Cervical spine
- Thoracic region
- Full spinal region

Limited evidence available to support the use of the AAI outside of the AMCT protocol (AAI technique):

- Lumbar spine, sacroiliac, and coccygeal region

Given the conclusions of this study, until further research is conducted surrounding the use of the AAI technique and the AAI within the AMCT protocol in the spinal areas where there is no evidence, practitioners are advised to use the activator sparingly in these spinal regions, informing the patient of a lack of evidence, until such time as further studies have been carried out that produce reliable and valid evidence in these spinal regions.

These abovementioned suggestions are to ensure practitioners are using treatment interventions that are supported with reliable and valid evidence to ensure informed consent can be given by patients and that interventions being used in clinical practice have evidenced-based literature supporting its use. (Kapp 2002; Drisko 2020).

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APPENDICES

Appendix A: FRC Letter of Approval

5 December, 2019

Ms RP Proome
Student No: 21533640

PO Box 263
Udloti Beach
4350

Dear Ms Proome

MTECH: CHIROPRACTIC

I am pleased to advise that:

1. The Faculty Research Committee approved the following:

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

A systematic review of the effectiveness of the use of the Activator Adjusting Instrument in treating spinal pain.

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**

2. Your request for funding totalling **R 8 000.00** subject to any literature referred to in Section A of the PG 4a form being accessioned by this University, and any equipment purchased shall become the property of the department.

NOTE: - This funding is not paid directly to you but is controlled by the Faculty Office. Any proposed changes to this funding allocation needs the approval of your supervisor, and Faculty Research Committee

The University Research Committee has stipulated that:

(a) Ownership of any patent registered in respect of the results of your Master's studies is retained by you as the initiator of the project;

(b) Should you make any drift from the results of your Master's studies, you will be required to repay pro rata, the **R 5 000.00** investment which the University Research Committee has made in approving your request for funding;

(c) If the Durban University of Technology provided the equipment/materials for the creation of artefacts, this cost would be refunded to the University if such artefacts were sold and

(d) Durban University of Technology is given first refusal in respect of any possible future sale by you of any patent that may be registered in respect of your said project.

(e) All journal articles, referenced in your dissertation, are to accompany your ring-bound copies when submitting for examination purposes.

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

Yours sincerely

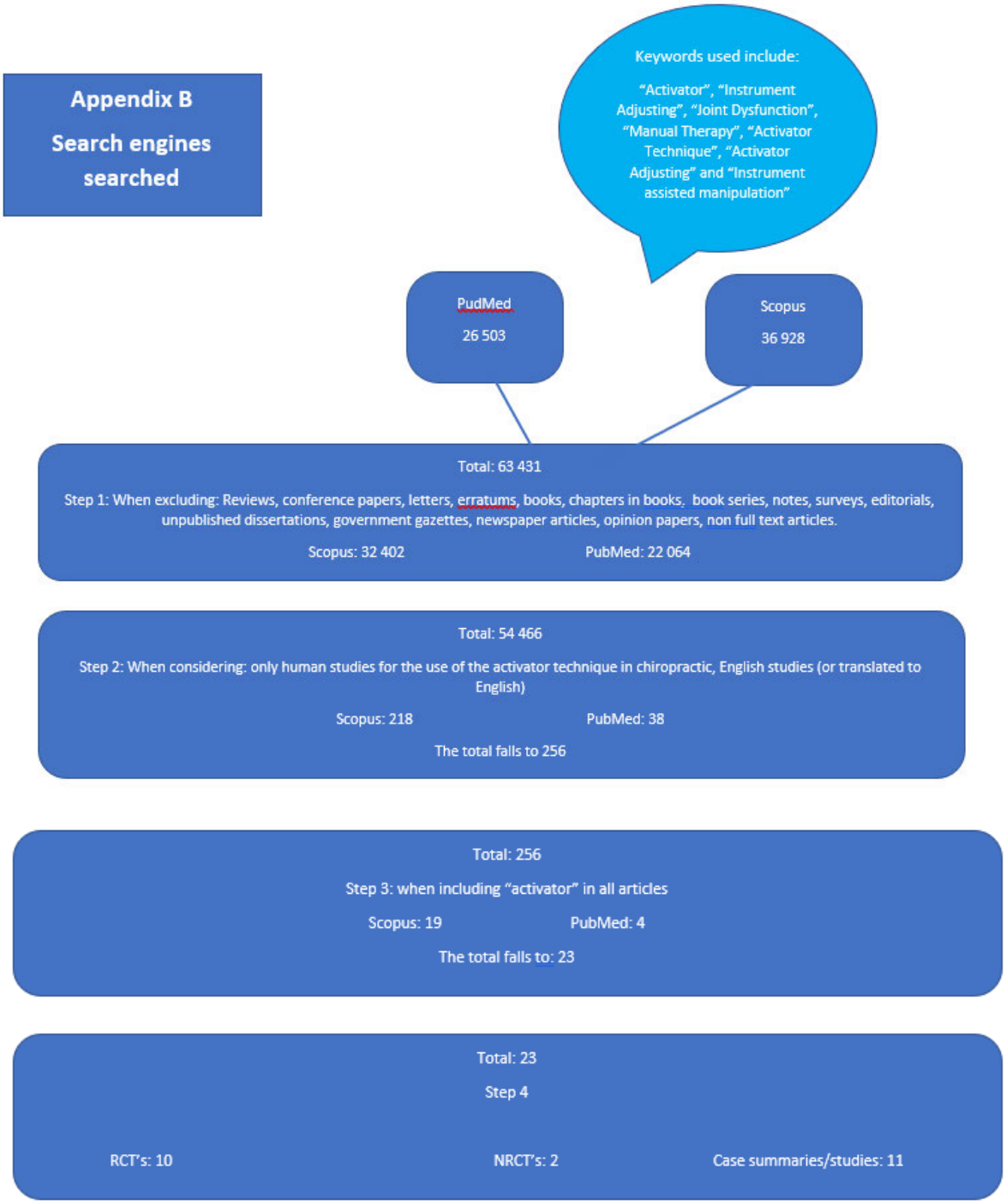
Ms S Perumal
FACULTY RESEARCH OFFICER

21/01/2020

Student's signature in acceptance of the conditions contained herein.

Date:

Appendix B: Flow chart of article selection



Appendix C: Memorandum of Agreement

Title of Research:	A systematic review of the effectiveness of the use of the Activator Adjusting Instrument (AAI) in treating spinal pain.
Researcher:	Roxanne Patricia Proome.
Supervisor:	Dr. C. Korporaal (MTech:Chiropractic, CCFC, CCSP, ICSSD).

Introduction and purpose of the study

This study is a systematic review of the effectiveness of the use of Activator Adjusting Instrument (AAI) in the treatment of spinal pain. The Activator Methods Chiropractic Technique (AMCT) is often described in terms of its protocol as well as technique and intervention. The Activator protocol and technique differ and this study focuses on the technique itself, rather than the protocol. This study aims to review and summarise the evidence available of the use of the AAI in treating spinal pain and from that be able to develop an evidence-based summation of previous studies.

Outline of the procedure

Articles relevant to the study will be collected from electronic databases. Inclusion and exclusion criteria are used to find the relevant articles, this has then been followed by a hand search to ensure that all relevant articles are included. The final list of articles has been randomly allocated into 3 groups. Each group will be randomly allocated to 2 separate reviewers. A week after the reviewers have been sent this MoA, a follow up email will be sent to confirm the receipt of the document as well as to check if they have any concerns or queries. The articles will then be reviewed using the PEDro scale, Newcastle-Ottawa Scale and the Liddle scale. Reviewers will be allowed a maximum of 8 weeks to complete the review of all studies allocated to them (average number of articles per reviewer is 11). The above processes will be blinded to ensure that the reviews are independent.

Benefits

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

Remuneration

An honorarium of R1000.00 will be awarded to each reviewer as a token of appreciation for the time and effort you will contribute to the completion of this study.

Should you have any questions or uncertainties please do not hesitate to contact:

- Dr. C. Korporaal -083 246 3562/ charmak@dut.ac.za

Statement of Agreement to participate in the study

I _____(Full Name),

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

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

Reviewer's Name and Signature: _____

Date: _____

Researcher's Name and Signature: _____

Date: _____

Supervisor's Name and Signature: _____

Date: _____

Appendix D: Email to appoint reviewers

Dear Prof

I am currently a Chiropractic Master's student at the Durban University of Technology. I am conducting a systematic review of the effectiveness of the use of the Activator Adjusting Instrument in treating spinal pain. When looking for reviewers to take part in this systematic review, I read about your interests within the field. Following that, I would like to know if you would be interested and able to participate as a reviewer in this systematic review I am doing?

I will be allocating each reviewer their articles and will have them sent to each reviewer during September 2020, where there will be an 8 week time frame for the articles to be reviewed and sent back, to either myself or my research supervisor – Dr Charmaine Korporaal. Should you be interested, I have attached the Memorandum of Agreement which contains the pertinent information.

If you have any questions, please don't hesitate to contact me or Dr Korporaal.

Kindest regards,

Roxanne Proome.

Appendix E: PEDro Scale

PEDro Scale:

Reviewer:	
Article Title:	

Please cross out 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 F: Newcastle-Ottawa Scale

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, G.A., Shea, B., O'Connell, D., Peterson, J., Welch, V. and Losos, M., et al. *The Newcastle-Ottawa Scale (NOS) for assessing the quality if nonrandomized studies in meta-analyses.*

Appendix G: Liddle Scale

Liddle Scale: Case Report/Series

Reviewer:	
Article Title:	

EVALUATION CRITERIA FOR THE STUDY:	Comments:	Code Option: A, B1, B2, C, or I
1. Are the study participants well-defined in terms of time, place and person?		
2. What percentage of individuals refused to participate?		
3. Are outcomes measured in a standard, valid and reliable way?		
4. Are outcomes measured in the same way for both intervention and control groups?		
5. Are factors other than the intervention e.g. confounding factors, comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?		
6. What percentage of individuals recruited in to the study are not included in the analysis? (loss to follow-up).		
7. Is the analysis by intention to intervene (treat)?		
8. Are results homogeneous between sites? (multicentre/multisite studies only).		
OVERALL ASSESSMENT OF THE STUDY:		
1. How well was the study done to minimise bias? IF coded as B1, B2 or C, what is the likely direction in which bias might affect the study results?		
2. Is the overall effect of the study due to the study intervention?		
3. Explain if there is any practical/ethical reason why an RCT cannot be done.		
4. Include any other comments		

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

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