Traction for low back pain, the evidence is flawed

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Grant David Plumbley

Student ID: 14162333

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Declaration confirming content of digital version of thesis

I confirm that the content of the digital version of this thesis

Traction for low back pain, the evidence is flawed

is the final amended version following the examination process	Yes
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Student's name	Grant Plumbley
Student ID:	14162333
Student's signature	
Date	12 March, 2018

Preface and/or acknowledgements

Thanks to all that has gone before

I must give enormous thanks and gratitude to all the published authors of the primary scientific literature, the researchers of the systematic reviews, and the clinical practice guideline committee members. Their contributions to our past and current understanding of the epidemiology, clinical assessment, diagnosis, and efficacy of the many treatments applicable to the conundrum of low back pain has been immense. It has and will continue to be, a long, difficult, and controversial journey. I now have great appreciation of the many hours and dedication that such research requires, and applaud all those diligently striving to achieve the best for patients presenting with low back pain. This paper contains a professional critique of the past research, and armed with advancements in time and hindsight, highlights historical deficiencies with the sole purpose to illuminate future research into low back pain, and improve management of this costly condition.

Thanks to all that surround me

This thesis could not have been completed without the gracious, invaluable support of my wife and four boys, extended family and friends, work colleagues, supervisors and staff of Massey University, as well as casual conversations and email correspondence with numerous experts in the field of research. I would also like to thank Dr. Giresh Kanji and the New Zealand Pain Foundation for their scholarship and contribution towards this masters project.

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Abstract

Research suggests the burden of low back pain is growing despite recent advances in investigative technology and the explosion in research. Evidence based practice is necessary within physiotherapy. However, the best evidence component must be clinically appropriate, accurate, and grounded within pertinent research. The selection of participants and the methodological designs of the studies must be appropriate to provide results valid to everyday clinical practice. Systematic reviews and meta-analyses consider primary research to critically analyse research questions, and formulate scientific conclusions on the efficacy of interventions. These research derived conclusions then inform clinical practice guidelines which are envisioned to improve clinical practice. These guidelines are also utilised by educational facilities to flavour their curriculum, and by insurance and governmental policy writers in accrediting specific interventions. Information from today will dictate the beliefs, attitudes, and practices of future graduates, and determine approved treatment options. The reported negative conclusions on the efficacy of traction as an intervention for low back pain have resulted in traction no longer being recommended within clinical practice guidelines, any remaining sporadic use questioned by professional colleagues and policy writers, and it no longer taught at undergraduate level. This is despite its long history, popularity amongst some practitioners, anecdotal evidence supporting its use in the clinical setting, and its demonstrable effects in scientific studies. This masters project argues that the cause of the disparity lies within incongruous study designs, which are not valid to clinical practice. Specifically, caused by the misappropriation of historical definitions and classifications vis-à-vis low back pain cohorts. This has resulted in substantial heterogeneity within study populations themselves, both between groups and between studies, which along with other methodological flaws and inappropriate reporting, has given rise to unwarranted conclusions. These fundamental errors have made the conclusions of scientific trials, systematic reviews, and clinical practice guidelines erroneous, and inapplicable to everyday clinical practice. The ‘evidence based’ recommendations of the

inefficacy of traction has largely caused the demise of this intervention within most clinical practices. It is essential that research derived evidence based guidelines are better informed to improve the management of chronic low back pain.

No more controversial subject exists in Medicine that the treatment of backache. Certainly, there is none in which a body of scientific men allow their judgement to be so strongly swayed by emotion…There is no other disorder in which the temperament of the consultant rather than the nature of the condition determines selection of treatment (Cyriax, 1975, p. 440)

Chapter 1. Introduction

Low back pain (LBP) has been recognised as a leading contributor to disability for many decades, and is frequently managed in primary care. Often people suffering from LBP present to a musculoskeletal physiotherapist for expert, evidence informed assessment, treatment, and management of their pain. Due to its growing global burden, research into LBP is prolific, entering the terms “low* back” OR “lumbar*” OR “low* spin*” OR “non*specific low* back” OR “sciatica” OR “sacroili*" OR “LBP” OR "low* back pain" OR "lbp" OR "SIJ*" into the EBSCO search engine with a limiter on the years of 1960 until 30 June 2017, returned 500,734 results. Despite this plethora of research the global burden of LBP is reported to be increasing, with a 42.6% increase in disability adjusted life years (DALYs) across all ages between 1990 to 2010 (Murray et al., 2013), placing strain on individuals, families, friends, whānau, work, health systems, and governmental and insurance policy writers.

Due to the common occurrence and growing burden of LBP Koes, Bouter, and van der Heijden (1995) looked at the quality of RCTs studying the efficacy of treatment interventions for LBP. They found that there were many interventions for LBP across many medical practitioners, but that none seemed to be superior to any others. As a result, the treatment and management of LBP varied between, and within, medical disciplines. These variations implied a lack of consensus about appropriate assessment and treatment of LBP, even suggesting that some patients may be receiving inappropriate or suboptimal care (Bigos, et al., 1994).

In an attempt to foster better scientific management of LBP and to curtail this increasing burden, it was felt that epidemiological and clinical research should inform the development of Clinical Practice Guidelines (CPGs). There were early attempts to establish scientific approaches and CPGs, including the Quebec Task Force on spinal disorders (Spitzer, 1987) that proposed an early diagnostic classification system, the Dutch College of GPs (Faas et al., 1996), and the Workcover Corporation in Australia[a].

A key problem faced by early committees tasked to provide these guidelines, was how to decide which interventions were most beneficial for sufferers of LBP. A large amount of research had been carried out, but the quality of this research varied considerably. Bloch (1987), performed a search on interventions, and found that from 757 studies on LBP, only eight were RCTs, which are considered the gold standard for clinical research. Bigos et al. (1994) performed a systematic review (SR), and found that for most topics within the assessment, treatment, and management of acute LBP, the quality and clinical applicability of studies were limited. The inclusion and exclusion criteria for participants were often incompletely described, or too broad with wide variations in age, symptoms, symptom duration, examination findings, and prior treatments.

Bigos et al. also found studies inadequately described the baseline demographic and clinical characteristics of subjects. Many not differentiating acute from chronic patients, or controlling for factors known to cause significant variation in outcome, such as prior back surgery. This lead to heterogeneity within and between studies. As well as these fundamental ommissions, studies also had other methodological flaws, such as inapproproiate statistical analysis, or insufficient subjects to attain adequate statistical power, or significant statistical differences which were not clinically significant.

Koes et al. (1995) concluded from their SR that although a considerabe number of RCTs had been undertaken, the overall methodological quality was disappointingly low with major

[a] www.workcover.com

flaws, and further trials with much greater attention to design were needed. Van Tulder, Koes, and Bouter (1997) also found that the design, execution, and reporting of RCTs needed to be improved for various interventions into acute and chronic LBP.

Van der Heijden et al. (1995) was the first to perform a SR specifically on the efficacy of traction for back (and neck) pain. They also found that due to the overall poor methodological quality of the studies reviewed, it was not possible to formulate a strong and valid judgment about lumbar (or cervical) traction.

In fact, they stated that there was no conclusive evidence to suggest that traction was an ineffective therapy for back (or neck pain). In addition, they recommended that future studies should avoid the methodological flaws they observed, more attention should be given to the proper execution of the RCTs, and the crucial features of their design and results should be presented.

Paradoxically, van der Heijden et al. (1995) concluded; “The available RCTs do not allow conclusions about the effectiveness of (cervical or) lumbar traction. Therefore, intervention studies do not support the common practical recommendations or clinical guidelines about traction that are mainly based on the rationale of spinal elongation” (p. 103).

In line with accepted practices regarding SRs, van der Heijden et al. came to the correct conclusion, as it was based upon the poor methodological literature that they identified at the time. However, the fact it was informed by poor studies seemed to be later overlooked, and this conclusion by van der Heijden et al. was misappropriated by others to mean that traction was ineffective for LBP, and may have provided an early death knell for traction in clinical practice.

Recognising the negativity and conflicts surrounding traction as a result of van der Heijden et al. (1995), Harte, Baxter, and Gracey (2003) found that the evidence against the use of traction for LBP was debatable, due to the continued lack of methodological rigor in the RCT studies they examined, as well as the limited utilisation of clinical parameters commonly

considered in clinical practice. Their conclusion was that until further trials which address these areas are designed, no firm conclusions nor recommendations can be made regarding the efficacy of traction in treating people with LBP.

The overwhelming conclusion from these historical researchers, was that the CPGs seem to have been informed by inappropriate conclusions and the critical factor to advance our understanding of LBP was the requirement to improve research standards. Yet despite this controversy, traction has continually been claimed to be an ineffective intervention in SRs on the efficacy of traction for LBP (Clarke, et al., 2005, 2007; Wegner et al., 2013), and consequently not recommended within major CPGs.

1.1 Rationale

Although the poor quality of research had been identified in the past, concerning to the concept of evidence based practice (EBP) is it may not have been heard, and this may have contributed to the unwarranted demise of traction as a physiotherapeutic intervention for LBP. Especially considering its apparent anecdotal effectiveness in the clinic (Krause, Refshauge, Dessen, & Boland, 2000). Only recently has acknowledgement of the poor methodology in past studies become more vocal and accepted (Deyo et al., 2014). Unfortunately this recognition seems to have come rather late.

While EBP is crucial to physiotherapy, it is essential that accurate, clinically appropriate, and pragmatic CPGs are informed from rigorous research. With sound population selection criteria, consistent with the accepted beliefs and definitions at the time, with similar baseline prognostic characteristics, and subjected to appropriate methodological designs. It seems from the conclusions of Deyo et al. that these fundamental factors may have been absent. This thesis will illuminate if estabished definitions were recognised and correctly utilised within academia particularly with respect to traction.

Past researchers may have been working in comparative silos. The efficient dissemination of paper information was more difficult than is possible today with recent advances in

internet technology and current ease of access to electronic library databases internationally. The purpose of this thesis is to collate and expand on the weaknesses previously identified in the methodological designs, to investigate if there was justification of these past critiques on their quality, and to examine if the conclusions from SRs and recommendations within CPGs were justified, and ask what effect these resources may have had on the utilisation of traction in present day clinical practice.

This collation of pertinent literature has not been previously undertaken, and it is envisioned that this will illustrate if there were fundamental errors occurred within established definitions, and encourage relevant stakeholders to undertake careful critique of evidence based on their own clinical experience, and not just abide by CPGs without critical clinical reasoning and debate. It is imperative that patients, health professionals, policy makers, and researchers are made aware that CPG recommendations concerning traction may be founded within studies using inappropriate definitions and other methodological deficiencies. The result of which may be incorrect conclusions and recommendations.

It is critical that the conclusions and recommendations on the efficacy of traction are informed by scientifically sound research, are clinically valid, and are nestled appropriately within an EBP model. The assumption that RCTs are well designed, the expectation that SRs are exceptionally undertaken by fastidious researchers, and then correctly used to inform CPGs to dictate the clinical practice of physiotherapists, is therefore called into question if the recommendations are based upon poor research evidence. This has significant implications for physiotherapy clinical practice within New Zealand and globally.

1.2 Primary Aims

The primary aims of this thesis are;

1. To critically examine past research regarding the efficacy of traction for LBP
2. To illuminate how research contributes to CPGs, and encourage practitioners to be critical of evidence by utilising and applying their already well established clinical reasoning skills.

1.3 Chapter Outline

To achieve these primary aims the outline of this thesis will be as follows;

Chapter 1. Introduction

As discussed

Chapter 2. Background

- Provides background information explaining the historical concept of evidence based medicine, detailing the vital importance of evidence based practice, why it was developed, its philosophy, and how it should be applied in everyday clinical practice (section 2.1).
- Describes the rich history of traction, the variety of its application, its anecdotal clinical effectiveness (section 2.2), and how the research may support its theoretical mechanical physiological effects (section 2.2.1).

Chapter 3. Review of Literature

Consists of an extensive review of literature to detail significant and pertinent literature. When understood, this may explain the disparity between the negative conclusions of research, SRs, and CPGs that traction is not effective, as compared to its historical popularity and anecdotal effectiveness of its clinical application.

This will be achieved by;

- looking at the uncertainty apparent within the epidemiological research into LBP, highlighting weaknesses within the global burden of disease statistics, and detailing confusing research quotes on the incidence of LBP (section 3.1).
- discussing the historical irregularities in the definition of LBP (section 3.2), with respect to its location (section 3.2.1), when it is accompanied by referred leg symptomology (section 3.2.2), difficulties in diagnosis and sub-grouping LBP

pathology (section 3.2.3), and finally the practical differences of this inherent uncertainty of pathoanatomical diagnosis within the clinic as compared to RCTs (section 3.2.4).

- ❖ explaining the importance of correctly delineating the duration of LBP into acute, sub-acute, or chronic pain, along with similar biopsychosocial and prognostic characteristics, which ensures homogeneity both within and between study cohorts (section 3.3), and also considering the natural history of LBP (section 3.3.1).
- ❖ briefly describing the contribution of other recognised methodological flaws within past research (section 3.4).

Chapter 4. Results - Chronological Narrative reviews

This is the results chapter. This will consist of two chronological narrative reviews, one looking at the SRs undertaken on the efficacy of traction and supporting literature, and the second NR looking at prominent CPGs. As there are few clear guidelines for writing a narrative review (NR), this NR will follow Ferrari (2015) who recently published guidelines for improving NR writing in areas related to clinical research.

Chapter 5. Discussion

Will provide a synthesis of the information provided within Chapters 2 and 3, and the results of the two narrative reviews in Chapter 4, to detail an argument investigating if the current CPGs are based on valid methodologically sound research, and are making an appropriate contribution within an effective EBP model.

Chapter 6. Conclusion

Will conclude with a simple overview of the thesis and clinical pearl

Chapter 2. Background

This chapter will explain the concept of evidence based practice (section 2.1), and give an indication of the rich history of traction, its anecdotal clinical effectiveness (section 2.2), and provide a brief summary of the chapter (section 2.3).

2.1 The history and importance of evidence based practice

As early as the 1970s, it was shown that the postulation that medical decisions and subsequent treatments were being made appropriately was wrong. The assumptions, that due to the rigors of medical education, the use of continuing education and the clinicians individual clinical experience, the availability of scientific journals, and the exposure to colleagues, so ensuring physicians always did the right thing, were shown to be incorrect. Wennberg and Gittelsohn (1973) documented wide variations in practice patterns within hospitals in Vermont USA, by simply explaining that since physicians were recommending different things for the same patients, it was impossible for each to claim that they were doing the right thing. Archie Cochrane recognised this and published his seminal book (Cochrane, 1972), calling for an international register of randomised controlled trials, and wanting explicit quality criteria for appraising published research, but neither goal was achieved in his lifetime. It took 20 years from this seminal publication before the first Cochrane centre opened.

Later when reflecting on his contribution to evidence based guidelines, Eddy (2011) a physician and independent health care consultant in Aspen, Colorado, identified that at this time “medical decision making was not built on a bedrock of evidence or formal analysis, but was standing on Jell-O” (p. 55).

As a consequence of Eddy’s work challenging common medical practice, he was invited by The American Cancer Society to rewrite its guidelines for cancer screening (Eddy, 1980). This was seen as the first application of using formal methods, evidence, mathematical

modelling, and cost-effectiveness analysis in designing a national guideline. In his preamble, Eddy (1980) highlighted that the Cancer Society had four main concerns;

1. there must be good evidence that each test or procedure recommended is medically effective in reducing morbidity or mortality
2. the medical benefits must outweigh the risks
3. the cost of each test or procedure must be reasonable compared to its expected benefits
4. the recommended actions must be practical and feasible

As Eddy became more vocal in his critique of medical practices he went on to describe how the complexity of medical decisions were inherently within wide ranges of uncertainty, often leading to errors in medical reasoning. Eddy described how clinical management decisions and institutional teachings were founded on the 'if…….then' statement, and mainly based within individual thoughts and clinical practices, and seldom based on evidence (Eddy, 1984).

The introduction of the first clinical guideline into cancer screening and his critique of medical practice was met with a predictable mixed response. Some hailed the report as long overdue, others condemned the Society for daring to challenge current practices, and some simply disagreed with the guidelines that related to their specialty areas. It was soon recognised that guidelines would need to be adaptive and responsive to reflect new research and varied professional opinions, and consequently a committee charged with the responsibility of periodically reviewing and discussing existing recommendations was formed. These committee discussions were understandably quite heated. Of particular interest to this thesis, it quickly became apparent that central to these debates were fundamental errors in description and definition, and the chair of the committee was reported as paraphrasing Socrates, declaring that they first needed to begin with the concept, "the beginning of wisdom is the definition of terms" (Holleb, 1985, p. 195).

It is apparent that controversy and confusion over the definition of terms is still readily apparent today and quickly identified within the literature on LBP, but only recently has the magnitude of these inconsistencies in definition and diagnosis been fully appreciated. This thesis will develop and expand on this argument and highlight the processes followed to derive historical and current CPGs for traction therapy as an intervention for LBP.

Although Eddy had been using the term “evidence-based” in speeches and workshops as early as 1985, he first published the term in an article with respect to evidence-based *guidelines* (Eddy, 1990). The concept of evidence based *medicine* (EBM) was accredited to Sackett and his colleagues in the 1980 – 1990s (Sackett, Haynes, Guyatt, & Tugwell, 1991), but first coined by Guyatt et al. (1992). Here EBM differed in its application, using it to describe how evidence should inform medical education and individual physician decision making in the clinic. So looking at the clinical application of EBM, rather than in the design of guidelines, coverage policies, or performance measures as Eddy had envisaged within his evidence based definition.

Sackett et al. (1996) published their definition of evidence-based medicine as, “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research (p. 71).

Sackett (1997) later expanded on the definition of EBM, explaining that individual clinical expertise related to the knowledge that individual clinicians acquire through clinical experience and clinical practice. Importantly, increasing clinical expertise was seen to be reflected in many ways, setting it apart from Eddy’s evidence based guidelines approach. Particularly in achieving a more effective and efficient diagnosis, but also incorporating the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in determining clinical decisions about their care. Best available external clinical evidence meant clinically relevant research, often from the basic sciences of

medicine, but primarily from patient centred clinical research into the accuracy and precision of diagnosis, the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens.

Sackett felt that the external clinical evidence must be fluid, simultaneously invalidating previously accepted diagnostic tests and treatment, and replacing them with new ones that are seen to be more powerful, more accurate, more efficacious, and safer. Practitioners needed to combine both individual clinical expertise, and best available external evidence, and that neither alone is enough.

Eddy (2011) reflected that despite their differences in interpretation and application, himself, Sackett, and others such as Cochrane, began a movement which has ensured that EBM has become part of the lexicon. Numerous websites, books, courses, programs, and departments in medical schools are now dedicated to it. The consequence being that newer generations of practitioners and undergraduates now take for granted the requirement for evidence, explicit formal analysis, and individualised treatment prescription, no longer cognizant that this was not the case just a few decades ago.

Continued developments over the past 30 - 40 years saw the term EBM morphed into evidence based practice (EBP). Evidence based practice is essentially using the EBM conceptualization of clinical experience, best available evidence, and patient preferences and expectations (Fig. 1).

Figure 1. The Evidence Based Practice Model

But broadening its application to encompass all clinical practice across entire health care teams with various organisations adopting this shared EBM approach in order to best guide clinical decision making (Dawes et al., 2005). The five steps of EBP were first described by Cook, Jaeschke, and Guyatt, (1992) and since been subjected to trials of teaching effectiveness (in brackets);

1. Translation of uncertainty to an answerable question (Richardson et al., 1995)
2. Systematic retrieval of best evidence available (Rosenberg et al., 1998)
3. Critical appraisal of evidence for validity, clinical relevance, and applicability (Parkes et al., 2001)
4. Application of results in practice (Epling et al., 2002)
5. Evaluation of performance (Jamtvedt et al., 2003)

With respect to physiotherapy authors have looked at EBP and felt that although physiotherapists need to improve their knowledge, skills and behaviour towards EBP, they

concluded that physiotherapists generally have a positive opinion of EBP (Da Silva, Costa, Garcia, & Costa, 2015; Moitra & Neogi, 2016; Scurlock-Evans, Upton, & Upton, 2014) Barriers identified which hinder the implementation of EBP in physiotherapy are;

- lack of time
- inability to understand statistical data
- lack of support from employer
- lack of resources
- lack of support from colleagues for EBP implementation
- lack of interest
- lack of generalisation of results
- the process of implementation
- guideline quality and quantity.
- concern for the individual patient's needs coupled with scepticism about application of research findings to individuals

It is therefore encouraging that physiotherapists can appreciate the value of EBP, but also that they are questioning of the guidelines that inform them.

It seems many are aware of the importance of EBP, and we can assume much more likely to use CPGs to inform the research component, as they are very unlikely to have the time to read and critique the individual studies that are published. This is understandable as Dr. P. Sizer (personal communication, August 22, 2015) mentioned at the NZMPA Biennial Scientific Conference in August 2015[b], "once we were scratching at the walls for evidence, now we are climbing the walls so as not to drown in it".

Busy medical professionals are unable to assimilate the shear amount of research. Some may follow the results and conclusions found in SRs, and meta-analyses, but many more

[b] https://nzrai.wildapricot.org/Resources/Documents/NZMPA%20Conference%202015%20Flier.pdf

rely on CPGs, which are formed using these sources. These CPGs will then help guide their attitudes and beliefs towards various interventions, to justify their particular approach, or to discredit another's, both within and between professions. It is imperative therefore, that these CPGs are accurate, applicable, and crucially, relevant to clinical practice.

Otherwise once commonly used clinical interventions, such as traction as discussed in this thesis, will no longer be recommended, subsidised within governmental health or private insurance policies, or taught at undergraduate level. Krause et al. (2012) concluded that traction is actually supported by good anecdotal evidence, and that past studies were poorly undertaken. They concluded that mechanical intervertebral separation has been demonstrated, and the suggested effects of pain modulation have sound scientific basis for instance.

Any unwarranted removal of these potentially effective interventions from the lexicon will ultimately affect the treatment of patients with LBP. Djulbegovic and Guyatt, (2017) state "Central to the epistemology of EBM is that what is justifiable or reasonable to believe depends on the trustworthiness of the evidence, and the extent to which we believe that evidence is determined by credible processes (p. 416).

Often CPGs seem to contradict what is actually experienced in clinical practice, where practitioners see the success of their treatment every day. Some clinicians believe CPGs to be accurate, so closely follow the guidelines, and adjust their clinical practice to suit, and others inherently doubt the recommendations found in CPGs and may continue with older established techniques. There may be some justification in these doubts as will be discussed throughout this thesis.

2.2 The history of traction, and the variety of its clinical application

Lumbar traction has been variously described as being used in the treatment of LBP, since prehistoric times (Mathews & Hickling, 1975), since antiquity (Pellecchia, 1994), or since Hippocrates (DeVries, 1985; Saunders, 1979; Weber, 1973).

Lumbar traction continued to be used through the 19th and 20th centuries by many physicians, for the treatment of scoliosis, rickets, and various cause of backache, such as herniated discs, sciatica, degenerative disc disease, pinched nerves, and other mechanical back conditions (Cyriax, 1975; Sari, Misirlioglu, Akarirmak, Hussain, & Kecebas, 2014). It became more prevalent in the 1950s and 1960s based on Cyriax (1975) publications on the efficiency of spinal traction for the treatment of discogenic back and leg pain. Cyriax described the beneficial effects of traction as;

- an increase in the intervertebral space from the distraction
- tensing of the posterior longitudinal ligament which then exerts centripetal force at the back of the joint
- suction to draw the protrusion toward the centre of the joint.

Lumbar traction is a rather vague term, and doesn't do justice to the variety of its application. It is a form of decompression therapy that is presumed to have positive physiological effects on the spine, and is performed using a variety of positions, fixtures, ropes and pulleys attached to the patient, and either to static weights (Fig. 2), or attached to automated machines (Fig. 3), or attached to a clinician (Fig. 4), or by utilising gravity; where two types of gravitational therapy have been used, head-up traction either lying (Fig. 5), or either sitting or standing (Fig. 6 and Fig. 7).

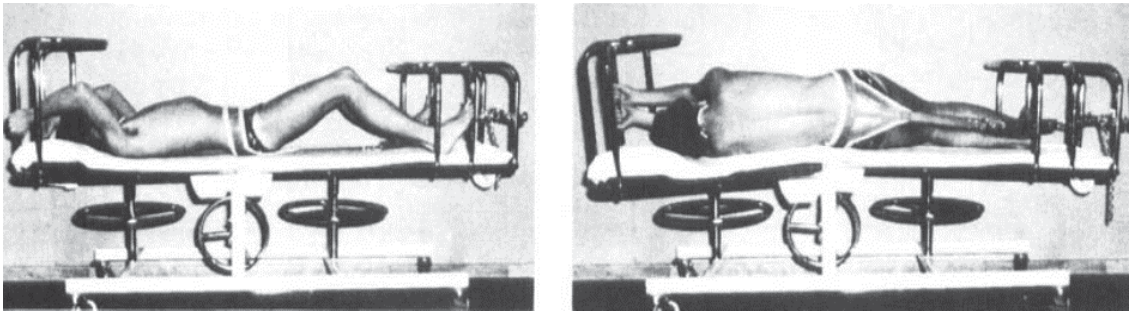


Figure 2. Auto-traction, various positons (Larsson et al., 1980, permission given)

Figure 3. Prone lying automated traction (Sibley et al., (ed), 2016, permission given)

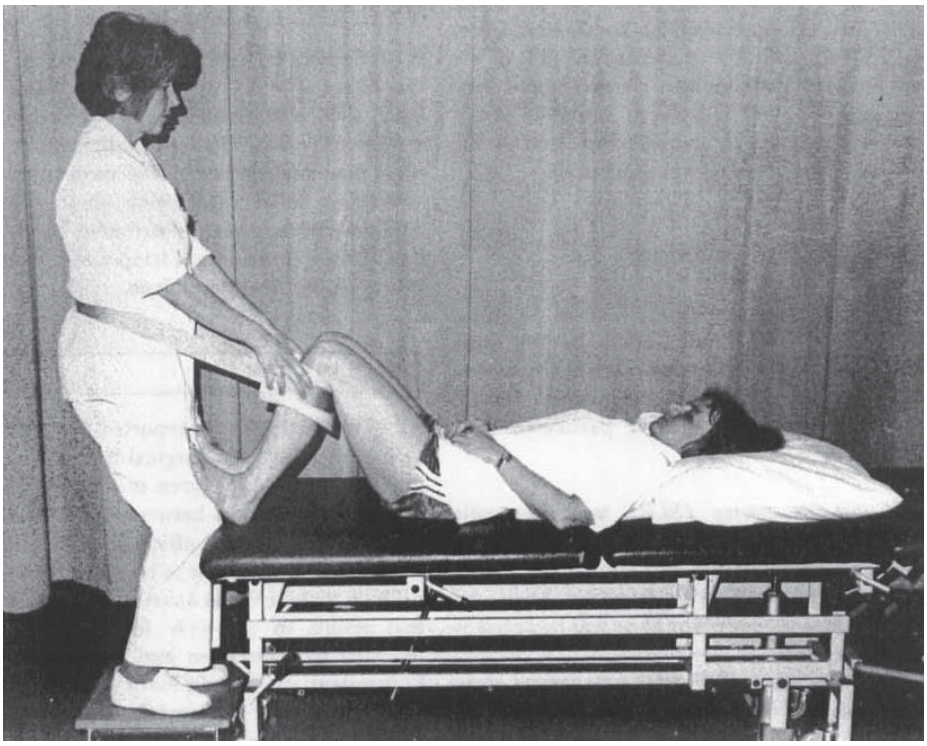


Figure 4. Manual traction (Ljunggren et al., 1992, permission given)

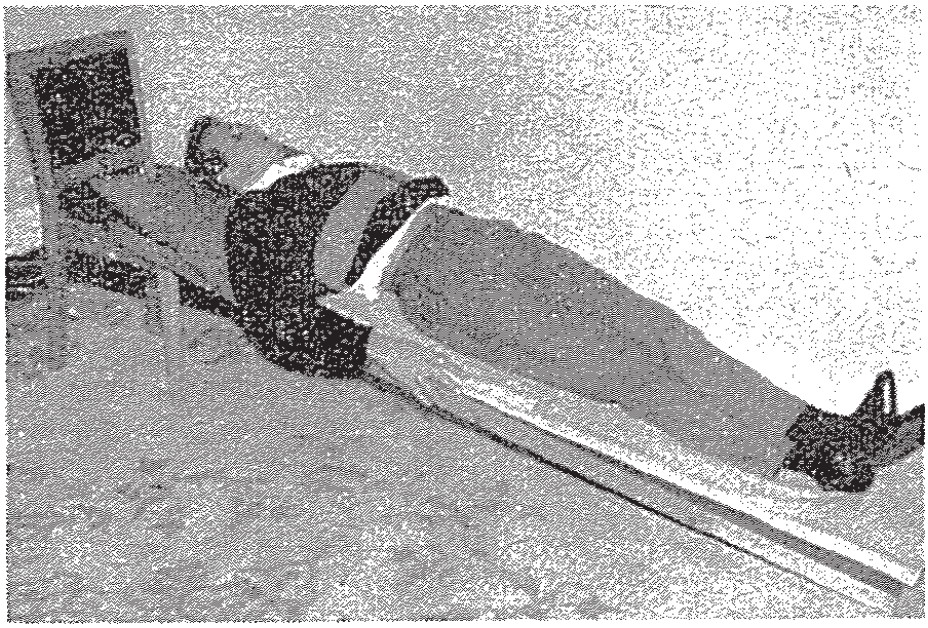


Figure 5. Gravitational Sliding Board Traction (Gray, 1963, permission given)

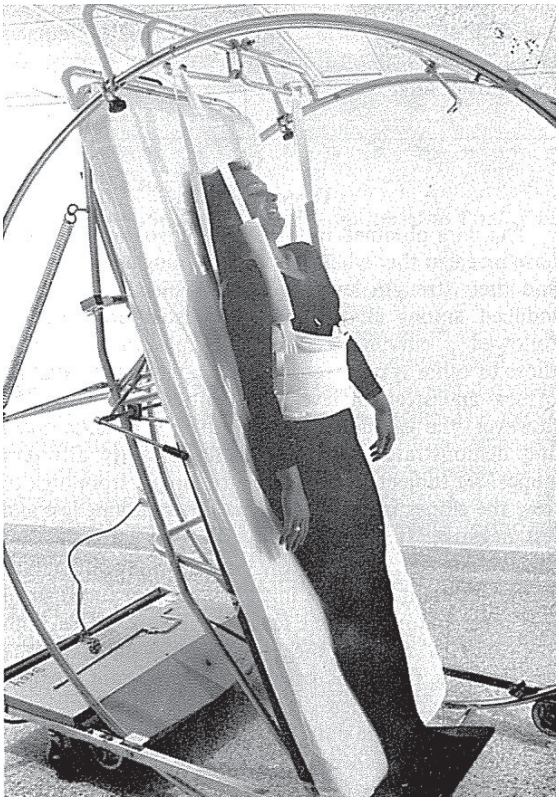


Figure 6. Gravitational Lumbar Reduction Traction (Oudenhoven, 1978, permission given)

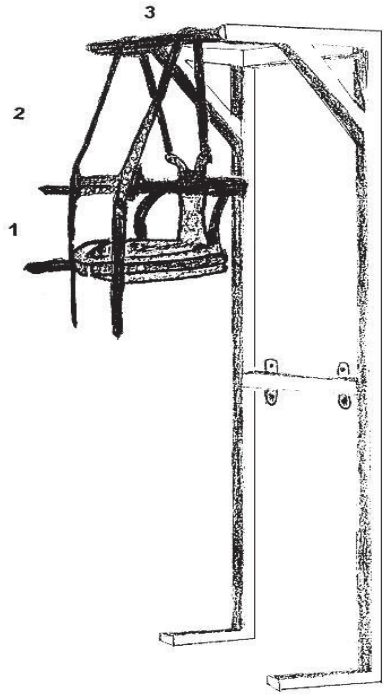


Figure 7. Upright Gravitational Traction, suspension corset (1), straps (2), and bar attached to frame anchored to the wall (Tekeoglu et al., 1998, permission given)

Or by inversion spinal traction where the patient is head down in an inverted position held either by the ankles or another part of the lower extremities (Fig. 8, Fig. 9, and Fig. 10).

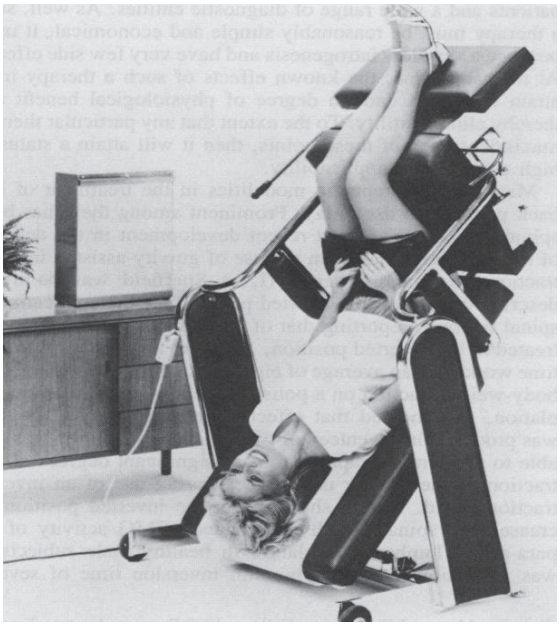
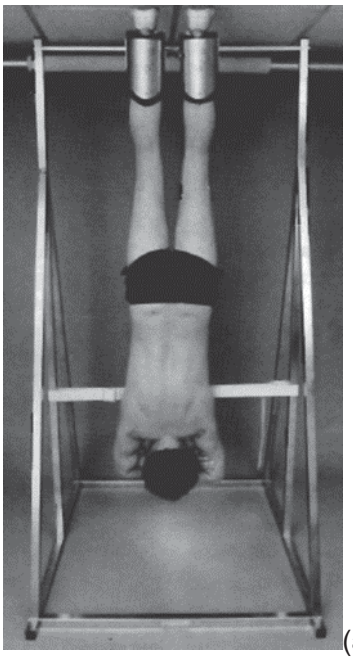
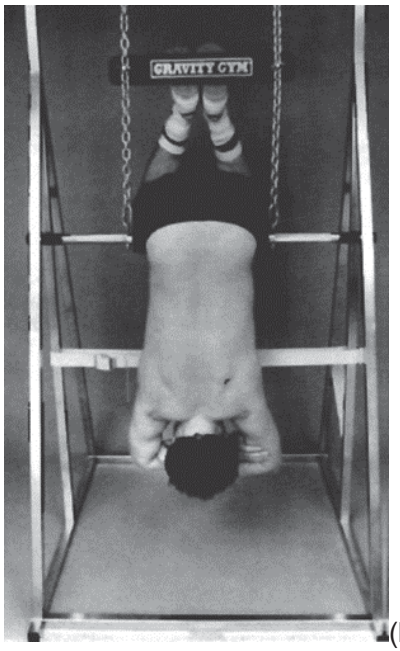


Figure 8. A participant is secured in the Inverchair at full inversion (Vernon et al., 1985, permission given)


(a)


(b)

Figure 9. Gravity Boots (a) and Gravity Gym (b) (Ballantyne et al., 1986, permission given)

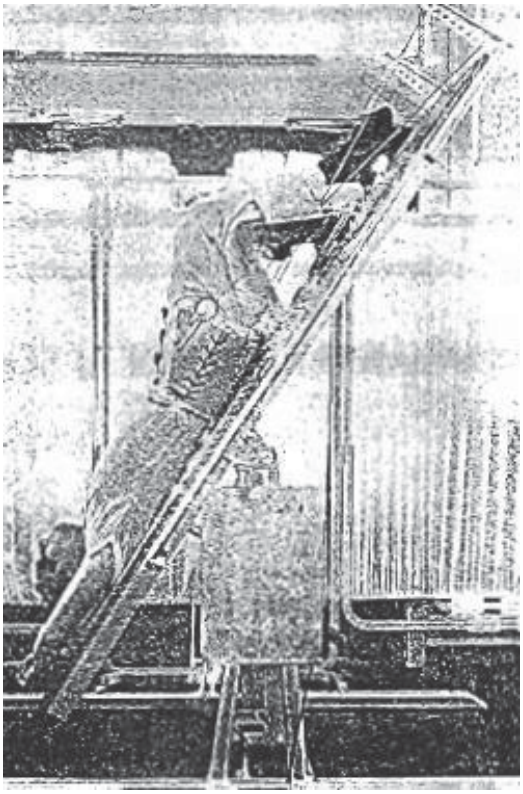


Figure 10. Adapted Tilt-table Inversion Traction (Sheffield, 1964, permission given)

Here the traction is force is gravity (Hasçelik, Güler, Oğuz, & Başgöze, 1992; Weisberg, 1994).

Depending on the design, traction can be delivered with the hips and knees either flexed or extended, which has the effect of changing the focus at the spinal level, or held with a constant force, or performed intermittently.

Although gravitational traction has a long history, dating back to pre-historic times, its clinical application was not as pronounced, although more recently there seems to be a resurgence of studies on the clinical application of inversion in particular (Kim et al., 2013; Prasad et al., 2012; Rademeyer, 2013). Technology has evolved to enable a motorised tilt table to precisely control the angle of inversion, as in the study by Kim et al. (2013) (Fig. 11).

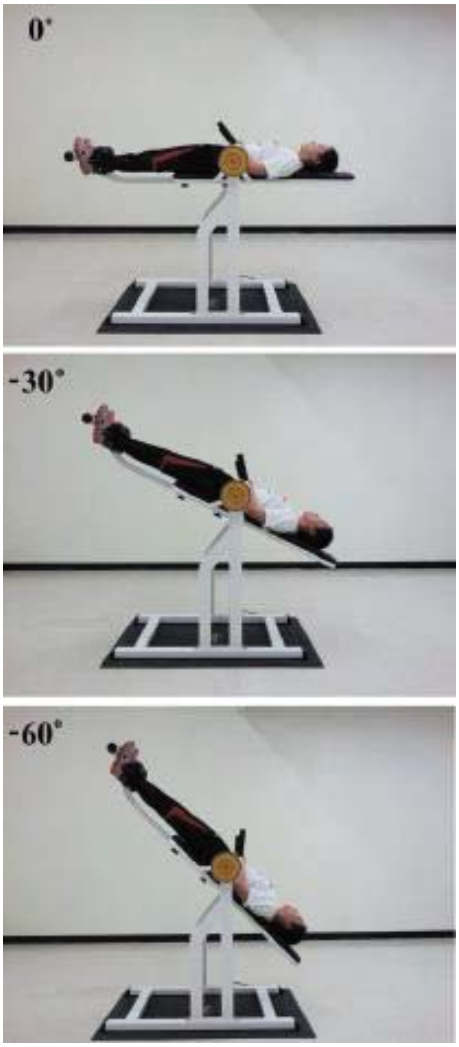


Figure 11. Angles of inversion traction (Kim et al., 2013, permission given)

The purpose in illustrating these diverse traction apparatus is to give an indication of the wide variety of design and positioning vis-à-vis lumbar traction in clinical practice, and to indicate how an individual patient with LBP may possibly benefit from one option over another.

2.2.1 How the research explains traction may work

It has been reported that traction diminishes the compressive load on intervertebral discs and apophyseal joints, causes a flattening of the lumbar lordosis, stretches lumbar spinal muscles and ligaments, reduces the size of discal herniation, increases the space within the spinal canal, widens the neural foramina, decreases thickness of the psoas muscle, decreases muscle spasm, widens intervertebral foramina and apophyseal joint spaces, and relieves LBP (Cyriax, 1975; de Vries & Cailliet, 1985; Güvenol, Tüzün, Peker, & Göktay, 2000; Lehmann & Brunner, 1958; Letchuman & Deusinger, 1993; Onel, Tuzlacı, Sari, & Demir, 1989; Reilly, Gersten, & Clinkingbeard, 1979; Sari, Akarırmak, Karacan, & Akman, 2005)

Reilly et al. (1979) administered three lots of 70 lb intermittent horizontal lumbar traction for 15 minutes, with 15 minutes rest while varying the degree of hip flexion from 0 to 45 to 90 degrees in 10 female subjects. They measured vertebral separation by lateral roentgenograms by outlining and marking the vertebral bodies and measuring interspaces with fine-point callipers, where it was found that the most significant separation occurred with hips flexed at 90 degrees. Their data showed an increase in posterior intervertebral heights from T12 to S1, and no changes in anterior intervertebral heights were reported, and concluded that hip flexed to 90 degrees produced maximal posterior vertebral interspace separation.

Sari et al. (2005) used a CT scanner to look at the spine of 32 participants with protruded disc herniations, 27 of 32 (84.4%) at L4-L5, and 5 patients (15.6%) at L5-S1 under horizontal traction with approximately 45 degrees of hip and knee flexion (Fig. 12).

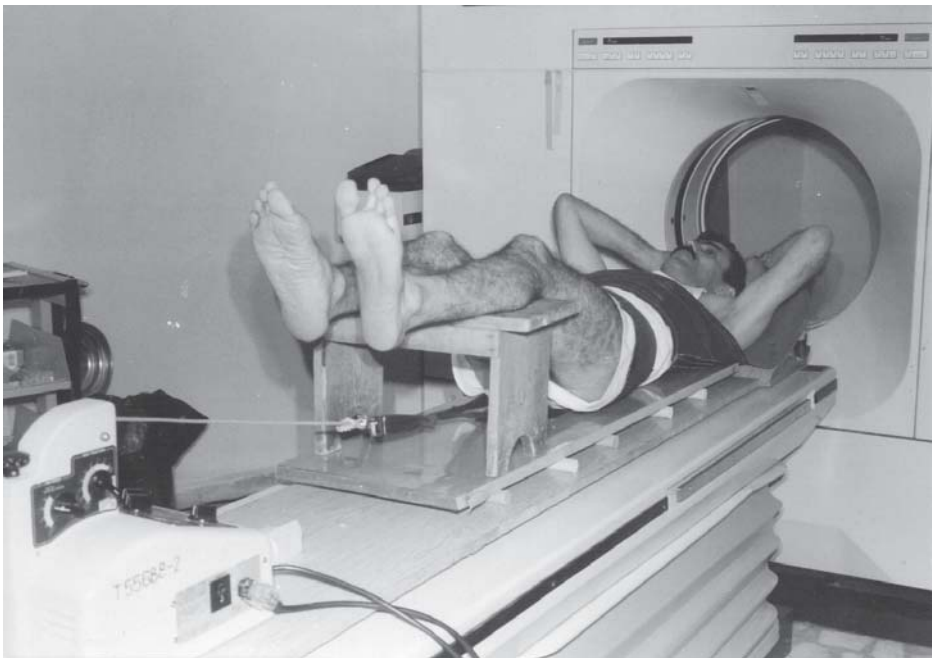


Figure 12. Positioning of the patient on the traction boards (Cerrahpasa Experimental Lumbar Traction Model) and gantry of the CT-scanner before and during traction administration (Sari et al., 2005, permission given).

Sari et al. found there was a significant reduction in the area of the herniation for levels L4-5 (p=0.0001) and L5=S1 (p=.0.028)

- The anterior disc height remained unchanged at L1-2, L2-3, L3-4, L4-5, L5-S1
- The posterior disc height increase significantly at all levels, L1-2 (p=0.008), and other levels (p= 0.001)
- The L1-S1 spinal length increased significantly (p=0.0001)
- The spinal canal area increased significantly (p= 0.0001)
- The neural foramen diameter increased significantly (p=0.0001)
- And the psoas muscle thickness decreased significantly (p=0.0001)
- In addition the intraobserver error was found to be +/- 0.39 millimetres

Despite these intuitively positive mechanical effects, its historical clinical popularity, and the anecdotal evidence supporting its clinical effectiveness, the use of lumbar traction remained controversial. Due to the reported negative results, conclusions, and recommendations

concerning lumbar traction studied intensively in RCTs, and which were subsequently included with SRs, and later informed CPGs. Unfortunately as will be discussed in chapter 4, the literature concerning the efficacy of traction in the treatment of LBP is conflicting and perhaps not fully appreciated. Sari et al. (2014) described this confusion as due to differences in the type of traction, treatment techniques, treatment durations, diagnostic categories, and outcome measures used, making it difficult to compare studies or reach definitive conclusions about its clinical effectiveness.

2.3 Summary

Traction is anecdotally a clinically effective treatment for LBP. However, there have been many scientific studies undertaken on the efficacy of traction on LBP with or without sciatica that have produced inconsistent, contradictory, non-significant, or inappropriate results. Despite the recognition of methodologically poor research, the current use of traction as an intervention for LBP is currently not supported by SRs or CPGs. This dichotomy between clinical practice and scientific research may question if the research conclusions of traction not being an effective intervention for LBP is externally valid to clinical practice. Important definitions will be detailed in Chapter 3 and a critique of the pertinent literature will be presented in Chapter 4 with reference to the primary literature in Appendix A, to examine if this is so.

Chapter 3. Review of Literature

This chapter will detail significant and pertinent literature, which when appreciated may explain the disparity between the conclusions of RCTs, SRs, and CPGs that traction is not recommended for the treatment of LBP as it is not effective, as compared to the historical popularity and anecdotal effectiveness of its clinical application. This literature review will cover epidemiological research into LBP (section 3.1), definition of LBP, NSLBP, and referred leg symptomology (section 3.2), duration of LBP and natural history of LBP (section 3.3), and other methodological flaws in LBP research (section 3.4), and brief summary (section 3.5).

3.1 Epidemiological research into low back pain

Numerous researchers have stated, and consequently it has become part of the common lexicon of patients and practitioners alike, that LBP is a very common condition that most people will experience at some time in their lives. Maher, Underwood, and Buchbinder, (2016) state in their abstract, that NSLBP affects people of all ages and is *a leading contributor to disease burden worldwide*. This comment, may be slightly misleading, and at worst sensationalist.

Referring to the statistics gathered during the Global Burden of Disease (GBD) studies and the interactive compare function held within the Viz Hub at the Institute for Health Metrics and Evaluation (IHME),[c] it can be appreciated firstly that in 2015 it's LBP (and not NSLBP), and secondly that LBP is actually ranked ninth in terms of disease burden worldwide. When expressed as disability adjusted life-years (DALYs), i.e. when diseases associated with mortality are included, having risen from 13 in 1990 (Fig. 13).

[c] https://vizhub.healthdata.org/gbd-compare/

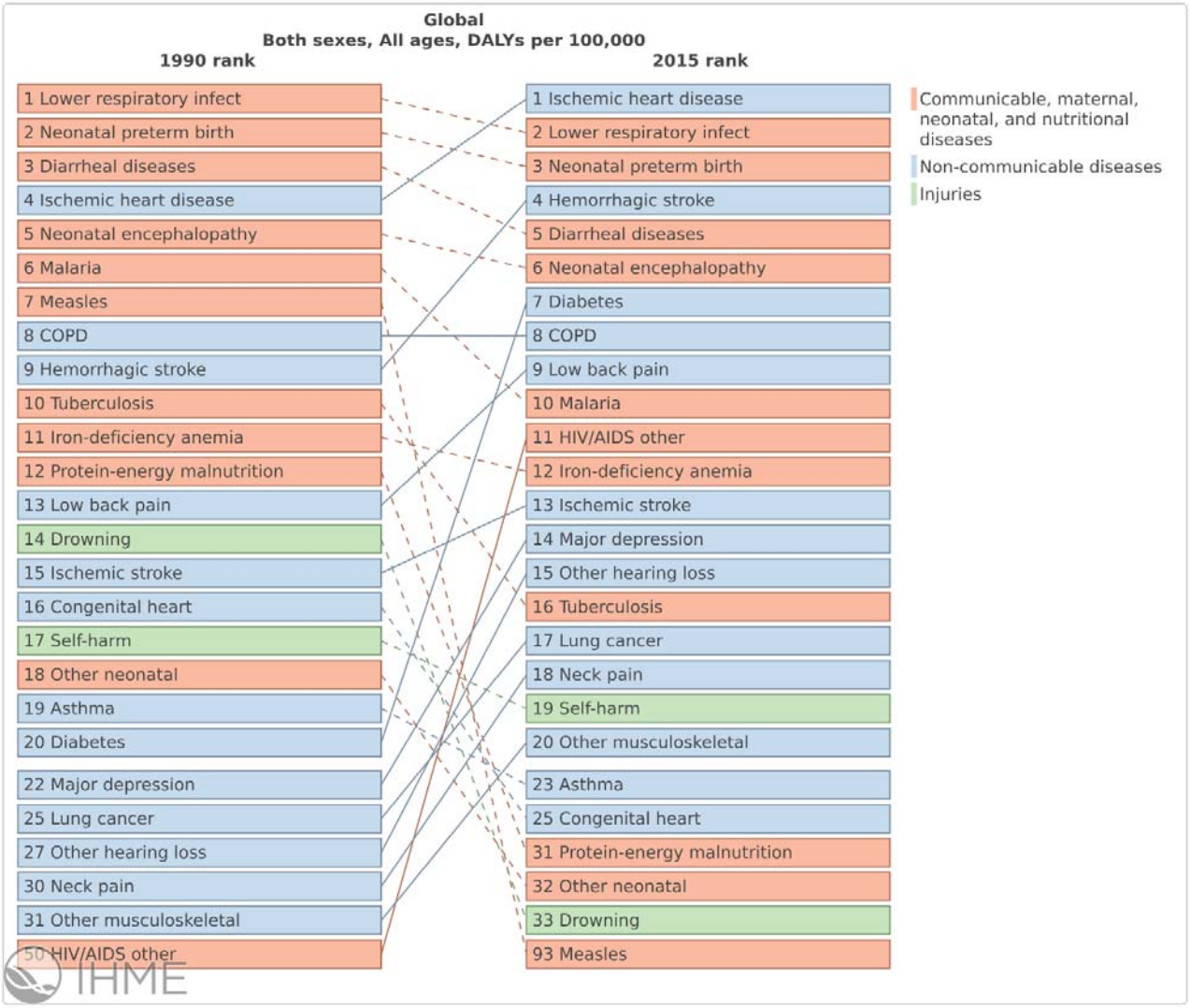


Figure 13. *GBD, LBP, Both Sexes, All Ages, DALYs per 100,000 (IHME, permission given)*

So arguably LBP should perhaps be more accurately described as the leading cause of years lived with disability (YLDs) globally, when those diseases associated with mortality are removed (Fig. 14), and not as the top contributor to disease burden.

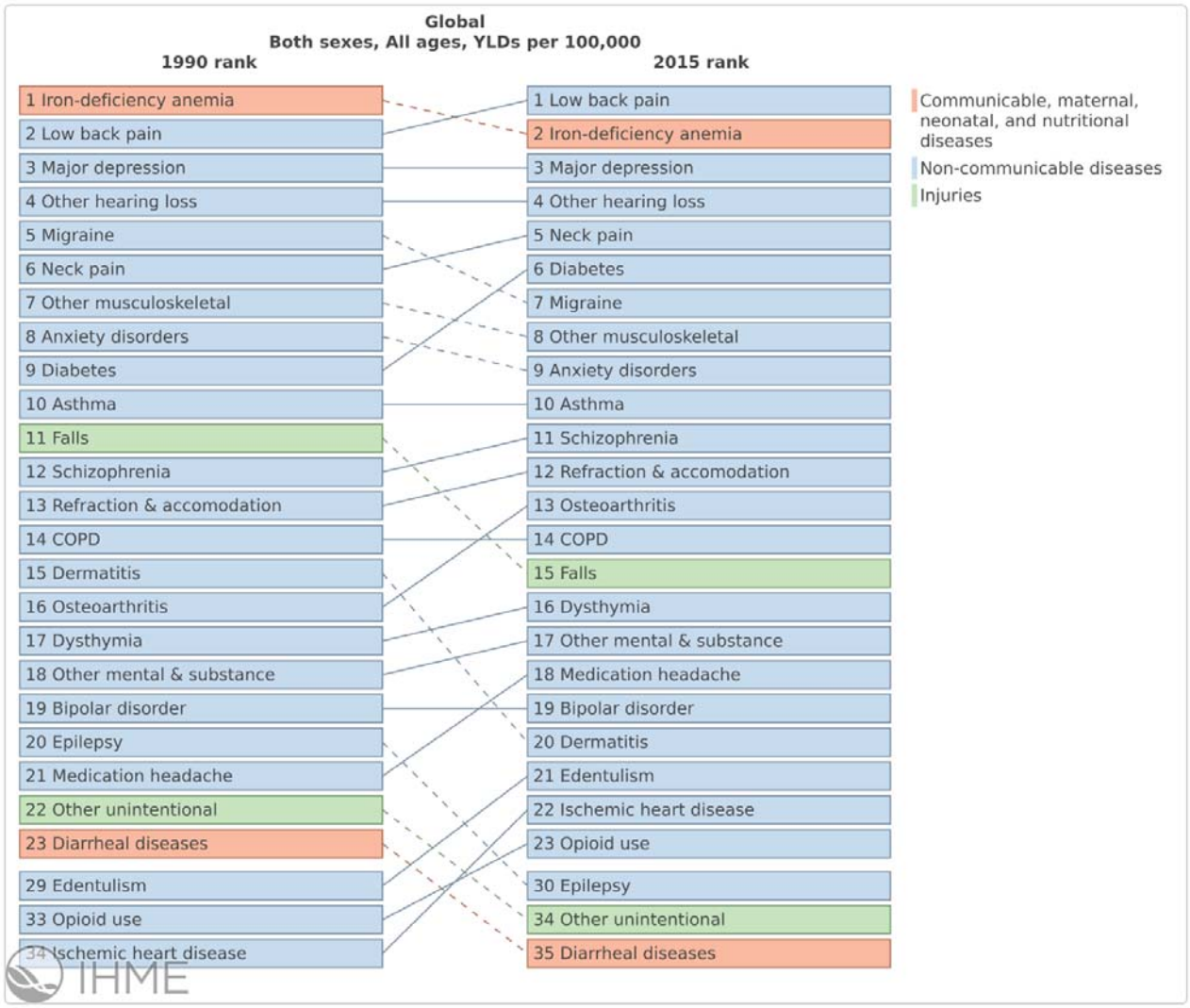


Figure 14. GBD, LBP, Both Sexes, All Ages, YLDs per 100,000 (IHME, permission given)

Of interest too, is that in both figures the IHME class LBP as a non-communicable disease, and not as an injury. Considering that the World Health Organisation state that "Noncommunicable diseases (NCDs) kill 40 million people each year, equivalent to 70% of all deaths globally".[d]

[d] http://www.who.int/mediacentre/factsheets/fs355/en/

The sensationalist terms “I’ve thrown my back out”,[e] “I’ve put my back out”,[f] or “I’ve slipped a disc”, are familiar expressions. An often quoted prevalence (number of cases in the population) for LBP in scientific journals and lay media alike, is that over 80% of the population will get LBP sometime in their lifetime. This data is taken from a single study by Cassidy, Carroll, and Côté, (1998), who found a prevalence of LBP of 84% in Saskatchewan adults, so the generalisability may be doubtful. Yet this figure is very often quoted in LBP literature, and extrapolated to apply globally, when it may only apply to this particular Canadian province at this one time of collection. For instance Saskatchewan summer temperature can reach up to 45 °C (113 °F) and in winter, temperatures below −45 °C (−49 °F) have been recorded, which certainly does not apply in New Zealand, and would suggest different stressors, both physical and emotional, on the body may be expected.

The effect of using this prevalence number is that this inflated figure is then often quoted in subsequent research and reports, potentially contributing to the sensationalism of LBP, as authors do not consult the source article of Cassidy et al. (1988). This snowballing of inaccurate information can be seen in Dagenais, Tricco, and Haldeman (2010) in their assessment of CPGs, erroneously stating that LBP can be expected in 84% of the *general adult population* (p.g. 515), and again in Nijs, et al. (2015), who states LBP affects 70% – 85% of the adult population at some point in life, citing Becker et al. (2010) who actually state 50% – 85%, and who in turn again cite Cassidy et al. (1988).

This effect is even evident when you review the most recent SR of LBP CPGs. Wong et al. (2017) state in their introduction that *more than 80% of people* experience at least one episode of back pain during their lifetime, citing again Cassidy et al. (1988). It is clear that these authors are generalising from this one study on Saskatchewan adults.

It is potentially misleading to claim that nearly, approximately, or more than 80% of people will experience back pain, as it may not be evidence based, it may be better to always

[e] https://www.alwaysfysio.nl/en/threw-my-back-out/
[f] https://www.mumsnet.com/Talk/general_health/828675-I-think-I-have-put-my-back-out-for-the

include the range. Unfortunately, this inflated figure has also become part of common folklore[g] [h] of the prevalence of LBP, which has the effect of continuing its sensationalism. Below can be seen the data from a selection of studies, demonstrating how much the reported lifetime prevalence of LBP has varied, but also how often this mid 80s figure features, and also the variable prevalence points and periods used. (Table 1).

Table 1. Variation in the reported prevalence of LBP

Author(s)	Prevalence %		
	Lifetime	Point	Period
Cassidy et al., (1998)	84	-	-
Walker (2000)	11 - 84	12 - 33	22 - 65
Ozguler et al., (2000)	At least 1 day in previous 6 months;		40.8 (male) 45.4 (female)
	Sick leave for LBP in the previous 6 months;		9.5 (male) 7.8 (female)
Becker et al., (2010)	50 - 85	15 - 30	-
Hoy et al., (2010)	-	1.0 - 58.1	1 year
Hoy et al., (2012)	38.9	18.3	30.8 (1 month) 38 (1 year)
Hoy et al., (2014)		9.4	Global
Balagué et al., (2012)	As high as 84	-	-
Deyo et al., (2014)	39	-	38 (1 year)
Nijs et al., (2015)	70 – 85	-	-
Saragiotto, et al., (2016)	39	-	9.4

Hoy, Brooks, Blyth, and Buchbinder, (2010), who were responsible for analysing the data used in the LBP GBD (2005) study, recommended caution when interpreting the results of epidemiological studies, due to the extent of methodological variation between studies especially regarding the;

- prevalence period used
- reliance on how recurrence is defined which also depends on how remission is defined
- substantial heterogeneity between studies on estimated low back pain duration
- nature and extent of measures taken to minimize bias

[g] www.spine-health.com/conditions/lower-back-pain
[h] www.med.unc.edu › Home › News › 2009 › February

- recall period
- age and sex distributions
- representativeness of the sample
- overall sample size
- validation of the instruments used to measure prevalence
- random methods used in selecting the sample population
- extent of non-response and whether any measures were taken to deal with non-response bias.

Heterogeneity is unfortunately a recurring theme within research into LBP and will be explored throughout this thesis. The first indication of the effects of heterogeneity can be appreciated within the wide spread and inconsistent use of prevalence figures in Table 1.

Hoy et al. (2012) later detailed the results of a LBP SR which informed the GBD (2010) study looking at all the population-based studies published from 1980 to 2009. They found that the mean point prevalence (at any one time) was 18.3%. This was significantly lower than the one month prevalence of 30.8% ($T = -9.8$, $P < 0.001$), and the one month prevalence was significantly lower than the one year prevalence of 38.0% ($T = -4.0$, $P = 0.001$). There was no significant difference between the 1 year prevalence and the lifetime prevalence of 38.9%. This mean lifetime prevalence of LBP (38.9%) was much lower than they expected, and it was postulated this was particularly influenced by low rates from recent studies conducted in some developing and emerging countries. However this figure of 38.9% can be appreciated to be much less than the often quoted figure of 84%.

Hoy et al. (2014) again reviewed the information they had gathered for the LBP GBD (2010) study and re-estimated that the global age-standardised point prevalence of LBP (from 0 to 100 years of age) as 9.4% (95% CI 9.0 to 9.8). Also in light of the feedback they received following the publication of the LBP 2010 GBD study, they concluded that although the process and rigor undertaken by the GBD 2010 team to estimate the global and regional

burden of LBP is an important advancement on previous GBD studies, they accepted some of the study's limitations that had been highlighted. Significantly Hoy et al. (2014) encouraged researchers to improve methodology on defining LBP in epidemiologic studies; to assist future reviews, enable comparisons between countries, and improve the understanding of LBP.

3.2 Definition of low back pain

A review into the literature involving research into LBP is opening a Pandora's Box of pain, the area is prolific which makes it difficult enough, but is also littered with numerous inconsistencies of definitions vis-à-vis the epidemiology, assessment, treatment, and overall management of LBP. Unfortunately these have made the past research into LBP inconsistent, contradictory, and therefore inconclusive.

Despite early identification of these flaws they have been largely unrealised, or ignored. Past studies have been inappropriately undertaken and analysed, leading to inaccurate or inapplicable conclusions, and these have been used to inform CPGs, which in the field of physiotherapy has resulted in the removal of interventions which had good clinical and anecdotal evidence to support their use. An intervention that has suffered the consequences of this research is traction which has been used for centuries, but is no longer recommended by all but one CPG (Dagenais et al., 2010) (section 4.3.2).

Section 3.2 will describe how fundamental errors have been committed and largely overlooked with respect to the location of LBP (section 3.2.1), definition of LBP and the classification of referred leg symptomology (section 3.2.2), difficulty in further sub-grouping LBP (section 3.2.3), and applied differences in pathoanatomical diagnosis within clinical practice and RCTs (section 3.2.4)

3.2.1 Location of LBP

Rossignol, Rozenberg, and Leclerc (2009) stated that a major obstacle to research is the lack of standardized definitions for LBP. Itz, Geurts, van Kleef, and Nelemans (2013), stated that definitions differ widely between studies, even the comparably simple definition of isolated LBP has been variously described as pain;

- in the thoracic and lumbar region,
- localized between the scapulae and the gluteal folds,
- below thoracic T6 vertebra,
- between T12 vertebra and the buttock crease.

In 1994 the International Association for the Study of Pain (IASP) provided a definition for LBP, suggesting that studies prior may have been inconsistent, and that those published after should have included this definition in their methodology;

> as pain perceived as arising from anywhere within a region bounded superiorly by an imaginary transverse line through the tip of the last thoracic spinous process, inferiorly by an imaginary transverse line through the tip of the first sacral spinous process, and laterally by vertical lines tangential to the lateral borders of the lumbar erectores spinae. Pain located over the posterior region of the trunk but lateral to the erectores spinae is best described as loin pain to distinguish it from lumbar spinal pain. If required, lumbar spinal pain can be divided into upper lumbar spinal pain and lower lumbar spinal pain by subdividing the above region into equal halves by an imaginary transverse line (Merskey & Bogduk, 1994, p. 11)

This difficulty agreeing on, or conforming to, the location of LBP immediately causes concern regarding the quality of the research into LBP. It seems hard to comprehend studying LBP if there was not even a consensus definition of where it has to be felt, and this deficit echoes

the concerns of the Cancer Society committee (section 2.1) and the need to have agreed definitions (Holleb, 1985).

3.2.2 Definition of low back pain and the classification of referred leg symptomology

This concern for lack of consensus on definitions of LBP is further complicated when LBP is associated with referred leg symptoms, and whether the primary complaint is back or leg dominant (Hall, 2014), and deciding whether the referred leg symptoms are somatic, radicular, or radiculopathy in nature. Dependent on how these leg symptoms respond to various positions and tests utilised within the clinical assessment, this distinction is vital when clinically assessing and formulating a differential diagnosis, and then deciding upon a particular physiotherapeutical intervention.

This clinical distinction continues to be immensely difficult, and more confusing when these referred leg symptoms have been historically termed sciatica. Although the cause(s) of referred leg symptoms may be variable, and not always identifiable, this clinically reasoned distinction between the types of referred leg symptoms is imperative. In clinical practice you also have the ability to 'change' the differential diagnosis depending on how the LBP and leg pain responds within, and between clinical sessions. The IASP (Merskey & Bogduk, 1994) identified the need for the distinction between referred leg symptoms. They recognised LBP with radicular pain and radiculopathy, differs from LBP and somatic referred pain. In addition there is also a difference between radicular pain and radiculopathy, as each have different mechanisms (Bogduk, 2009; Bogduk & Govind, 1999; Devor, 1996; Howe, 1979; Howe, Loeser & Calvin, 1977; Kawakami, Weinstein, & Olmarker, 1996; Merskey & Bogduk, 1994; Smyth & Wright, 1959; Tamaki & Hashizue, 1996). A review by Konstantinou and Dunn (2008) reported that the prevalence of referred leg symptoms ranged from 1% to 43%, with this wide range largely due to the varying definitions of referred leg symptoms used in individual studies.

Due to its continued use in literature, Merskey and Bogduk (1994), and later Bokduk (2009) stressed that the term sciatica was arcane and should be abandoned, as it stems from an era when the mechanisms of referred pain were not understood, and any referred leg symptoms was attributed to irritation of this peripheral nerve that passed through the region of pain. The unfortunate legacy of this term is that it is still applied erroneously to any or all pain of spinal origin perceived in the lower limb. Bogduk (2009) concludes that due to this strong possibility that somatic referred pain has been mistaken for radicular pain in the past, studies of the prevalence of radicular pain are not reliable. If we extrapolate this then it is reasonable that it also contributes to the heterogeneous selection of study cohorts.

More recently, Hall (2014) also discusses how in common usage the term sciatica has unfortunately come to mean all back-related leg pain, and a key finding by Lin et al. (2014) was that the possible terms used to describe a study population with radiating leg pain (or symptoms) were still being used inconsistently and interchangeably. Despite a better understanding of the mechanisms associated with some terms, and the attempts to publish consensus definitions.

Shultz, Averell, Eickelman, Sanker, and Donaldson (2015) also confirmed the difficulty in identifying the patho-mechanics of low back related leg pain, stating that it is complex and that lumbar disc herniation, lumbar spinal stenosis, radiculopathy, and or neurophysiological pain can result in varying pain patterns and / or symptom descriptions. Consequently we need to urgently dismiss the term sciatica from future studies, and more critically avoid those studies which historically used the term.

This is not a new concept, as Waddell et al. (1982) first suggested a clinicopathological distinction needed to be made between referred leg pain of somatic origin, and nerve root leg pain causing radicular and radiculopathy symptoms, but this seems to have been overlooked. Waddell et al. also stated that definite distinctions were needed between acute and chronic pain (see section 3.3).

As a result of their work, they suggested the diagnostic triage of LBP into three subgroups, and subsequent research has provided evidence to support the clinical use of these categories (Chou et al., 2007; Chanda et al., 2011; Balagué et al., 2012);

- non-specific low back pain (NSLBP)
- nerve root pain
- specific spinal pathology

Waddell went on to become known as one of the eminent researchers within LBP, and over time (Waddell, Feder, McIntosh, Lewis, & Hutchison, 1996; Waddell, 2004), as well as others such as Greenhalgh and Selfe (2006) went on to estimate that;

- 95% of back pain cases presenting in primary care are thought to be attributable to mechanical or nonspecific back pain,
- less than 5% are thought to be related to true nerve root pain (arising from a disc prolapse, spinal stenosis, or surgical scarring),
- 1% of patients are thought to have serious spinal pathologies such as tumours, infections, inflammatory conditions, or other conditions requiring urgent specialist investigation and treatment.

Waddell's triage is widely accepted and dictates that LBP, when caused either by specific spinal pathology or nerve root involvement (which by definition is radicular or radiculopathy in nature), should not be considered within NSLBP.

Nerve root pain (radicular or radiculopathy), should be clinically identified and clinically differentiated from leg symptoms which are somatic in nature, and excluded if the cohort studied is NSLBP. Thus the confusion caused by the catch-all term sciatica. The realisation of the importance of this differentiation, as well as the clinical reasoning and assessment used to facilitate distinction, should be discussed and appreciated within the method of all

study designs, depending on the research question. Somatic referred leg symptoms can be correctly included within the NSLBP category as although they emanate from an uncertain source, they do not involve any pathology of the nerve root itself. Clinical judgement is required to correctly distinguish referred leg symptoms of somatic, radicular, or radiculopathy in nature. The confusion over LBP when associated with referred leg symptoms is still evident.

A recent article by Slaughter, Frith, O'Keefe, Alexander, and Stoll (2015), with the stated purpose of promoting best practice for LBP in an occupational environment, classified NSLBP as pain localized to the low back area that cannot be attributed to a definite source. Disturbingly, perhaps indicative of the misinformation surrounding LBP, and despite this article's purpose to promote best practice, this definition of NSLBP is incorrect. NSLBP does not have to be localised to the back, and is often accompanied by somatic referred pain into the leg.

Also NSLBP has been described as a vague term concealing a multitude of conditions, some or all with different aetiologies (Ozguler, Leclerc, Landre, Pietri-taleb, & Inserm, 2000). Any innervated structure in the lumbar spine can cause symptoms of LBP, with or without associated referred symptoms into the extremity, or extremities (Bogduk, 2009). This long list of potential structures includes somatic referred pain arising from structures in the lower back; muscles, ligaments, zygapophyseal joints, facet joints, annulus fibrosis (disc), thoracolumbar fascia, sacro-iliac joint (SIJ), or vertebrae (Deyo & Weinstein, 2001).

Past research utilizing single diagnostic blocks has shown that the SIJ is responsible for a proportion of LBP. Schwarzer, Aprill, and Bogduk (1995) concluded that the prevalence of sacroiliac pain to be at least 13% and perhaps as high as 30% in chronic LBP. Maigne, Aivakiklis, and Pfefer (1996) selected patients with LBP with high index of suspicion for SIJ pathology, performed a double nerve block, and established the actual frequency of SIJ dysfunction in this population as 18.5%. Manchikanti et al. (2001) studied 120 chronic LBP patients with precision diagnostic blocks; including medial branch blocks, SIJ injections, and

provocative discography. They showed that only 2% of patients were diagnosed with SIJ pain, in 40% (95% CL, 31%, 49%) of the patients facet joint pain was diagnosed, and in 26% (95% CL, 18%, 34%) of the patients discogenic pain was diagnosed. Other authors have confirmed that it is still difficult to distinguish SIJ from other causes of LBP (Cohen, Chen, & Neufeld, 2013; Laslett, Young, Aprill, & McDonald, 2003; Simopoulos et al., 2012; Szadek , van der Wurff, van Tulder, Zuurmond, & Perez, 2009; Vanelderen et al., 2010).

It is also possible that a patient may have co-existing pathology, resulting in combinations of somatic and radicular referred leg pain, and the prevalence of cases with more than one source of pain is unknown (Laslett et al., 2003). A recent article by Juch et al. (2017) detailed three pragmatic multicenter, nonblinded randomized clinical trials on the effectiveness of minimal interventional treatments for participants with chronic LBP. They found a positive diagnostic block at the facet joints in 251 participants, for the sacroiliac joints in 228 participants, and for a combination of facet joints, sacroiliac joints, or intervertebral disks in 202 participants.

In addition, the hip-spine effect or syndrome first described by Offierski (1983), and more recently by Prather, Cheng, May, Maheshwari, and VanDillen (2017), and Gómez-Hoyos, et al. (2017), describes where hip pathology is involved in producing or worsening LBP by either disturbing the normal lumbo-pelvic kinematics, or through the somatic referred pain mechanism. A number of hip pathologies such as flexion deformities, osteoarthritis, congenital hip dislocation, and limited hip range of motion have been linked to lumbar disturbances. It is clear therefore that even when we use the term NSLBP, it is highly likely not to be only localised to the low back area, and extensive clinical assessment and reasoning is required to at least rule out SIJ or hip pathology.

Slaughter et al. (2015) also state that LBP with associated radiculopathy involves radiation of pain down the leg(s), and may include weakness, or decreased tendon reflexes. Louw Diener, Landers, Zimney, and Puentedura (2016), state that to be defined a radiculopathy, symptoms needed to be predominantly leg pain, with or without neurological deficit.

Again these definitions are questionable. Bogduk (2009) explains that a radiculopathy occurs, either when sensory fibres are blocked and numbness is the symptom and sign, or when motor fibres are blocked which leads to muscle weakness. The other feature of radiculopathy is diminished reflexes which occur as a result of either a sensory or motor block. The numbness is dermatomal in distribution and the weakness is myotomal, and fundamentally a radiculopathy is not defined by pain, but is defined by these objective neurological signs. This is in direct conflict and questions the articles by Slaughter et al. (2015), and Louw et al. (2016) and their definition of a radiculopathy.

Bogduk (2009), also explains that radicular pain is not due to a discharge exclusively from nociceptive afferents, such as found in various anatomical structures which are responsible for somatic referred pain; but rather from heterospecific discharge in the affected nerve. He defines this so evoked sensation as very unpleasant, but not exactly pain in the classical nociceptive sense, and that radicular pain is commonly referred into the legs.

According to Bogduk (2009), by definition a radiculopathy may not actually be painful, but rather will always be accompanied by sensory deficit, weakness, or decreased tendon reflexes; whereas radicular symptoms will be appreciated as neuropathic pain, but not be associated with neurological signs. Therefore to stress again, studies on 'sciatica' are not reliable (Bogduk, 2009; Lin et al., 2014; Merskey & Bogduk, 1994; Schäfer et al., 2014; Shultz et al., 2015; Stafford, Peng, & Hill, 2007). From this discussion we can appreciate that the patho-mechanics of LBP when accompanied by related leg symptoms are complex, and remain commonly misunderstood.

It is readily apparent and concerning that in past studies and SRs on the efficacy of traction for back pain that NSLBP and LBP have been confused, and nerve root pain loosely termed sciatica, has been erroneously included within studies on NSLBP (Bogduk, 2009; Borman, Keskin & Bodur, 2003; Coxhead, Meade, Inskip, North, & Troup, 1981; Diab & Moustaffa, 2013; Gudavalli et al., 2006; Konrad, Tatrai, Hunka, Vereckei, Korondi, 1992; Larsson et al., 1980; Letchuman & Deusinger, 1993; Lidström & Zachrisson 1970; Lin et al., 2014; Mathews

et al., 1987; Mathews & Hickling, 1975; Merskey & Bogduk, 1994; Ozturk, Gunduz, Ozoran, & Bostanoglu, 2006; Pal et al., 1986; Schäfer et al., 2014; Sherry, Kitchener, & Smart, 2001; Shultz et al., 2015; Sweetman, Heinrich, & Anderson, 1993; Tesio & Merlo, 1993; van der Heijden, Beurskens, Dirx, Bouter, & Lindeman, 1995a; Werners, Pynsent, & Bulstrode, 1999).

Although referred leg symptoms are common, clearly not all are caused by nerve root involvement, with radiation also known to be somatically referred from various structures. As Lin et al. (2014) conclude, there is clearly a need to establish consistent definitions within the area of LBP to facilitate communication in clinical practice and research, whether when making treatment recommendations, or to allow meaningful comparison between studies.

3.2.3 Difficulty in further sub-grouping LBP and NSLBP

Even allowing for the possibility of correct delineation into NSLBP, with judicious exclusion of dysfunction caused by nerve root involvement or specific spinal pathology, and the exclusion of the term sciatica, by definition the term nonspecific still defines uncertainty over the exact patho-physiological cause of the spinal pain. There may also be coexisting spinal conditions which may be tarnishing the presumed NSLBP clinical presentation, which may be made up of one, or a combination of NSLBP pathology (say from muscular, ligamentous, SIJ, or hip), and introducing population heterogeneity.

It is also pertinent to note the large size of this NSLBP population, with 85 – 99% of cases fitting into this unspecified category (Lehtola, Luomajoki, Leinonen, Gibbons, & Airaksinen, 2016; Manek & MacGregor, 2005; Waddell, 1987, 2005). Hall (2014) stated that the unhelpful and indeed detrimental diagnosis of NSLBP leads to an ineffective one-size-fits-all treatment routine. It is this very process that has been followed by the researchers and remaining unrecognised by later authors of the SRs, in studying traction for NSLBP by assuming this one size fits all treatment paradigm.

This means that past studies have been judging the efficacy of traction on NSLBP as a whole, which seems overly simplistic considering a third may either be due to SIJ, or facet, or combinations of pathology, some of which may actually be exacerbated by traction. Weber (1973) made the comment that when judging the effects of traction, one must be aware that back ailments are a heterogeneous group of diseases with complicated aetiology, and both organic and psychic in nature.

In addition to future researchers having to acknowledge, identify, and comply with the need to differentiate and separate nerve root pain from NSLBP, some researchers are also proposing further sub-grouping of the NSLBP category. The NSLBP category is large, so to delineate it into even more specific subgroups would result in more homogeneous study populations, and so help identify appropriate and specific pain treatment options. (Apeldoorn, Bosmans, Ostelo, de Vet, & van Tulder, 2012; DeLitto, Erhard, & Richard, 1995; Itz et al., 2013). However, the evidence to support that subgroups can be identified, or that a specific type of management is available for each subgroup, is questionable (Kamper et al., 2010). Chanda et al. (2011), stated that this heterogeneity within the category of NSLBP has proven to be a major challenge in clinical trials, with no consensus reached regarding the appropriate sub-grouping of this NSLBP population.

With respect to identifying a potential sub-group of LBP patients who may respond to lumbar traction, it was suggested by Fritz, et al. (2007), that a subgroup of patients which are likely to benefit from mechanical traction may exist with the following characteristics;

- characterized by the presence of leg symptoms
- signs of nerve root compression
- or one of either peripheralisation with extension movements, or a crossed straight leg raise.

Stynes, Konstantinou, and Dunn (2016) described and appraised papers that classify or subgroup populations with low back-related leg pain (LBRLP), and summarised how leg pain

due to nerve root involvement is described and diagnosed in the various systems. They stated that the identification of clinically relevant subgroups of LBP is still considered the number one LBP research priority in primary care. They also emphasised that an important subgroup of LBP patients are those with LBRLP, as it is associated with increased levels of disability and higher health costs than LBP. They accentuated that distinguishing between the different types of LBRLP is important for clinical management, but also has research implications, as homogeneous groups would be expected to respond more favourably to certain management options.

Stynes et al. (2016) also felt that there is still no clear agreement on how to define and identify LBRLP due to nerve root involvement, and that the classification of LBRLP merits more attention. Especially in primary care settings where most of these patients are assessed and managed, and this should start with agreement on criteria that reasonably distinguishes nerve root pain, from somatic pain. Stynes et al. concluded that a greater understanding of the profile of LBRLP patients could help shape future research questions and directions in this subgroup of patients in terms of prognostic and effectiveness studies.

It can be seen that there remains no answer to this uncertainty, and this leads to an important clinical consequence; the results of well-meaning and well-directed treatment to a structure, presumed clinically and / or by investigation, to be the nociceptive source of the patient's pain, will understandably fail if this presumption is wrong. Waddell (1987), explains that as time goes by without a 'fix' for the LBP, it becomes more chronic in nature. This inherently leads to more anxiety in the patient and a greater chance of pain catastrophizing and fear avoidance behaviours developing, due to a combination of an individual's innate perception of the total pain experience. This is extrinsically driven by their interactions with medical practitioners, conversations with friends and family, and the influences of the media. This causes a shift from the predominantly biomedical model, where pain is seen to be a direct consequence of the underlying tissue injury or pathology and the associated presumption that the symptoms will diminish if the pathology is removed, to the more

complex biopsychosocial model (Fig. 15), which is the result of the interaction between biological, psychological and social factors (Engel, 1977; Waddell, 1987).

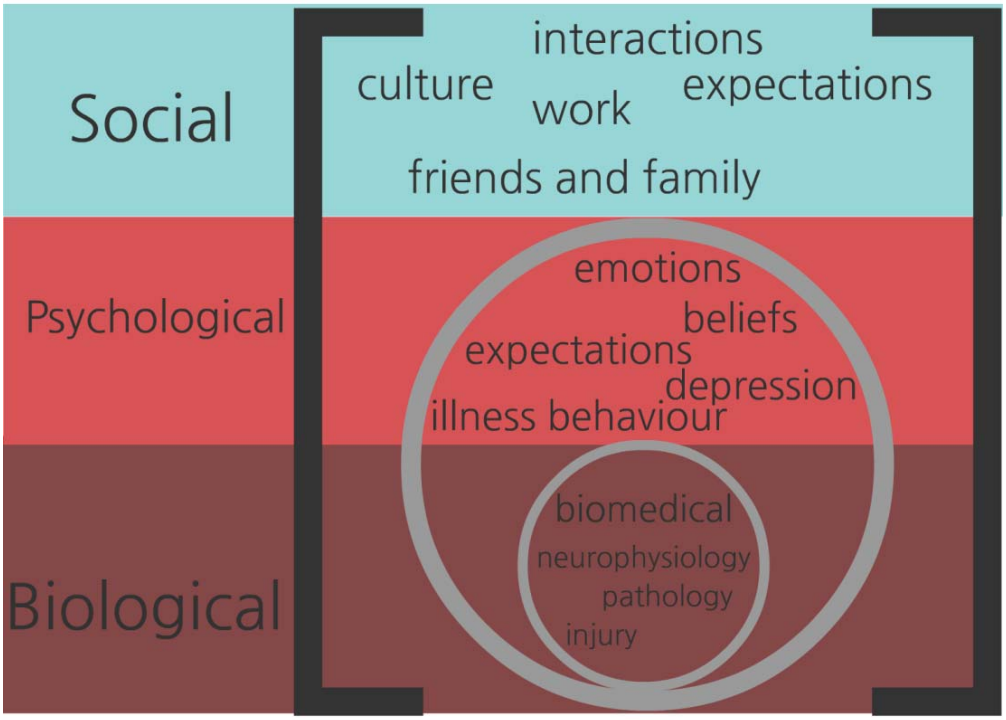


Figure 15. Biopsychosocial model with embedded Biomedical model (adapted from Waddell, 1987)

Psychosocial factors in particular become more important in the transition from acute to chronic LBP (Bekkering et al., 2003), as the patient may struggle with why the pain is not responding as expected, along with developing central changes involving increased sensitisation within pain perception at the spinal cord and brain. Ford, Story, and McKeenen (2003) stated that the majority of studies that relate to the classification of back pain have focused only on a single dimension of the problem, rather than consideration being given to all dimensions of LBP. Waddell (2005), later suggested that these dimensions consist of pathoanatomical, neurophysiological, physical and psychosocial factors (section 3.3).

3.2.4 Applied differences in pathoanatomical diagnosis within clinical practice and RCTs

Chanda et al. (2011), stated that this heterogeneity within the category of NSLBP has proven to be a major challenge in clinical trials, with no consensus reached regarding the appropriate sub-grouping of this NSLBP population. So consequently within the majority of LBP patients in general and NSLBP in particular, there remains uncertainty over which potential pathology an individual may have. These arguments would suggest that it remains very difficult to confidently place homogeneous participants into an appropriate intervention within rigid RCT designs. In clinical practice it is accepted to have a working or differential diagnosis from which to inform the choice of intervention. The fluid clinical environment allows for this uncertainty, and for it to be constantly reviewed and updated depending on the response of the patient.

The evidence that we can be specific in pathoanatomical diagnosis of LBP is dubious (Hildebrandt, 2013). A SR by Malik, Cohen, Walega, and Benzon (2013) concluded that there is currently no clear definition of a presumably painful disc, and no reliable means exist for its diagnosis. Another by Maas et al. (2016) stated that the diagnostic accuracy of patient history and / or physical examination to identify facet joint pain is inconclusive. Mistaken conclusions regarding these subgroup effects will result in people being denied a beneficial treatment, or even receiving an ineffective, potentially harmful treatment.

A SR looking at research into sub-grouping was undertaken by Saragiotto et al. (2016) to examine the continued claims made by a large group of people that NSLBP can be divided into subgroups of people who will respond better to one specific treatment than to any another (Kent and Keating 2004, 2005). The sub-grouping of participants offers the possibility of a larger treatment effect within a subgroup, rather than the inconsistent effects found when applying generic treatments to a heterogeneous population of people with NSLBP (Fritz et al., 2007; Kamper et al., 2010). The identification of subgroups has also

been proposed as an important research priority internationally for many years (Borkan, Koes, Reis, Cherkin, 1998).

However despite this need to identify more succinct sub-groups, there has also been methodological limitations within sub-grouping studies, such as failing to pre-specify the hypothesis of the subgroup effect, performing a large number of post hoc subgroup analyses, and undertaking inappropriate statistical analysis, making the findings susceptible to several biases (Sun et al., 2012; van Klaveren, Vergouwe, Farooq, Serruys, & Steyerberg, 2015). So although recognised as important it remains uncertain how LBP can be more accurately identified. This causes a fundamental difference between clinical practice where a differential diagnosis is identified, which remains fluid and can alter depending on how the patient responds to certain treatments and changing the management as a result; and the RCT where a cohort of supposedly diagnostically certain (and fixed) patients are randomised to a predetermined and persistent treatment regime.

3.3 Duration of low back pain

If there is a need to delineate duration of LBP into categories termed acute, subacute and chronic, then the definition of this needs to be agreed upon and consistent. It can be seen that historically variable definitions have been used for these different categories of pain making comparisons between studies difficult and causing heterogeneity (Table 2).

Table 2. Variation in the definition of pain duration used in sample of pertinent literature

Guideline	Year	Acute	Sub-acute	Chronic
Philadelphia Panel Evidence-Based Clinical Practice Guidelines on Selected Rehabilitation Interventions for Low Back Pain	2001	< 4 weeks	4 weeks to 12 weeks	> 12 weeks
Australian Acute Musculoskeletal Pain Guidelines Group	2003	< 5 weeks	5 weeks to 3 months	> 3 months
NZ Guidelines for Acute LBP in association with ACC	2004	< 3 months	Seemingly not recognised	> 3 months
The European Commission, Research Directorate-General, department of Policy, Coordination and Strategy	2006	< 6 weeks	6 – 12 weeks	≥ 12 weeks
National Collaborating Centre for Primary Care, NICE guidelines	2009	< 6 weeks	Seemingly not recognised	> 6 weeks and < 12 months
The Institute of Health Economics, Alberta, Canada	2012	< 6 weeks	6 weeks to 3 months	> 3 months
Cochrane Systematic Review by Wegner et al.	2013	< 4 weeks	4 weeks to 12 weeks	> 12 weeks

Balagué et al. (2012) state that in about 10 – 15 % of patients, acute LBP develops into chronic LBP. This would lead itself onto an exploration of another area of controversy concerning when this change from acute to chronic occurs, and what factors may be involved. Also given the variation in duration seen, if it's not by time then how may this change-over be best measured; and finally what are the consequences of including patients with acute and chronic pain within the same cohort.

Gudavalli et al. (2006) discussed that while disparity within treatment modalities between clinical trials of chronic LBP may have facilitated conflicting evidence, additional problems can be attributed to substantial variation in the definition of the word chronic as related to LBP. Andersson (1999) for example, found five distinct definitions:

1. Pain lasting longer than 7–12 weeks
2. Pain lasting longer than expected
3. Recurrent back pain

4. Symptoms resulting in loss of days at work or disability
5. Convenience diagnosis for individuals disabled for other reasons (including psychological)

Gudavalli et al. (2006) point out that both time frame and recurrence of LBP vary among studies, and are further complicated when you consider symptom severity. Subjects with mild pain respond differently to a single treatment strategy in comparison to subjects who are in severe pain. Also studies of patients with chronic LBP may also include patients with leg symptoms of uncertain aetiology, and so chronic LBP is an extremely complex syndrome. Gudavalli et al. also found within their research that there seemed to be a lack of understanding of potential subgroups in the clinical population, and that patients should be classified into subgroups and included into clinical trials according to the prognosis of individual subgroups to specific treatment regimes.

Turk (2005) suggested that patients with a variety of chronic pain syndromes may be clinically hampered by the patient homogeneity myth, which was described as the erroneous belief that patients given the same diagnosis are sufficiently similar in important variables related to treatment.

Chanda et al. (2011) concluded that there is currently limited information regarding differences in clinical features between the duration of pain classifications; and that pain characteristic differences, as a function of back pain duration, clearly warrant further investigation.

Crins et al. (2015) described pain that persists beyond the expected tissue healing time, rather than an arbitrary time period, as being chronic pain. This would seem a very sound definition; for instance functional recovery following anterior cruciate ligament reconstruction surgery is accepted to take 9 – 27 months (Shelbourne, Klootwyk, & DeCarlo, 1992; Samaan et al., 2015). This would not necessarily be classed as chronic pain, or associated

with any undue psychosocial involvement, but a perfectly normal expectation. But alternatively some individuals may exhibit some undue psychosocial factors but these would not be attributable to temporality. These influences of pain duration seem to have been undervalued, or ignored in previous studies.

The importance of this delineation of acute from chronic is now more recognised. The pathophysiology of LBP can change dependent on the characteristics of each individual and their perception of pain; simultaneously affecting and effecting pain duration. Low back pain can be pathoanatomical, psychosocial, and neurophysiological, with Butler and Moseley (2014) recently suggesting it can be influenced by, and also affect, the immune system.

However, Waddell (1987) claimed that chronic pain is a completely different clinical presentation than acute pain, not only in terms of time, but also due to the increasing biopsychosocial effects of chronic pain. He discusses the emergence of the understanding of pain shifting from a purely body response, to being fundamental to an individual and connected to the mind, from whence he suggested that the biopsychosocial model of pain be applied to address the increasing concerns over LBP disability and its medical management. He felt that chronic pain becomes increasingly dissociated from the original physical source and sometimes there may be little left of the initial underlying nociceptive stimulus, and it is accepted that due to the chronicity and irrespective of the reason, these patients are very likely to have a greater contribution from the psychosocial factors (Mayer et al., 2014). The extended chronicity also results in central and peripheral neural sensitisation (Butler & Moseley, 2014).

The resultant chronicity leading further away from the biomedical model of pain, where pain is seen as a direct consequence of underlying pathology (Bekkering et al., 2003), more applicable to acute pain and the time necessary for tissue repair; and more into the biopsychosocial model of pain (Waddell, 1987), with patients potentially falling deeper into the “vortex of disability and despair” (P. Bell, personal communication, circa 2000).

Some practitioners even believe that it remains plausible that chronic NSLBP is a misnomer and these patients actually have a specific type of LBP which has been undiagnosed, misdiagnosed, or mistreated, leading to chronicity with associated psychosocial factors, but which would still fit into a biomedical model once the 'correct' diagnosis was discovered and appropriately treated (Côté, Durand, Tousignant, & Poitras, 2009). However, it is accepted that due to the consequential chronicity and irrespective of the reason, these patients are very likely to have a greater contribution from psychosocial factors which would also need to be addressed in concert with appropriate treatment directed at the pathoanatomical cause (Mayer et al., 2014).

This is also pertinent to undergraduate education where Domenech, Sánchez-Zuriaga, Segura-Ortí, Espejo-Tort, & Lisón (2011) found that a brief but strictly biomedical education syllabus exacerbated maladaptive beliefs in students, and consequently resulted in inadequate activity recommendations; whereas students taught a brief biopsychosocial approach displayed a reduction in fear-avoidance beliefs ($P < 0.001$) and pain impairment beliefs ($P < 0.001$), which were strongly correlated with an improvement in the clinicians' activity and work recommendations given to the patient. They concluded that the implications of their study were paramount for both the development of continuing medical education, and in the design of the training curriculum for undergraduate students.

Darlow et al. (2012) expanded on this, finding that there was strong, consistent evidence to suggest that the attitudes and beliefs of patients with LBP were associated with the attitudes and beliefs of the health care practitioners (HCP) with whom they consulted. So it is plausible that the position of the pathophysiological leaning, attitudes, and beliefs of clinicians and researchers along this biopsychosocial continuum, may influence the patients' expectation of recovery; and consequently affect outcomes, leading to practical differences within individual practitioners and clinics, and between clinical practice and clinical trials.

It seems an intervention performed within the real world clinical environment can either be influenced negatively or positively, dependent on the HCPs own beliefs and attitudes

towards pain. This subjective experience of pain is influenced not only by the objective severity or physical deformity, but also to the individuals' innate attitudes and beliefs, and the influences of friends, family, media and technology, as well as from their interactions with the medical profession (Darlow et al., 2012). This effect has been historically omitted within clinical trials. This unique perception of pain can alter pain behaviour as well as psychological state, leading to wide variations in illness behaviour and perception, as highlighted within the biopsychosocial model (Waddell, 1987), and potentially mask actual, yet unrealised, positive responses to interventions.

It has been suggested that chronic pain may even be best treated in a multi-disciplinary environment to fully address the full biopsychosocial continuum (Kamper et al., 2014; Snelgrove & Liossi, 2013), and there is still uncertainty over when and how the shift from predominantly biomedical to biopsychosocial occurs (Laisné, Lecomte, & Corbière, (2012).

3.3.1 Natural history of low back pain

To further confuse the design of past studies the natural history of LBP is quite favourable, for example in 'sciatica' (see section 3.2.2) from assumed acute disc herniation, 36 % of patients report major improvement after 2 weeks, and up to 73 % have resolution of their leg pain by 12 weeks (Peul et al., 2007; Svensson, Wendt, & Thomeé, 2014). Due to this natural resolution, Svensson et al. (2014) recommended adopting a structured physiotherapy treatment model before considering surgery for patients with symptoms such as pain and disability due to lumbar disc herniation.

Zhong et al. (2017) looked at the spontaneous regression of lumbar disc herniation (LDH) at repeat epidurography. Zhong et al. identified that the phenomenon of LDH reabsorption had been recognized, and its overall incidence was 66%. Concluding that the phenomenon of spontaneous recovery combined with appropriate conservative treatment should be the first choice for treating LDH.

Meaning that in any cohort some participants will improve, regardless of and independent to the intervention being investigated. This spontaneous recovery would need to be equivalent within groups and between studies to ensure homogeneity, and likely require large populations.

3.4 Other methodological flaws in LBP research

Quantitative research around LBP in general has been accepted to be poor due to other deficiencies in methodological designs. In itself, this should have rendered many of the conclusions that we have formed and accepted regarding LBP epidemiology, clinical assessment, diagnosis, treatment, rehabilitation, and surgery, to be inaccurate and misleading.

These previously identified methodological flaws relating to the design and methods used to collect and analyse data within research into LBP have subsequently been verified and accepted (Beurskens et al., 1997, Henschke et al., 2012, Koes et al., 1995, Pellecchia 1994, van Tulder et al., 2007). These authors have identified more practical weaknesses, such as;

- methods used for randomisation,
- lack of blinding of subjects, assistants and researchers,
- number of subjects, and low power,
- lack of a control group,
- the choice of outcome measures used and their relevance or ability to detect relevant clinically significant changes,
- statistical analysis used,
- number of drop-outs and the effect on intention-to-treat analysis, compared to the per protocol analysis,
- lack of a follow-up period used to provide a measure of the longer term effect of interventions,
- failure to distinguish between statistically significant and clinically significant results,

- accuracy and appropriateness of the analysis of results and the subsequent conclusions and generalisations made.

Beckerman et al. (1993), looked at 400 RCTs on the efficacy of physiotherapy for musculoskeletal disorders. They used their own points scoring system similar to Koes et al. (1995), van der Heijden et al. (1995), and van Tulder et al. (1997) to rank studies. Beckerman et al. concluded that the methodological quality appeared to be low, and the efficacy of physiotherapy was shown to be convincing for only a few indications and treatments. However, they stressed that it was inaccurate to conclude that physiotherapy has no effect, solely due to the prevalence of serious methodological flaws within the studies. It remains controversial that the conclusions from these poor studies were analysed in SRs and reported in CPGs.

3.5 Summary

This chapter has identified numerous explanations for the discrepancy between the anecdotal clinical support for traction, and the negative scientific recommendations. In addition to those universally accepted methodological flaws identified during and post randomisation, it is imperative that prior to randomisation heterogeneity is avoided by ensuring fastidious participant selection. To achieve this researchers need to ensure equivalence of diagnosis within accepted definitions, duration, and prognosis of LBP in the study cohort, and then consider the appropriateness of the intervention for that particular diagnostic subgroup and whether it mimics and is externally valid to clinical practice. Overlooking any of these identified methodological factors, from participant selection through to analysis of results, will produce misleading and inappropriate conclusions. This will have important consequences in clinical practice where busy professionals rely on published RCTs, SRs, and especially CPGs to help inform their clinical practice, and may not have the time, ability, or realise the need to critically analyse them within reference to their own clinical reasoning and experience.

Chapter 4. Results - Chronological Narrative Reviews

Applying the findings from the background (Chapter 2) and review of literature (Chapter 3), this results chapter will consist of two chronological narrative reviews to examine if the literature was cohesive and resulted in scientifically and clinically appropriate conclusions and recommendations. The first will focus on SRs and include critique of the primary studies they referenced, as well as other supporting literature, and the methodology within the SRs themselves. The second will focus on the processes used within CPG development, and recommendations of the CPGs informed by the primary research and findings of the SRs. As there are few clear guidelines for writing a narrative review (NR), this NR will follow Ferrari (2015) who recently published guidelines for improving NR writing in areas related to clinical research. Ferrari states that a historical NR is irreplaceable to track the development of a scientific principle, or clinical concept, and suggested the preferred format is introduction (section 4.1), methods (section 4.2), results (section 4.3), analysis (section 4.4), and discussion (Chapter 5). Ferrari suggests that a NR may be organised in chronological order, to give a historical perspective and to more easily track developments along a timeline, with a summary of the history of research when clear trends are identified.

4.1 Introduction

These are the first narrative reviews designed to focus on the pertinent historical literature on the efficacy of traction for LBP, with the purpose of outlining how methodological flaws, although identified and appreciated by some authors at the time, seem to have been repeatedly overlooked within SRs. There have been four systematic reviews of the primary literature (Appendix A), the first by van der Heijden et al. (1995), and three later undertaken within the Cochrane Collaboration specifically looking at the efficacy of traction for LBP; Clarke, van Tulder, Blomberg, de Vet, van der Heijden, and Bronfort, (2005), Clarke, van Tulder, Blomberg, de Vet, van der Heijden, Brønfort, and Bouter, (2007), and Wegner, Widyahening, van Tulder, Blomberg, de Vet, Brønfort, Bouter, and van der Heijden, (2013).

The immediate observation is that these SRs, as well as some other pertinent literature, have involved a similar group of researchers. This is important, as reviewers screen the pertinent literature to include studies which they consider, based on their research experience to be relevant and have a low risk of bias. However, each of the SRs admit that in the absence of overwhelming scientific evidence on the efficacy of traction for LBP, their conclusions are based on qualitative assessment and opinion of the authors. These opinions within the SRs have been imperative in informing the subsequent CPGs regarding the efficacy of traction for LBP, and for determining the use of traction in clinical practice for patients with LBP.

These chronological narrative reviews will centre on the four SRs undertaken on the efficacy of traction for LBP, and will closely examine and critique the primary literature to discover if this literature was worthy of inclusion into the SRs. I will also detail pertinent information from related literature, including discussions, conclusions and recommendations, to illuminate this discussion. The chronological review will also provide a critique of the methodology of the SRs and CPGs themselves. The detailed chronological synthesis and critique of the primary literature included within three of the SRs, but not Clarke et al. (2005) as this is included within the Clarke et al. (2007) SR, and subsequent CPGs can be found in Appendix A.

It is also imperative to state that this NR should not be suspected of suffering from any bias, as it is simply investigating and presenting pertinent literature set against the critical points identified within the earlier chapters; particularly the rationale used to select the study cohorts within the primary research itself, and the methods and justification utilised by the authors of the SRs and CPGs. It is also important to highlight that this NR will focus on the methodological process in the selection of the study cohorts within the primary research themselves, and not detail the other commonly accepted methodological flaws found within RCTs which were discussed in section 3.4.

The argument in this NR is that heterogeneity in cohort selection alone, would be enough to invalidate the results and conclusions of any trial, and exclude them from SRs.

4.2 Method - Literature search

The databases searched for this NR were housed within the Massey University EBSCO search engine; Discover, Medline, PubMed, Web of Science, CINAHL Complete, Scopus, Cochrane database, PEDro, and Google Scholar, and also reference lists in all the pertinent literature were examined to identify key studies for discussion.

The keywords used to search the aforementioned databases were: traction, horizontal traction, inversion, gravitational traction, low back pain, nonspecific, non-specific, LBP, NSLBP, referred leg pain, sciatica, systematic review*, and clinical practice guideline*.

The search period included articles up to July 31, 2017.

All the primary literature referenced by the SRs were also sourced and reviewed in depth (Appendix A).

4.3 Results

The results will consist of a NR of systematic reviews and pertinent historical literature (section 4.3.1), a NR of clinical practice guidelines and processes (section 4.3.2), and a summary timeline of the important literature from Chapters 2, 3, and 4 (section 4.3.3)

4.3.1 Systematic reviews and pertinent historical literature critiqued within a chronological narrative review

Prior to the first SR by van der Heijden et al. (1995), one of the first critical articles on the use of spinal traction by Saunders (1983) concisely forewarns of the focus of this thesis, that research studies need to be of sufficient quality and also mimic how traction is clinically performed,

> Spinal traction is a time-honored method for the treatment of disc protrusion, degenerative disc disease, and joint dysfunction. Effective treatment is not as easy or as simple to administer as it may appear. Many variations of technique exist, some of questionable value. It must be emphasized that spinal traction is only a part of the total management-treatment regimen, which includes other forms of physical therapy. Without a total management program, spinal traction, like many other empiric methods, has little chance of long-range benefit. Consequently, physicians prescribing spinal traction must be prepared to apply proved diagnostic methods and other treatment methods (p. 31)

It seems reasonable that subsequent research and SRs needed to be cognizant of this critical statement.

Pellecchia (1994), recognised that both Cyriax (1975, 1984), as well as Saunders, and Saunders (1993) had developed detailed guidelines for administering traction in the clinic. Each guideline described a very fluid clinical application of traction, explaining that the patient may be positioned prone or supine, with the traction belts exerting a pull to the anterior or posterior aspect of the joint, with knees and hips flexed or extended, and using the criteria of patient comfort, pattern of pain responsiveness, limitation of trunk movement, as well as treatment goals and effectiveness, to determine appropriate patient and pelvic strap positioning, and temporal factors.

In addition, mechanical traction could be administered statically or intermittently, with the presentation of the individual patient and theoretical clinical reasoning available at the time dictating which may be used first, but importantly allowing the practicing clinician to change the protocol itself, or desist with traction altogether, if the traction paradigm initially selected was not successful.

Pellecchia (1994) rightfully acknowledged that each were based largely on anecdotal clinical practice rather than from controlled investigation. Pellecchia stated that many factors such

as patient position, treatment mode, traction force, duration, and frequency, all need to be considered when administering mechanical lumbar traction, which may make scientific investigation more involved.

The purpose in outlining Saunders (1983), Cyriax (1984), Saunders and Saunders (1993) and Pellecchia (1994) is to highlight how the clinical practice of traction was undertaken at the time, and allow comparison with the subsequent scientific literature. With this knowledge, it can be appreciated if the clinical practice of traction was mirrored within the methodological design of RCTs, or appreciated by van der Heijden et al. (1995), and subsequent SRs and CPGs.

Van der Heijden et al. (1995) stated in their introduction that;

> Although RCTs potentially provide the most valid and precise results, flaws in their design and conduct can result in overestimation or underestimation of treatment effects, and consequently can lead to false-positive or false-negative conclusions. Therefore, we will place strong emphasis on the quality of the methods of the studies selected for review (p. 94).

They state that the quality of the design and conduct of the selected studies was assessed according to the accepted methodological principles of intervention research at the time (Meinert, 1986; Feinstein, 1985; Pocock, 1983). To rank quality of the studies van der Heijden et al. (1995) used a points scoring method similar to an earlier review by Koes et al. (1995), and later by van Tulder et al. (1997), this comprised of four categories and 16 criteria, every item was given a certain weight relating to its possible contribution to the validity and precision of the study. Consequently a study could earn a maximum methodology score of 100 points. This early attempt at a SR on the efficacy of traction for LBP seems flawed. The weighted rating system as described is arguably poorly informed. (Table 3).

Table 3. Scoring systems as used by Koes et al., (1995), van der Heijden et al., (1995) and van Tulder et al., (1997)

	Criteria	Weight		
		Koes et al., 1995	Van der Heijden et al., 1995	Van Tulder et al., 1997
Study Population				
A	Description of inclusion/exclusion criteria	1	2	2
	Homogeneity	1		
B	Comparability of relevant baseline characteristics (Koes et al. describes 1 point each for;	5	10	5
	duration of complaints	(1)		
	value of outcome measures	(1)		
	age	(1)		
	recurrence	(1)		
	radiating complaints)	(1)		
C	Randomisation procedure described	2	4	4
	Excludes bias	2		
D	Dropouts described for each study group separately	3	4	3
E	<20% loss to follow-up	2	8	4
	<10% loss to follow-up	2		
F	>50 subjects in the smallest group	8	12	17
	>100 subjects in the smallest group	9		
Interventions				
G	Interventions standardized and described	5	5	10
	All reference treatments put in protocol and described	5		
H	Pragmatic study/control group adequate	5	5	5
I	Co-interventions avoided	5	6	5
J	Placebo controlled, comparison with placebo	5	4	5
Measurement of effect				
K	Patients blinded		6	5
	Placebo controlled, attempted blinding	3		
	blinding evaluated and fully successful	2		
	Pragmatic study, patients fully naive	3		
	Time restriction (no physio ex for >1 yr)	2		
	Naiveness evaluated and fully successful	2		
L	Outcome measures relevant;	10	10	10
	pain	(2)		
	global measure of improvement	(2)		
	functional status	(2)		
	spinal mobility	(2)		
	medical consumption	(2)		
M	Blinded outcome assessment, each point under L earns two points	10	10	10
N	Follow up period adequate		4	5
	During or just after treatment	3		
	After 6 months or longer	2		
Data Presentation				
O	Intention-to-treat analysis	5	5	5
P	Frequencies of most important outcomes presented for each treatment group, presentation of mean or median with standard error	5	5	5
		100	100	100

Although this assessment criteria is intensive and rightfully considers all aspects of methodological design, this NR is only concerned with the first two criteria; specifically description of the inclusion and exclusion criteria and homogeneity (Table 3, Part A), and also comparability of relevant baseline characteristics, specifically duration of complaints, and radiating complaints (Table 3, Part B). Van der Heijden et al. considered that a prognostic homogeneous study population would be recruited if trial participation is restricted to a subgroup of patients with identical treatment susceptibility and prognoses. They explained how randomisation scatters confounders, the known and unknown determinants for prognosis and treatment susceptibility, over the groups which ensures they are comparable.

This is true providing that the participants within these groups are primarily and fundamentally comparable at randomisation, in terms of their clinical presentation, susceptibility, and prognosis. Crucially, traction also needs to be an appropriate intervention for their particular diagnosis, and consequently to be externally valid, would need to be utilised for that specific presentation in clinical practice. Underestimating the importance of these prerequisites, van der Heijden et al. considered that despite some incomplete information, the studies that they included were methodologically sound with respect to restriction to a homogeneous population (Table 3, Part A). This was the first reasoning error.

They also felt that although they did find common methodological flaws concerning incomparability of prognosis at baseline (Table 3, Part B), that most studies were also methodologically sound with respect to prognostic homogeneity of the selected population. This was the second reasoning error.

Van der Heijden et al. identified 14 studies on lumbar traction, (Bihaug, 1978; Coxhead et al., 1981; Larsson et al., 1980; Lidström & Zachrisson, 1970; Ljunggren, Weber, & Larsen, 1984; Mathews & Hickling, 1975; Mathews et al., 1987; Pal, Mangion, Hossain, & Diffey, 1986; Reust, Chantraine, & Vischer, 1988; van der Heijden et al., 1991; Walker, Svenkerud,

& Weber, 1982; Weber 1973; two trials in Weber, Ljunggren, & Walker, 1984). They scored only two of these as greater than 50 points, van der Heijden et al. (1991), and Mathews et al. (1987).

Of note is that van der Heijden et al. (1991) was later excluded from subsequent revisions (Clarke et al., 2005, 2007; Wegner et al., 2013) as it was a pilot trial, consequently it will not be further discussed here.

Mathews et al. (1987) state their inclusion criteria as LBP and sciatica (with onset of the most recent feature within 3 months), and local tenderness, asymmetrical restriction lumbar movements, asymmetrical SLR or positive femoral nerve stretch, and nerve root pain. Mathews et al. purposely excluded participants with uniradicular neurological deficits. However, they do not explain how they defined this. Considering this, the use of the term sciatica, and the full assessment criteria not stated within the study, it is highly likely that their cohort suffered from heterogeneity caused by including somatic and radicular referred pain (no neurological deficits), as well pain referred from SIJ and hip pathology.

Also in the cohort that undertook traction, pain duration ranged from zero days to 13 weeks, encompassing a wide variation of acute, subacute, and even chronic pain participants. It can be appreciated that the study was undertaken on a heterogeneous group of participants with LBP and sciatica of varying pain duration, so despite scoring greater than 50 points from including other criteria, this was irrelevant, the study should have been excluded from their SR.

However despite van der Heijden et al. (1995) missing these points, their conclusion was fair; that due to the overall poor methodological quality of the studies reviewed it was not possible to formulate a strong and valid judgment about lumbar (or cervical) traction.

The next review also sitting outside of the Cochrane Collaboration, was undertaken by Van Tulder et al. (1997) entitled “Conservative treatment of acute and chronic nonspecific low back pain: a systematic review of randomized controlled trials of the most common interventions”, which included a section on traction. Despite the title restricting their

assessment to NSLBP, paradoxically the author's state within their methods section that studies on patients with LBP were also included.

Van Tulder et al. also devised their own scoring system but with variation in how the points were allocated (Table 3). In addition to the critique of the rationale of using a scoring system anyway, the illogicality to further drop the weighting associated with comparable baseline characteristics seems to be a questionable decision and highly perplexing. It provides further support for the underappreciation of the critical importance of ensuring appropriate and balanced participant selection.

They went on to describe definitions of acute LBP as pain persisting for 6 weeks or less, and chronic LBP as lasting 12 weeks or more, resulting in a sub-acute category (6-12 weeks). Interestingly van Tulder et al. accepted that the primary studies they reviewed could include their participants with sub-acute pain alongside acute LBP (so in effect a 0 to 12 week category), or alternatively could include sub-acute pain alongside chronic LBP in their cohorts (6 to 12+ weeks). It seems that this would introduce a significant risk of heterogeneity both within and between studies.

With respect to traction for acute LBP, which they stated as pain persisting for less than 6 weeks, but could include sub-acute pain up to 12 weeks, they identified only two low quality RCTs (Larsson et al., 1980; Mathews & Hickling, 1975). Larsson et al. (1980) performed auto-traction for the treatment of lumbago-sciatica, on participants with or without symptoms of neurological deficit but who had a positive straight leg raise, and whose duration of symptoms varied between 2 weeks and 3 ½ months, which puts this study outside of their own 12 week definition for acute (plus sub-acute) pain.

The second paper by Mathews and Hickling (1975) was on participants with sciatica (pain felt down the back of the leg) or cruralgia (pain felt down front of the leg), with or without LBP, excluding those with recently acquired neurological deficit, and participants had pain

duration from 3 to 43 weeks (with a mean of 14 weeks) in the intervention group, and 1.5 to 46 weeks (with a mean of 12 weeks) in the control group.

The immediate concerns regarding van Tulder et al. (1997) including these two papers within a SR of acute NSLBP are why;

- primary literature including participants with LBP, lumbago-sciatica or cruralgia, and/or neurological deficit, and positive neural straight leg raise, are within a review on the conservative treatment of acute NSLBP. These are nerve root classifications and are not within NSLBP (section 3.2).
- why both of these studies included participants whose duration of pain had lasted longer than the inclusion criteria of 12 weeks as set by van Tulder et al. and thus having chronic pain.

Van Tulder et al. went on to state that there was limited evidence supporting traction as more effective than placebo for acute LBP; but due to the serious transgressions as discussed above, this conclusion is inappropriate.

They identified one high quality RCT on the effectiveness of traction for chronic LBP, van der Heijden et al. (1995a) which was actually another pilot trial consisting of only 25 participants, with LBP for 3 months or longer. As it was also a pilot trial it should not have been considered. Also, within the method section it states that to be enrolled participants were required to have persistent NSLBP and / or sciatica, which is a nonsensical term (section 3.2). They stated that there is limited evidence that traction is not effective for chronic LBP, but as discussed this was based on totally inappropriate research studies included in their review and analysis. Van Tulder et al. (1997) also stated that " We believe that the quality of the design, execution and reporting of RCTs should, and indeed can, be improved, to establish strong evidence for the effectiveness of the various therapeutic interventions for acute and chronic LBP (p. 2137).

Krause et al. (2000), also identified that the efficacy of traction was unclear due to the generally poor design of past clinical trials, and that subgroups of patients most likely to benefit had not been specifically studied. They concluded that traction seemed most likely to benefit patients with acute (less than 6 weeks' duration) radicular pain, with concomitant neurological deficit. Krause et al. also suggested that the apparent lack of a dose-response relationship may mean that low doses were probably sufficient to achieve benefit, casting further doubt on the conclusions found in studies which had compared high traction forces to low traction forces (a supposed placebo), and finding no significant differences between groups.

Vroomen, de Krom, Slofstra, and Knottnerus (2000) looked at the conservative treatment of sciatica, noting that most patients with sciatica (which they attributed to disc protrusions) are initially managed conservatively given that the natural course seems to be favourable. They concluded that neither traction, (exercise therapy, nor drug therapy) were unequivocally effective, but also identified that the methodologic quality of trials they reviewed varied greatly.

Also identifying these deficiencies, Harte et al. (2003) expressed concern that the UK Royal College of General Practitioners guidelines (Waddell, McIntosh, Hutchinson, Feder, & Lewis, 1999) stated that traction did not appear to be effective for LBP or radiculopathy, thereby discouraging many clinicians from using it. They questioned this CPG recommendation as it was based on the only available SR by van der Heijden et al. (1995), who concluded that there was *no conclusive evidence* to suggest that traction was an ineffective therapy for back (or neck) pain due to the poor methodological quality of the studies. Borman et al. (2003) agreed that the literature on the efficacy of traction in the treatment of LBP is conflicting and despite the lack of compelling evidence that lumbar traction is clinically effective, concluded that there was also insufficient evidence of inefficacy to discard this method, particularly in patients with lumbar discopathies.

Harte, Gracey, and Baxter (2005) surveyed the attitude of physiotherapists in the UK towards traction following the publication of the UK Royal College of General Practitioners guidelines in 1996 and again in 1999, each stating that there was little evidence to support the continued use of traction in the management of LBP. Harte et al. (2005) found that past surveys had shown that the use of traction had varied somewhat between countries. A 1995 study demonstrating its use in 7% of LBP patients in the Netherlands (van der Heijden et al., 1995a). A 1997 study showed 21% in the United States (Jette & Delitto, 1997), a 1999 study showed its use on 7% of the LBP patients in the Republic of Ireland and the UK (Foster, Thompson, Baxter, Allen, 1999), in Canada a 2001 study up to 30% of patients with acute LBP and sciatica (Li & Bombardier, 2001), and a 2002 study revealing 13.7% in Northern Ireland (Gracey, McDonough, & Baxter, 2002). The results of Harte et al. (2005) indicated that 41% (n=507) of the respondents still used traction, but found 45% (n=553) did not, and regardless of practice setting, traction was *most commonly* used for the treatment of *subacute LBP*, and used less frequently with acute or chronic LBP.

Importantly, and which confirms the highlighted discrepancies between how traction is applied in clinical practice, as compared to clinical trials. The results also showed that patients received traction most commonly as part of a package (median, 100%; mode, 100%; IQR, 80%–100%), with only a small proportion receiving traction with advice alone (median, 0%; mode, 0%; IQR, 0%–15%). Traction was rarely used in isolation (mean, 0.85%; median, 0%; mode, 0%; IQR, 0%), and used most commonly to treat nerve root pain (median, 77.5%; mode, 100%; IQR, 50%–95%), and less frequently to treat stiffness (median, 5%; mode, 0%; IQR, 0%–25%), or generalized pain (median, 0%; mode, 0%; IQR, 0%–20%).

Also the most common positions for applying traction was supine either lying with the knees and hips flexed to 90° (67%, n=340), or lying supine with a pillow under the knees (19%, n=98). The most common reasons given for traction weight choice was; the size, weight, and build of the patient (74%, n=374), and the irritability, severity, and intensity of pain (53%,

n=266). The factors that most commonly influenced the choice of treatment duration were severity and irritability of the condition (43%, n=219), response to treatment at this or a previous episode (29%, n=147), and whether the condition was in the acute or chronic stage (22%, n=113).

Analysis showed that those patients with suspected nerve root pathology were likely to be seen two or three times a week (48%, n=200; 35%, n=143, respectively), whereas stiffness was treated one or two times a week (39%, n=106; 49%, n=134, respectively), and pain received treatment most commonly twice a week (56%, n=137). Frequency of treatment was influenced by several factors including the response to treatment (47%, n=237), the availability of appointments (46%, n=234), the severity and irritability of the patient's condition (40%, n=205), and whether the patient was acute or chronic (22%, n=110). Respondents were asked to estimate the number of weeks that traction was required to obtain a lasting response; the mean time was four weeks (mode, 3 – 4 wks; median, 3 – 4 wks; range, 1 – 15 wks).

The main reasons given by the UK physiotherapists for disagreeing or being undecided about the CPG were that traction appeared to work in clinical practice (71.6%, n=363), and less commonly, that the guidelines were based on poor quality research 4.7% (n=23).

This data offers up some interesting points of difference when clinical practice is compared to the methodological designs of experimental studies that have been referenced in reviews with respect to the efficacy of traction for LBP. It is apparent that traction is used clinically on only a small proportion of LBP patients (commonly less than 10%), most frequently with sub-acute pain, and most commonly on patients with nerve root irritation, with or without neurologic signs (78%). Also the positioning of the patient, the amount of force, the duration and frequency of treatment was largely based on individual responses to traction.

This critical information provides an important contribution to the dichotomy between clinical practice and the conclusions from RCTs and SRs. Research had been undertaken on

patients with generalised LBP (often incorrectly labelled NSLBP) with or without sciatica, which was regarded as a homogeneous group, when in fact this is a hugely heterogeneous group, with conditions that are more likely to respond to a particular treatment regime suited to a more specific classification (Fritz & George, 2000).

Harte et al. (2005) stated that;

> In future clinical trials that examine the effectiveness of traction, it is important to address not only methodologic quality but also the appropriateness of the intervention (Harte et al., 2003), particularly because inappropriate treatment procedures or inadequate treatment doses may lead to serious performance bias (Bjordal & Greve, 1998). A trial may be of a high methodologic quality, but if its treatment procedures are inappropriate, that weakness will affect the strength of the overall conclusion (Bjordal, Couppe, & Ljunggren, 2001) (p. 1164).

They also agreed that past trials on the effectiveness of traction are of poor methodological design, and suggested that using a pragmatic design within clinical practice, and incorporating the findings of their survey, would ensure a high-quality study that is clinically relevant.

Recognising the lack of a robust review, the Cochrane collaboration issued their first SR updating that of van der Heijden et al. (1995). Consequently Clarke et al. (2005) was published. Surprisingly they did not seem to appreciate the valid critiques and poor methodological standard of the past studies as previously highlighted.

Within Clarke et al. (2005) there is seen again clear juxtaposition of the terms LBP and NSLBP. Between the title of the SR stating “Traction for low-back pain with or without sciatica” and their selection criteria stating, “randomized controlled trials (RCTs) involving traction to treat acute (less than four weeks duration), sub-acute (four to 12 weeks) or chronic (more than 12 weeks) non-specific LBP with or without sciatica” (Clarke et al., 2005, p. 1). Once again this nonsensical term can be appreciated, this time within a Cochrane SR.

Clarke et al. (2005) also recognised and discussed the debate around the effect of traction force; with Beurskens et al. (1997) claiming that force is required to achieve separation of the vertebra and widening of the intervertebral foramina, and that forces below 20% of bodyweight constitute a placebo (sham or low dose) traction. In contrast to Harte et al. (2003), and Krause et al. (2000) who later countered this by claiming any force is therapeutic, as discussed in section 2.2. Although they recognised this debate, as well as the paper by Harte el al. (2005) regarding the current usage of traction in combination with other treatment modalities, they continued with their SR.

Within this SR, study selection, methodological quality assessment, and data extraction were done independently by sets of two reviewers. As the available studies did not provide sufficient data for statistical pooling, a qualitative analysis was performed. They identified 24 RCTs, involving 2177 patients (1016 receiving traction) in the review. However, only five trials were considered high quality, although how the authors rated the studies is unfortunately not included within the methodology of the review, apart from mention of them being judged against 11 set criteria.

Clarke et al. (2005) presented their findings under these headings;

1. Traction versus placebo, sham or no treatment

    1a. Traction versus placebo, sham or no treatment for patients with a mix of acute, subacute and chronic LBP with or without sciatica

    1b. Traction versus placebo, sham or no treatment for patients with a mix of acute, subacute and chronic LBP with sciatica

2. Traction versus other treatments

    2a. Traction versus other treatments for patients with a mix of acute, subacute or chronic LBP with or without sciatica

2b. Traction versus other treatments for patients with a mix of acute, subacute and chronic LBP with sciatica

2c. Traction versus other treatments for patients with chronic LBP and sciatica

3. Different types of traction

3a. Comparison of different types of traction for patients with a mix of acute, sub-acute and chronic LBP with or without sciatica

3b. Comparison of different types of traction for patients with chronic LBP with or without sciatica

3c. Comparison of different types of traction for patients with chronic LBP and sciatica

Supported by the arguments provided within Chapter 3, and the resultant heterogeneity within the primary literature that Clarke et al. (2005) identified within heading 1 (1a and 1b), heading 2 (2a and 2b), and heading 3 (3a and 3b), these will be automatically excluded. Due to the fundamental error of not ensuring cohort equivalence of prognosis at baseline; considering mixed pain duration and with or without sciatica as a homogeneous cohort, which immediately invalidates the results and conclusions from these studies.

A critique of the design of the primary studies identified under categories 2c (Ljunggren, Walker, Weber, & Amundsen, 1992; Sherry et al., 2001; Weber et al., 1984), as well as that under 3c (Ljunggren et al., 1984) will be presented as they may be more homogeneous. Albeit considering the continued use of the term sciatica, and as such the probability that nerve root pain will be included within NSLBP with or without sciatica, as the method stated earlier.

Ljunggren et al. (1992) randomised 51 participants to either isometric exercise, or manual horizontal traction (Fig. 4). Participants were inpatients with lumbago-sciatica due to a

proven herniated intervertebral lumbar disc, who had been admitted to the Department of Neurology and all considered potential candidates for disc surgery. Inclusion criteria were radiating pain, neurological symptoms and signs corresponding to a lesion of the L5 and/or S1 nerve root, confirmed by a lumbar myelogram in conformity with the clinical findings.

There is no indication of the clinical assessment criteria used, but sciatica was used to define radiating pain and neurological symptoms in these surgical candidates. To illustrate the presence of spontaneous recovery, one patient was later excluded following lumbar myelography, leaving 50 patients to be randomised. Patients with previous spinal surgery, spondylolisthesis, or root entrapment caused mainly by hypertrophic facet joints or a narrow bony canal, and cauda equina were excluded, however there is no mention if patients with non-mechanical or inflammatory conditions were identified and also excluded. However due to this spontaneous recovery in one participant, there remains questions over the accuracy and relevance of the diagnosis, and uncertainty of how many other participants may have had a spontaneous recovery of their LBP during the trail.

Although they state that the traction group had a mean duration of symptoms of 4.8 months, and the isometric group of 5.3 months (Ljunggren et al., 1992, Table 1, p. 208), within the text of the same page they state that random allocation to the treatment groups was performed regardless of age, sex, or *duration* of symptoms. They provide no definition of chronic pain duration, or report each individual's duration of pain, which in combination with the statement above suggests variability in pain duration. Alluding that Clarke et al. (2005) may have made an error of judgement assuming this study to be purely a chronic category.

Although this study by Ljunggren et al. (1992) was a valiant attempt to reduce the heterogeneity within the cohort selected; the uncertainty in the clinical assessment and depth of exclusion criteria, along with the mixed pain duration, leads to further concerns in regards to the validity of their conclusions for the efficacy of traction on LBP. What this study on clearly differentiated LBP with radiating pain and nerve root symptoms is doing within a

SR of NSLBP is also contentious. And will in line with the argument presented throughout this thesis, invalidate it.

The study by Sherry et al. (2001) also seems to have an improved design, 44 participants recruited through advertisements in local newspapers with LBP and associated leg pain, with confirmed disc protrusion or herniation on CT scan or MRI. However, there is no indication within the primary article of their definition or clinical assessment of LBP and the associated leg pain, or if they excluded SIJ or hip pathology. It is accepted that MRI or CT scans are not specific, nor sensitive enough to confirm pathology, due to the uncertainty with respect to reporting and incidence of false positives (Fardon & Milette, 2001; Fardon, et al., 2014; van Tulder et al., 1997a).

The participants all had chronic pain of greater than three months duration (mean / range years), intervention group (8.4 / 0.25 – 30), and control group (6.2 / 0.5 – 28). However, although qualifying with respect to an isolated chronic pain population, there is a very wide range of pain (0.25 through to 30 years), this would suggest a mix of pain behaviours and the possibility of a variable and potentially large psychosocial overlay.

When considered together this introduces heterogeneity within and between groups, and invalidates the conclusions of this study in regards to the effectiveness of traction on LBP, again though erroneously included within a SR on NSLBP.

The final study by Weber et al. (1984) was a report on four trials, carried out over 11 years, with participants randomised to a particular intervention, or a placebo, or other active intervention. The trials consisted of 215 hospitalised bed rest patients, who all had herniated lumbar intervertebral discs, sciatica, radiating pain, and neurological symptoms and signs. The neurological symptoms corresponding to a lesion of the L5 or S1 root and consistent with a positive radiculogram. This inclusion criteria would seem to be suggestive of a radiculopathy, but this is highly reliant on the accuracy of their clinical diagnosis, which was

not presented, and the sensitivity and specificity of the radiculogram, which is variable (Williams & Germon, 2015).

An indication of this uncertainty of diagnosis was suggested as they later excluded three patients, one for extradural tumour, one as no disc prolapse was found in surgery, and one due to a spontaneous recovery. In addition, again as not specifically excluded, pathology from the SIJ and / or hip may have co-existed and responsible for some of the LBP and leg symptoms. The four trials within Weber et al. (1984), state that the duration of the illness were similar in the treated and control groups, but unfortunately provide no indication of the range. Therefore this omission, along with the uncertainty over the clinical diagnosis, and the inclusion of nerve root pathology again invalidates the findings of these four studies from this SR on NSLBP.

The one study identified under category 3c (Ljunggren et al., 1984) looked at 52 hospitalized participants with lumbago-sciatica and prolapsed lumbar intervertebral discs, admitted to neurological department, and considered for an operation. They all had radicular signs and symptoms consistent with L5 and/or S1 nerve root, and radiculographical findings in conformity with the clinical ones, a positive Lasegue's sign, and symptoms aggravated or unchanged during the last 2-4 weeks. Unfortunately no exclusion criteria was provided. Once again proving the uncertainty of diagnosis two patients were later excluded, as surgery revealed a ganglion in one, and no disc prolapse was found during surgery in another.

In this study, the chronic duration of pain was widely disproportionate also, with 18 - 190 weeks in the auto traction group, and 9 – 46 weeks in the manual traction group. Clarke et al. (2005) also noted that the groups were not comparable at baseline. It is difficult to accept why this alone did not invalidate it from their SR.

From this flawed research Clarke et al. (2005) conclude that the implication for practice from their SR is that, and recall that they set out to look at NSLBP;

> The evidence suggests that traction is probably not effective. The available studies consistently showed that neither continuous nor intermittent traction as a single treatment was effective for patients with a mix of acute, sub-acute and chronic LBP with or without sciatica. In trials studying patients with sciatica, the results were inconsistent and most of the studies had methodological problems (p. 7).

They report that with respect to traction as a *single-intervention* therapy in LBP, no high quality study supports the possible positive effects achieved by any of the traction modalities included in their review. However, and in agreement with Harte et al. (2005), they admit that there are *no studies* evaluating the role of traction modalities as one of the items in a broad and *multimodal pragmatic* management program, as occurs in clinical practice.

Clarke et al. (2005) then continue that there is no strong, consistent evidence regarding the use of traction due to the lack of high-quality studies, the heterogeneity of study populations, the lack of power making it impossible to detect any significant difference. They also confirm that high quality studies within the field were scarce, and crucially have not distinguished between patients with differing pain duration, with or without radicular symptoms.

These comments would seem to challenge their earlier clinical pearl that traction is probably not effective. It would also seem to be somewhat misleading considering their admission that the literature allows no firmly negative conclusion that traction, in a generalized sense, is not an effective treatment for LBP patients. Like many authors, they too recommend that any future research on the use of traction for LBP patients should distinguish between symptom pattern and duration, and should be carried out according to the highest methodological standards to avoid potential bias.

What is of concern, is that a SR housed within the Cochrane collaboration itself continues the confusion over the term sciatica, the juxtaposition of the terms LBP and NSLBP, and the underappreciation of the effects of variable pain duration, which prevent equivalence of prognosis at baseline and question the appropriateness of their conclusions.

A later SR by Clarke et al. (2006), which sits outside of the Cochrane group, seemed to soften on their earlier 2005 conclusion that traction is probably not effective, by claiming that *no firm negative conclusion* can be made, stating;

> that based on the current evidence, intermittent or continuous traction as a single treatment for LBP cannot be recommended for mixed groups of patients with LBP with and without sciatica. Neither can traction be recommended for patients with sciatica because of inconsistent results and methodological problems in most of the studies involved. However, because high quality studies within the field are scarce, because many are underpowered, and because traction often is supplied in combination with other treatment modalities, the literature allows no firm negative conclusion that traction, in a generalized sense, is not an effective treatment for patients with LBP (p. 1591).

This paragraph sums up the confusion within traction research. Either the evidence is good enough to make recommendations that traction is ineffective, or it is not. There would seem to be no middle ground, the only conclusion possible at this time, is that the evidence is not strong enough to support any conclusions.

Macario & Pergolizzi, (2006) concisely sum up these difficulties and questions validity to clinical practice, this quote simply questions why more resource was put into subsequent Cochrane reviews;

> For evidence-based practice to work, practitioners need the many articles available in the literature on a particular topic analyzed and synthesized. Also, to be useful, clinical trials must study treatments that the practitioner uses during his or her daily practice…..the practitioner caring for patients with chronic low back pain would typically offer various combinations of treatments…..Scientifically more rigorous studies with better randomization, more complete control groups, uniform selection

> criteria, evidence-based diagnostic measures, and standardized outcome measures are needed to identify the best responders to this conservative intervention (p, 176).

A later Cochrane SR by Clarke et al., (2007) updated the previous review with the addition of one extra study. As in the previous SR, once again there is confusion over the definitions of LBP (within the title), and NSLBP in the methods. They continue to use the definition of sciatica from Bigos et al. (1994), and remain oblivious or don't appreciate the effects of having heterogenic groups with variable pain duration.

They included 25 RCTs (2206 patients; 1045 receiving traction), of which five trials were considered high quality. Unlike Clarke et al. (2005), here they do state the methods used to assess the methodological quality of the RCTs as the updated guidelines of the Cochrane Back Review Group (van Tulder et al., 2003). This was a modified version of the criteria list of the initial SR by van der Heijden et al. (1995) as detailed in Table 3, however compared to the original criteria list (which was scored out of 100), these updated guidelines consist of eleven validity criteria scored either yes, no, or don't know (Table 4).

Table 4. Criteria List for the Methodological Quality Assessment

	Criteria List for the Methodological Quality Assessment	
A	Was the method of randomization adequate?	Yes / No / Don't know
B	Was the treatment allocation concealed?	Yes / No / Don't know
C	Were the groups similar at baseline regarding the most important prognostic indicators?	Yes / No / Don't know
D	Was the patient blinded to the intervention?	Yes / No / Don't know
E	Was the care provider blinded to the intervention?	Yes / No / Don't know
F	Was the outcome assessor blinded to the intervention?	Yes / No / Don't know
G	Were co-interventions avoided or similar?	Yes / No / Don't know
H	Was the compliance acceptable in all groups?	Yes / No / Don't know
I	Was the drop-out rate described and acceptable?	Yes / No / Don't know
J	Was the timing of the outcome assessment in all groups similar?	Yes / No / Don't know
K	Did the analysis include an intention-to-treat analysis?	Yes / No / Don't know

High quality studies they defined as RCTs that fulfilled six or more of the 11 validity criteria. However similar to the points scoring system concern still remains, as when the paper by

van Tulder et al. (2003) is consulted and consideration is given to the expanded operationalization stated for criteria C in Table 4 within this van Tulder et al. paper it states;

> Were the groups similar at baseline regarding the most important prognostic indicators? In order to receive a 'yes' groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s) (p. 1294).

From the arguments expressed in Chapters two and three, it is argued that these criteria were not meet in the referenced RCTs. Firstly as expected the authors were largely unable to separate out acute, sub-acute, or chronic LBP in their analysis; other than a few trials which they felt involved only patients with chronic LBP. They also decided to categorize studies as including patients 'with sciatica' if more than 2/3 of the patients were described as having sciatica, and that this may have included those with nerve root symptoms, as well as if there was a separate analysis of outcomes performed in those with sciatica.

There are three errors in this decision;

1. As have preceding SRs, they have chosen to include sciatica, which they recognised to be due to nerve root pain, within a SR on NSLBP, which as discussed in section 3.2 is nonsensical.
2. They have confirmed the warnings of Merskey and Bogduk (1994) that sciatica was a catch phrase for all referred leg symptomology, whether somatic, radicular, or radiculopathy in nature.
3. Also of interest is that the baseline 'percentage of patients with neurological symptoms' should be similar within groups. To get meaningful results the study cohort should be clearly delineated, treated with an intervention appropriate to their pathology, and analysed separately according to the presence or absence of neurological symptoms. But crucially as previously discussed in point 1 above, if the

SR is for NSLBP then studies inclusive of participants with neurological symptoms should not be included anyway.

Again the authors planned to undertake a quantitative analysis, but most of the studies did not provide sufficient data to enable statistical pooling, therefore, qualitative analysis was again performed. Clarke et al. (2007) chose to present the findings under headings which are more in line with the focus of this thesis; definition of LBP and presence of sciatica, and duration of LBP.

Definition of LBP and presence of sciatica

The authors state that after consensus they found that 80 (29%) of the 275 quality assessments (25 studies, 11 criteria) were scored as 'don't know'. The methodological criteria that were most frequently scored as 'don't know' were similarity of baseline characteristics, as well as treatment allocation, and randomization. They felt that In general, the methodological quality of the RCTs included in their review were low.

From the 25 studies they identified, they state that 18 of the studies included a *relatively homogeneous* population of patients with LBP and sciatica (Bihaug, 1978; Coxhead et al., 1981; Güvenol et al., 2000; Larsson et al., 1980; Lidström & Zachrisson, 1970; Lind, 1974; Ljunggren et al., 1984; Ljunggren et al., 1992; Mathews & Hickling, 1975; Mathews et al., 1987; Pal et al., 1986; Reust et al., 1988; Sherry et al., 2001; Sweetman et al., 1993; Walker et al., 1982; Weber, 1973; two trials in Weber et al., 1984), and the remaining seven studies included a *greater mix* of patients with and without sciatica (Beurskens et al., 1997; Borman et al., 2003; Konrad et al., 1992; Letchuman & Deusinger, 1993; Tesio & Merlo, 1993; van der Heijden et al., 1995a; Werners et al., 1999). There were no studies that exclusively involved patients who did not have sciatica.

The terms 'relatively', or 'greater mix' should not be used within a SR designed to provide scientific recommendations of an intervention, participants either are or aren't identical, and

this should form the primary basis whether to include or exclude a study. It has been discussed earlier in section 3.2 these groups will suffer from heterogeneity due to the confusion over the term sciatica (Merskey & Bogduk, 1994), and the juxtaposition of the terms LBP and NSLBP. On this basis alone these trials should be excluded from the SR due to heterogeneity.

Duration of LBP

Here Clarke et al. (2007) describe how in eight studies (Borman et al., 2003; Güvenol et al., 2000; van der Heijden et al., 1995a; Ljunggren et al., 1984; Sherry et al., 2001; Tesio & Merlo, 1993; two in Weber et al., 1984) participants included *solely or primarily* patients with chronic LBP of more than 12 weeks. That in one study (Konrad et al., 1992) patients were all in the sub-acute range (4 to 12 weeks). In 12 studies (Beurskens et al., 1997; Bihaug 1978; Coxhead et al., 1981; Larsson et al., 1980; Lidström & Zachrisson, 1970; Lind, 1974; Ljunggren et al., 1992; Mathews & Hickling, 1975; Mathews et al., 1987; Pal et al., 1986; Sweetman et al., 1993; Walker et al., 1982) the duration of LBP was *a mixture* of acute, sub-acute and chronic. And in five studies the duration was *not specified* (Letchuman & Deusinger, 1993; Reust et al., 1988; Weber 1973; and two in Weber et al., 1984).

The terms 'primarily', and 'mixture', and 'not specified', relating to whether the participants had pain of acute, sub-acute, or chronic duration, is again an indication of heterogeneity, and severely questions the similarity of prognosis at baseline of the participants within these trials. It was discussed in section 3.3 how the variability in the duration of pain compromises the effectiveness of traction when mixed durations are mistaken to be homogeneous.

From their analysis, arguably only the study by Konrad et al. (1992) could be included on the basis of subacute pain duration alone; but as discussed the participants had a *greater mix* of patients with and without sciatica, which again immediately invalidates it.

They stated that with respect to traction as a single-tool therapy in LBP, there were very few data in the literature (i.e., no high quality studies) supporting possible positive effects

achieved by any of the traction modalities included in their review, however they commented that no studies evaluated the role of these traction modalities as one of the items in broad and multi-modal pragmatic management programs. Clarke et al. (2007) recognised that high quality studies within the field were scarce; many were under-powered and did not distinguish between patients with differing pain duration, with or without radicular symptoms.

They suggest that the literature allows no firmly negative conclusion that traction in a generalized sense, is not an effective treatment for LBP patients. This is where the discussion within this SR should have ended. However, they go on to state the only conclusion possible, but it is an admission that the SR is so far removed from actual clinical practice that this conclusion cannot be externally valid; that because the results of the available studies involving *mixed groups* of patients with *acute, sub-acute and chronic LBP with and without sciatica* were quite consistent, continuous or intermittent traction as a *single treatment* for LBP is not recommended for this group. They are right to support the conclusion that neither can traction be recommended for patients with sciatica at present, due to *inconsistent* results and *methodological problems* in most of the studies. Arguably, it would be more accurate to have concluded that as the studies suffer from extreme heterogeneity, and other methodological problems, that until proven ineffective, the use of traction should be encouraged as long as it is based on sound clinical judgement.

In summary all practicing clinicians would accept that traction is not effective in all possible cases of LBP (of varying duration and varying pathology). In clinical practice traction is trialled as part of a multimodal treatment paradigm, and continued or desisted, based on the response and progress of an individual client (Harte et al., 2005; Madson & Hollman, 2015).

Clarke et al. (2007) did state that any future research on the use of traction for patients with LBP should *distinguish between symptom pattern and duration*, and should be carried out according to the *highest methodological standards* to avoid potential bias. The authors felt

that both the CONSORT[i] statement and their review provide information that can be used during the design of trials. Therefore, they were optimistic that future trials on traction for LBP, if there are any, will be conducted and reported in an adequate manner.

Gay and Brault (2008) considered that SRs of lumbar traction therapy have also not typically considered that different effects may exist based on the force of traction applied, and temporal parameters, such as how long a session should be, how many times per week, and over how many weeks. They also identified that traction trials have most often included patients with a mix of clinical presentations including back-dominant LBP, leg-dominant LBP, or a mixture of both.

Although they agreed that it was reasonable to suspect that traction therapies may affect these conditions differently, they correctly identified that there was insufficient evidence to support this hypothesis, and that properly designed RCTs were needed to determine if there are subgroups of LBP sufferers who benefit from specific traction therapies. Other patient variables they felt needed more consideration also included age and weight or body-mass index, sentiments which were also shared by Dagenais and Haldeman (2011).

Recognising the errors within the previous literature, and in line with the arguments presented in this thesis, van Middelkoop et al. (2011) performed a SR with a tightened selection criteria. Significantly they excluded from their review, studies on conservative treatments whose participants had amongst other considerations,

- variability of pain duration, (n=22)
- mixed participant population (n=25)
- studies including participants with specific causes of LBP (n=12)

After due consideration, they identified only one study that meet their criteria, Borman et al. (2003), but which they still felt had a high risk of bias. On review of the primary literature, it

[i] http://www.consort-statement.org/

compared motorized traction treatment plus standard physiotherapy, with standard physiotherapy only. Borman et al. describe their participants as having NSLBP with or without pain radiation. Importantly, although Borman et al. correctly identified the need to exclude those with neurological defects (radiculopathy) from a NSLBP population, there is no description of their clinical assessment used, they gave no definition of pain radiation (whether it was somatic or radicular referred pain), or what the clinical examination consisted of to differentiate between these. This is significant as they would have been required to also exclude radicular referred leg symptoms to be consistent with a study on a pure NSLBP cohort. They gave no indication if they excluded those with SIJ or hip pathology.

In addition Borman et al. describe the pain duration differently, leading to uncertainty of the duration of LBP studied. According to the abstract 'at least 6 weeks', whereas under materials and methods 'pain longer than 6 months'. Overall due to the uncertainty of the range of pain duration and of the clinical assessment criteria used, it should have been also excluded from this van Middelkoop et al. (2011) review, which would result in no suitable studies on traction.

Van Middelkoop et al. felt that based on the heterogeneity of the populations within the intervention and comparison groups, there was insufficient data to draw firm conclusion on the clinical effect of traction (or back schools, low-level laser therapy, patient education, massage, superficial heat/cold, and lumbar supports) for chronic LBP. Therefore, they felt that further research was very likely to have an *important impact* on their estimate of effect and would be likely to change the estimate. They felt that a focus of research into specific subgroups of LBP patients, for whom a certain intervention is most effective, was necessary.

A study by Henschke et al. (2012) considered the study design characteristics and risks of bias in RCTs of interventions for chronic LBP over the previous 30 years. They concluded it was difficult to observe any obvious trends towards improved methodology or reporting in these trials.

Schneider and Perle (2012) looking at manipulation, which is another physiotherapeutical intervention, found similar concerns;

- The diagnosis of NSLBP should be abandoned in favour of better classification and sub-grouping of patients. The intent should be to determine which type of treatment is best for which type of back pain patient.
- We should be looking at pragmatic treatment approaches
- Rather than studying ways to treat an acute episode of back pain, future research should study ways to prevent recurrent episodes of acute back pain, and which factors might be related to recurrence

The most recent Cochrane SR was undertaken by Wegner et al. (2013), and again despite the title claiming to be on LBP, they juxtapose NSLBP within the method. Wegner et al. (2013) utilised the latest methods of the Cochrane Back Review Group (Furlan et al., 2009), and the Cochrane Handbook for Systematic Reviews of Interventions (Higgins, & Green, 2011), to review the previous 25 papers as identified by Clarke et al. (2007), and also integrated seven new studies (Fritz et al., 2007; Gudavalli et al., 2006; Harte, Baxter, Gracey, 2007; Ozturk et al., 2006; Schimmel et al., 2009; Simmerman, Sizer, Dedrick, Apte, & Brismée, 2011; Unlu, Tascı, Tarhan, Pabuscu, & Islak, 2008) up to August 2012. The 32 RCTs involved 2762 participants in the review, but they considered only 16 trials, representing 57% of all participants, to meet their risk of bias selection criteria.

Wegner et al. (2013) also highlighted that because the majority of studies contained a mix of participants with acute, subacute and chronic LBP, they could not separate out these groups in analyses, other than in several trials involving only people with chronic LBP. They too decided to categorize studies as including people 'with sciatica' if more than 66% of the participants were described as having sciatica or if there was a separate analysis of outcomes in those with sciatica, which as highlighted earlier remains questionable.

Wegner et al. identified 23 of the studies had a *relatively* homogeneous population of people with LBP and sciatica (Bihaug, 1978; Coxhead et al., 1981; Fritz et al., 2007; Güvenol et al., 2000; Harte et al., 2007; Larsson et al., 1980; Lidström & Zachrisson, 1970; Lind, 1974; Ljunggren et al., 1984; Ljunggren et al., 1992; Mathews & Hickling, 1975; Mathews et al., 1987; Ozturk et al., 2006; Pal et al., 1986; Reust et al., 1988; Sherry et al., 2001; Simmerman et al., 2011; Sweetman et al., 1993; Unlu et al., 2008; Walker et al., 1982; Weber, 1973; two trials in Weber et al., 1984). Eight studies included a *greater mix* of participants *with and without sciatica* (Beurskens et al., 1997; Borman et al., 2003; Gudavalli et al., 2006; Konrad et al., 1992; Letchuman & Deusinger, 1993; Tesio & Merlo, 1993; van der Heijden et al., 1995a; Werners et al., 1999). There was only one study that exclusively involved people who did not have sciatica (Schimmel et al., 2009). Once again we continue to observe the use of the terms 'relatively homogeneous population' and 'greater mix of participants', and 'with or without sciatica' which again invalidate these studies.

Of interest is that although including a mixture of participants with and without sciatica, Gudavalli et al. (2006) later performed a subgroup analysis and concluded that this provided a possible explanation for contrasting results among other RCTs of chronic LBP treatments.

Schimmel et al. (2009) seems to be the only study possibly looking at a homogeneous population, those without sciatica (albeit with the continued use of the term sciatica). On review of the primary paper, Schimmel et al. (2009) did exclude participants with radicular pain, but there is no indication of the clinical assessment protocol that they used to determine this, or if they also excluded radiculopathy. Schimmel et al. recruited 60 subjects with chronic LBP all known to have had lumbar back pain for at least one year, with an episode of LBP for more than 3 months. This suggests a mix of truly chronic LBP lasting for at least one year, or alternatively intermittent, recurrent, or episodic LBP with minimal duration of 3 months over at least one year. They recognised that since chronic LBP was associated with cognitive and emotional factors, and a psychological examination was also completed at baseline, and determined to be equal between groups.

Schimmel et al. looked at a specific type of traction, Intervertebral Differential Dynamics Therapy (IDD) compared to its 'sham' alternative, with both groups also receiving concurrently a standard graded activity program. The results showed that participants in both groups reported a significant improvement in LBP, leg pain, daily function, and general health perception. The authors attributed this to the standard graded activity program, and to the 'attention' received during the 20 treatment sessions on the traction device. They concluded that adding axial, intermittent, mechanical traction of IDD Therapy was shown not to be effective.

There is an alternative viewpoint though. Considering the participants had already failed an exhausting list of conservative treatment options, likely to have been similar to the standard graded activity program over at least 1 year, it is possible that the sham group (control) actually received a traction force that was therapeutic. Given that they had failed conservative treatment previously, maybe the therapeutic sham traction had also assisted their recovery, by enabling a better response to the graded activity program, resulting in improvement. This study would have benefitted from a usual care group to enable a comparison to the natural history of spontaneous resolution of most LBP, although as pain duration was greater than 1 year this may not add anything to the design; or a control group who had just graded exercises to give them equivalent 'attention', or a cross-over design for the non-responders in each group.

Schimmel et al. felt that future studies on traction should focus on different patient groups and other parameters of traction, such as patient positioning, time and force characteristics. But, in stark contrast, concluded that practitioners should reconsider their treatment protocols because based on their study, traction has probably no place at all in the treatment of chronic LBP. They also emphasized the need for properly designed RCTs to evaluate specific new non-surgical therapies that were being marketed to the public.

Wegner et al. (2013) identified 10 studies which included solely or primarily people with chronic LBP of more than 12 weeks (Borman et al., 2003; Gudavalli et al., 2006; Güvenol et

al., 2000; Ljunggren et al., 1984; Schimmel et al., 2009; Sherry et al., 2001; Tesio & Merlo, 1993; van der Heijden et al., 1995a; two in Weber et al., 1984). In one study, (Konrad et al., 1992), participants were all in the subacute range (four to 12 weeks). In 17 studies, the duration of LBP was a mixture of acute, subacute and chronic (Beurskens et al., 1997; Bihaug, 1978; Coxhead et al., 1981; Fritz et al., 2007; Harte et al., 2007; Larsson et al., 1980; Lidström & Zachrisson, 1970; Lind, 1974; Ljunggren et al., 1992; Mathews & Hickling, 1975; Mathews, 1987; Ozturk et al., 2006; Pal et al., 1986; Simmerman et al., 2011; Sweetman et al., 1993; Unlu et al., 2008; Walker et al., 1982); in five studies duration was not specified (Letchuman & Deusinger, 1993; Reust et al., 1988; Weber, 1973; and two in Weber et al., 1984).

We continue to see the term *primarily*, witness the reported heterogeneous mix of pain duration, the inclusion of studies where duration was not specified, and again question why these studies have not been invalidated. The paper by Konrad et al. (1992) was critiqued earlier and should also have been excluded.

The clinical pearl from this SR by Wegner et al. (2013), was that the use of traction as treatment for NSLBP is not supported by the best available evidence, and that their conclusions are applicable to both manual and mechanical traction. Although in line with SR dogma, this seems an unfair conclusion, the evidence can neither refute nor support traction, as the methodological designs of the studies are simply not good enough.

In addition, the Wegner et al. felt that only new, large, high-quality studies may change the point estimate and its accuracy, but it should be noted that such change may not necessarily favour traction. Therefore in their opinion, *little priority* should be given to new studies on the effect of traction treatment alone, or as part of a package. This is in stark contrast to the earlier conclusion from Van Middelkoop et al. (2011) which was based on largely the same research but used a more rigorous selection criteria; and who concluded that further research was very likely to have an *important impact* on their confidence to estimate the efficacy of traction on sub-groups of LBP.

Considering the overwhelming evidence presented throughout this thesis regarding the clinical application of traction, its anecdotal support, the weakness of all the primary research on the efficacy of traction for LBP, and the recommendations from Van Middelkoop et al. (2011), the conclusion of Wegner et al. (2013) to give *little priority* to new studies on the effect of traction seems a questionable statement from a Cochrane SR which is utilised by practitioners to guide their clinical practice.

Although previous researchers had identified the methodological flaws within LBP research it seems to have gone unheard and only recently become more accepted due to the National Institutes of Health (NIH) Pain Consortium. They charged a Research Task Force to critically look at the past, and offer recommendations to improve the standards of future research into chronic LBP in general (Deyo et al., 2014).

Deyo et al. confirmed that in addition to the previously identified and accepted methodological flaws, studies also suffered from heterogeneity within the actual patient population selected to participate. Noting that studies used;

- varying case definitions for LBP itself,
- inconsistent definitions of acute, chronic, or recurrent LBP,
- variable criteria for determining whom to include and exclude,
- inconsistent baseline assessments and stratification criteria.

One key recommendation to come out of Deyo et al. was the need to establish research standards on chronic LBP, and to have the NIH facilitate and enable this process. It is concerning that there still remains an identified need for further guidelines to improve research, reporting and reviews. This leads to the obvious conclusion, that past studies, conclusions, and recommendations are fundamentally flawed, it justifies discussion on whether clinicians should rely at all on the current CPGs for LBP (either acute or chronic –

whatever we finally decide this distinction is) that have been developed, as they are deeply rooted within this poor research methodology.

To elucidate that this is still a current problem, Norton, McDonough, Cabral, Shwartz, & Burgess (2016) simply stated the recurrent theme, that comparing research studies of LBP is difficult due to heterogeneity, as there is no consensus among researchers on definitions with respect to LBP, inclusion criteria, or even the definition of an episode. This casts tremendous doubt on the validity of previous research, even the reported incidence and prevalence statistics, and the SR conclusions on the efficacy of interventions (in this case traction) used to manage LBP.

4.3.2 Clinical practice guidelines and process critiqued within a chronological narrative review

The first guideline to be developed on the management of LBP, the Quebec Task Force on Spinal Disorders (Spitzer, 1987), is unfortunately no longer available. However it was cited in Bigos et al., (1994) who used the bibliography from the Quebec task force report as their starting point in the literature search for their guideline, allowing similar inferences to be made. The Agency for Health Care Policy and Research (AHCPR) in the US required a guideline for the evaluation and treatment of acute low back problems in adults, and this was undertaken by Bigos et al., (1994). A copy of this review is still available allowing a critical examination of methods used in this guideline; involving definitions, the research considered and the conclusions reached.

The AHCPR convened a 23-member, multidisciplinary, private-sector panel. The panel defined back problems as activity intolerance due to back-related symptoms, and acute as limitations of less than 3 months' duration. Back symptoms could include pain, primarily in the back, as well as back-related leg pain (sciatica). They defined sciatica as back-related lower limb symptoms suggesting nerve root compromise, and categorised LBP into the three accepted categories; potentially serious spinal conditions, sciatica, and NSLBP (Waddell, 1982).

The panel agreed that the guideline needed to be anchored to published scientific evidence, and this would take priority over panel opinion in making recommendations. When the scientific literature was incomplete or inconsistent in a particular area, the recommendations would reflect the professional judgment of panel members and consultants.

Bigos et al. (1994) felt that to a much greater extent than acute problems, chronic low back problems are influenced by complex psychological, behavioural, socioeconomic, demographic, legal, and occupational factors, many of which are not easily controlled. For these specific reasons, the panel decided that chronic low back problems were beyond the scope of their guideline.

Of 31 articles screened for traction, they included six RCTs (Coxhead et al., 1981; Larsson et al., 1980; Mathews & Hickling, 1975; Mathews et al., 1987; Pal et al., 1986; Weber et al., 1984). Bigos et al. (1994) felt that these studies involved patients with acute LBP of less than 3 months' duration, but studies varied on whether patients with a history of previous low back problems were excluded. Bigos et al. made no comment on the homogeneity of the population selection or the equivalence of prognosis.

Bigos et al. concluded that there was no indication that traction in any form was beneficial in terms of pain relief, physiological status, and length of hospital stay, functional outcome, or perception of overall improvement, for patients with acute low back problems. The 23 member panel did not recommend traction in the treatment of patients with acute low back problems, and this set the benchmark for subsequent SRs and CPGs.

However it is disappointing that although Bigos et al. did identify the poor quality of clinical trials on LBP in general (section 1.1), they did not seem to appreciate this with respect to the studies on traction which they reviewed. It was previously described in section 4.3.1, and can be seen in more depth in Appendix A, how all these studies suffered from heterogeneity.

As an example of how CPGs can spread organically by other countries accepting the methodological quality of previous guidelines without performing their own critique of the

pertinent literature, the Bigos et al., (1994) guideline was voted to be adopted by the Ministry of Health in New Zealand[j] within their own CPG for acute low back problems in adults, thus perpetuating the poorly informed guidelines.

Waddell et al. (1996) prepared a CPG for the management of acute LBP for the Royal College of General Practitioners (RCGP) with input from the Chartered Society of Physiotherapy, Osteopathic Association of Great Britain, British Chiropractic Association, and National Back Pain Association. Unfortunately this CPG is no longer available. However Saunders (1998) looked critically at the evidence informing this guideline, and reports that within this CPG it stated that traction does not appear to be effective for LBP or radiculopathy, and that this conclusion was given a three star rating. Which was acknowledged as meaning that the weight of evidence was a generally consistent finding in the majority of acceptable studies.

According to Saunders (1998), Waddell et al. (1996) was based on three sources, the Quebec Taskforce on Spinal Disorders (Spitzer, 1987), the US Department of Health and Human Services report on acute Low Back Problems in Adults (Bigos et al., 1994), and the SR by van der Heijden et al. (1995).

The 1987 Quebec review reportedly listed two references in their text (Weber et al., 1984; Zylbergold & Piper, 1985). Weber et al. (1984) was discussed earlier within section 4.3.1 and should be excluded. Confusingly Zylbergold and Piper (1985) does not appear in any of the SRs on traction for LBP. However on obtaining the primary paper, the reason becomes quickly apparent, it is a study on cervical traction, and it too should have been excluded from a review on LBP. Bigos et al. (1994) was discussed above, and the primary research informing it within section 4.3.1, demonstrating its deficiencies. Finally van der Heijden et al.

[j] ACC and Core Services Committee. (1995). Clinical Practice Guideline: Acute low back problems in adults: Assessment and Treatment.

(1995), also discussed in section 4.3.1 who found that there was no conclusive evidence to suggest that traction was an ineffective therapy for back (or neck pain).

Saunders (1998) identified flaws in the RCGP CPG;

- In general, there is a lack good quality research on traction, with most articles containing significant flaws.
- Judgments about traction must be avoided without critically reviewing the articles.
- More RCTs that clearly define treatment methodologies and patient selection criteria are required
- Reports that say traction is ineffective, when based on these articles with such flawed conclusions, need to be opposed

The question is why these valid conclusions from Saunders were not heeded, and why these poorly designed studies continued to be referenced within the subsequent SRs undertaken by Clarke et al. (2005, 2007), and Wegner et al. (2013), which continued to inform future CPGs.

As highlighted this Waddell et al. (1996) is no longer available within the RCGP website, in fact they currently have no CPGs for LBP on the website itself. However, a google scholar search for the original CPG directs to a later brief version (Waddell et al., 1988), which references the original. It is not certain if Waddell et al. (1988) was published subsequent to the critique by Saunders (1998). However, there is no reference to traction at all within this later version of this CPG.

Bogduk (1999) recognised that traction was once a traditional treatment for LBP but had increasingly lost favour as international authorities decried passive treatments as ineffective, instead pressing for more active control and self-rehabilitation. Bogduk in line with the

National Health and Medical Research Council [k] did not favour the consensus method as used by the AHCPR (Bigos et al., 1994), and the RCGP (Waddell et al., 1996) to formulate their recommendations, and wanted his CPG to be evidence-based, to exclusively address back pain, and to not include LBP when associated with sciatica or disc herniation. For reasons discussed in section 3.2.

Bogduk discussed that there was limited evidence that traction is effective for acute LBP based on the results from the SRs of van der Heijden et al. (1995), and van Tulder et al. (1997). But the evidence provided by these SRs could not be considered for his CPG as closer inspection of the primary literature revealed that the participants also had sciatica.

Bogduk also considered a RCT by Beurskens et al. (1995) and the later 12 week and 6 month follow up undertaken by Beurskens et al. (1997). However on review of the primary paper, Beurskens et al. (1995) clearly state that the participants were required to have chronic (defined as greater than 6 weeks) NSLBP, *with or without radiation*. Also they state that the traction group contained a few more patients with pain radiating below the knee.

This questions the methodology of Bogduk as to why patients with chronic pain were included in a SR on acute pain. There are also questions around the pathoanatomical cause of the radiation into the leg; which as Merskey and Bogduk (1994) had concluded earlier for the IASP, could be somatic, radicular, or radiculopathy in nature.

Following consideration of this 'evidence' Bogduk concluded that due to its lack of efficacy, traction is not indicated in the management of acute LBP. However considering the ineligibility of Beurskens et al. (1995, 1997), van der Heijden et al. (1995), and van Tulder et al. (1997), it is uncertain what 'evidence' this is based upon and seems a misinformed recommendation.

[k] National Health and Medical Research Council. A guide to the development, implementation and evaluation of clinical practice guidelines. Commonwealth of Australia, Canberra, 1999.

In a critical response to the CPG by Bogduk (1999), Rosner (2001) felt that taking a broader perspective, there was a need to question the validity of using RCTs as a singular source of information regarding meaningful patient outcomes. As improper generalizations of the findings of RCTs from within highly restricted settings, were being inappropriately applied to the clinical setting. Leading to erroneous judgments from this overt lack of validly, as well as from the poor quality of the RCTs themselves. Rosner explained that the entire structure of EBM had become too reliant on the evidence supplied by RCTs, ignoring vital contributions from clinical expertise and patient involvement. Stating Sackett et al. (1996) who argued that;

> External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision (p. 72)

Rosner also points out that well-documented and significant methodologic problems also existed in the fundamental process of determining CPGs themselves. Most CPGs failed to maintain internal standards, or rate scientific evidence thoroughly and impartially, or include mechanisms for validation and periodic review and updating (Shaneyfelt, Mayo-Smith, & Rothwangl, 1999 ; Grilli, Magrini, Penna, Mura, & Liberati, 2000).

Furlan et al. (2001) also looked at the quality of published SRs on conservative therapies for chronic NSLBP. They included three on traction (Beckerman et al., 1993; van der Heijden et al., 1995; van Tulder et al., 1997). Furlan et al. excluded primary research including radicular syndrome and those with mixed populations of acute, subacute and chronic LBP. It is interesting to note that Furlan et al. continued the juxtaposition of NSLBP and LBP, with LBP in the title “A critical review of reviews on the treatment of chronic low back pain”.

On reading the primary review by Beckerman et al. (1993), it is clear that the results with respect to traction itself, were to be presented later within the yet unpublished van der

Heijden et al. (1995) SR. So in reality only two sources, van der Heijden et al. (1995) and van Tulder et al. (1997) which were both critiqued earlier, in section 4.3.1, and the deficiencies with respect to using the term sciatica and mixed pain duration exposed.

Furlan et al. (2001) felt that although the overall quality of SRs themselves were satisfactory, the heterogeneity and quality of the primary papers included in the reviews varied considerably. Consequently there was limited conclusive evidence about the effectiveness of a wide range of commonly used conservative interventions, including traction, for chronic NSLBP. This echoes the conclusions of Saunders (1998), and questions why literature continued to be published referencing this erroneous research.

Clinical guidelines from 11 different countries published from 1994 until 2000 were included in a review by Koes, van Tulder, Ostelo, Burton, and Waddell (2001), comparing national CPGs on LBP. They postulated that as the available evidence is international, it would be expected that each country's guidelines would give more or less similar recommendations, with possibly some variation to take account of local resources and practice. Indeed they found that the CPGs for the management of LBP showed them to be generally similar, with some notable differences in some recommendations which they suggested was due to variation in each socioeconomic climate, and the available evidence for some interventions being identified as inconsistent.

Koes et al. (2001) warned that general recommendations in CPGs are not always based on scientific evidence, but on consensus. Committees consider various factors, which may be biased by individuals in the committee, as well as the professional bodies they represent. This questions the easy proliferation of fictitious information. Individuals within the committees may be familiar with the pertinent literature, but not have realised its limitations. They accept previous international findings leading to the spread of misinformation. It is imperative that CPG committees reconsider all primary literature, and not solely rely on the results from previous CPGs or SRs.

Albright et al. (2001) concluded that there was actually poor evidence to include or exclude mechanical traction alone as an intervention for acute, sub-acute, or chronic LBP. Albright et al. cite four references for acute pain LBP. Three of which (Reust et al., 1988; Weber, 1973; Weber et al., 1984) are included within SRs and discussed within section 4.3.1, and also a study by Moret, van der Stap, Hagmeijer, Molenaar, and Koes (1998). It is interesting that Albright et al. (2001) considered a pilot trial to inform a CPG, as on review of this primary paper by Moret et al. (1998) the authors state that;

> Since the study was a pilot and feasibility study no conclusion can be drawn concerning the efficacy of vertical traction. The authors recommend that a larger study should be conducted with some changes in the protocol to evaluate the effect of this therapy in patients suffering from a lumbar radicular syndrome (p. 203)

Albright et al. (2001) provided three references which informed the CPGs for sub-acute pain (Mathews & Hickling, 1975; Pal et al., 1986; Mathews et al., 1987). These were critiqued earlier in section 4.3.1. Finally four references informed their recommendations regarding chronic pain (Beurskens et al., 1995, 1997; Lidström & Zachrisson, 1970; van der Heijden et al., 1995). Which were also discussed in section 4.3.1. Considering all this evidence, Albright et al. (2001) concluded that the efficacy of traction is unknown.

Despite this controversy over the efficacy of traction in the interim, the Ministry of Health and ACC [l] in NZ continued to endorse the recommendations based on the CPGs of the AHCPR (Bigos et al., 1994), and RCGP (Waddell et al., 1996) to formulate their own CPG through to 2004, continuing to spread this misinformation. Their latest CPG concludes that there was evidence of no improvement in clinical outcomes with traction, based on level of evidence from meta-analysis, SRs, or RCTs with a very low or low risk of bias, and directly applicable to the target population and demonstrating overall consistency of results.

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l http://www.acc.co.nz/PRD_EXT_CSMP/groups/external_communications/documents/guide/prd_ctrb112930.pdf

As highlighted and discussed throughout this results chapter, and with reference to Chapter 3, this is an erroneous statement. Misinformed by the poor methodological quality of the primary research and previous SRs considered by the RCGP and AHCPR, which have been shown not to be directly applicable to the target population, or demonstrate overall consistency of results.

It has been largely argued that the quality of the primary research was poor, however the methodological quality of the CPGs themselves has also been questioned (Furlan et al., 2001; Koes et al., 2001). Van Tulder, Tuut, Pennick, Bombardier, and Assendelft (2004) also assessed the quality of 17 CPGs published on acute LBP and they found that the quality of reporting of CPGs was disappointing. Although most CPGs clearly described the aim and target population, and the guideline development committees were mostly multi-professional, they identified many other methodologic flaws. Van Tulder et al. (2004) also provides support to the critiques within this thesis concerning the process of formulating CPGs, and suggests that these historic CPGs may have been poorly informed, produced and inappropriate.

These earlier findings were later confirmed by Arnau et al. (2006) who identified 17 guidelines published from 1994 to 2002. They found the methods used to develop CPGs therapeutic recommendations needed to be more rigorous. There were numerous deficiencies in many areas of CPG development. Most residing in the identification, evaluation, and synthesis of the scientific evidence. Often developers are faced with a limited number, if any, of appropriately designed studies upon which to base the recommendations.

Considering the previous reviews of Arnau et al. (2006), Furlan et al. (2001), Saunders (1996), and van Tulder et al. (2004), amid the growing evidence to support poor research, it remains questionable why these poorly informed historical primary studies continued to be utilised in the development of CPGs.

Chou and Huffman (2007) looked at SRs and randomized trials of non-pharmacologic therapies for acute or chronic low back pain (with or without leg pain) that reported pain outcomes, back specific function, general health status, work disability, or patient satisfaction. To grade methodological quality they used the Oxman criteria (Oxman & Guyatt, 1991) for SRs, and the Cochrane Back Review Group criteria for individual trials (van Tulder et al., 2003). According to the Oxman criteria, SRs receiving a score of four or less (on a scale of one to seven) have potential major flaws and are more likely to produce positive conclusions about effectiveness of interventions, and are deemed to be lower quality. Those receiving scores of five or more are graded as higher quality. They considered the trials receiving more than half of the maximum possible quality score as used in each independent SR, to be of higher quality regardless of the rating system used.

They based their results of the efficacy of traction for LBP after critique (Table 5) of Clarke et al. (2005, 2006), and Harte et al. (2003), both of which were previously discussed within section 4.3.1.

Table 5. Oxman Scale Quality Ratings for Included Systematic Reviews of Nonpharmacologic Therapies for Low Back Pain from Chou, Huffman, (2007).

Study, Year	Clarke et al., 2005, 2006	Harte et al., 2003
Search Methods?	Yes	Yes
Comprehensive?	Yes	Yes
Inclusion/Criteria?	Yes	Yes
Bias Avoided?	Can't tell	Yes
Validity Criteria?	Yes	Yes
Validity Assessed?	Yes	Yes
Methods for Combining Studies?	Yes	Yes
Appropriately Combined?	Yes	Yes
Conclusions Supported?	Yes	Yes
Overall Quality per Oxman Scale (1–7)	6	7

Chou and Huffman (2007) concluded that traction is no more effective than placebo, sham, or no treatment for either acute, subacute, or chronic LBP (with or without sciatica). It can be appreciated that in arriving at this conclusion Chou and Huffman chose to trust the analysis within the SRs undertaken by Clarke et al. (2005, 2006). However crucially, as argued in section 4.3.1, the studies within this SR did not meet the condition of participant

homogeneity, or provide any clinically relevant results. Unfortunately Chou and Huffman did not abstract the primary research themselves, trusting Clarke et al. (2005, 2006) to be a high quality SR, scoring it six from seven on the Oxman Scale.

It is notable that the study of Harte et al. (2003), although scoring seven from seven, did not seem to be considered too highly. Harte et al. (2003) had highlighted earlier that the evidence surrounding traction was actually conflicting, considering the recommendations at the time were based on the only SR by van der Heijden et al. (1995), who as discussed in section 4.3.1 actually concluded that there was *no conclusive evidence* to suggest that traction was an ineffective therapy.

Dagenais et al. (2010), provided the only synthesis of recommendations from CPGs within Australia, Belgium, Europe, Italy, New Zealand, Norway, UK and USA for the assessment and management of LBP. Noting every one of these CPGs recommended against the use of traction for acute and chronic LBP, and only one recommending its use for LBP with substantial neurologic involvement (Table 6).

Table 6. The recommendation regarding traction in CPGs (adapted from Dagenais et al., 2010)

	Australia	Belgium		Europe		Italy			NZ		Norway		UK	US Primary care		
Classification of LBP	A	A	C	A	C	A	C	N	A	C	A	C	C	A	C	N
Traction recommendation	No	No	No	No	No	No	No	-	No	No	No	No	No	-	No	Yes

A = acute, C = chronic, N = neurological. - = not mentioned

Dagenais et al. found that most of the CPGs originated in Europe, where some countries not only participated in multinational efforts, but also went on to develop their own national CPGs. This suggests that the same research methodology and biases, within the primary research, the subsequent SRs, and the CPG itself, would be carried over to successive CPGs, and the recommendations adapted to suit the particular legal, cultural or socioeconomic climates within each individual country.

Dagenais et al. also identified that it was unclear why some CPGs used much shorter thresholds, of 4 to 6 weeks to distinguish acute from chronic LBP, rather than the 12 weeks as recommended by the Cochrane Back Review Group (Furlan et al., 2009).

Dagenais et al. also echoed the earlier reviews, concluding that their existed major methodological flaw in SRs themselves. Especially that although many CPGs understandably relied on previous SRs to identify the relevant primary studies, some CPGs also relied on previous SRs for their quality assessments. Overstating the objective nature of the CPG process. The researchers who conduct their own SRs make numerous decisions regarding study eligibility, data extraction, and synthesis of results, all of which may impact their quality assessment and subsequent recommendations, therefore careful and independent critique is required.

Dagenais et al. state that limited trials of one or more *recommended* interventions guided by a clinician familiar with evidence-based assessment and management of LBP may be appropriate, with management decisions based on documented improvement noted with periodic outcome measures. This is a very sound approach, but with the evidence provided within this thesis, it should be expanded to include *all* interventions, rather than restricted to only *recommended* interventions, as the research to date has failed to accurately determine the efficacy or effectiveness of many interventions.

Perhaps the most sensible statement which should be the clinical pearl to be taken home with respect to the use and adoption of CPGs is that that trial and error is still likely to be required when managing LBP, considering that patients even respond differently to the same interventions, and that some form of multidisciplinary care may also be necessary.

In fact Dagenais et al. (2010) seemingly later agree that limited trials should apply to all interventions, "…should likely apply to all interventions for LBP, modifying the clinical approach and/or patient expectations when measurable outcomes fail to improve" (p. 527).

In another overview of CPGs on NSLBP, Koes et al. (2010), state that the aim of their study was to present and compare the content of (inter)national CPGs for the management of LBP. Guidelines including specific subgroups of patients with lumbosacral radicular syndrome were not to be considered. Once again we see this apparent juxtaposition of the terms NSLBP and LBP. Also within the primary literature of one of the 15 CPGs they identified, the NZ Acute LBP Guide (2004), it states;

> Acute low back pain is common and episodes by definition last less than 3 months. In a few cases there is a serious cause, but generally the pain is non-specific and precise diagnosis is not possible or necessary. If the pain radiates down the leg, below the knee, there is a greater chance that symptoms are caused by a herniated disc (p. 4).

And later, "back pain with radiating leg pain should be managed in the same way recommended for acute low back pain" (p. 14).

These statements clearly indicates that radicular syndrome was considered within the NZ CPG (2004) as it was based on Bigos et al. (1994) and Waddell et al. (1996). Again we witness the same methodological flaws within pertinent literature and prominent researchers. The research into LBP cannot be separated from that of NSLBP (with no radicular symptoms), as the evidence is the primary literature has neglected to accurately delineate the two, and the fatal consequences of this omission is still not universally appreciated by practicing clinicians and current researchers.

Pillastrini et al. (2012) rated the methodological quality of CPGs for the management of chronic NSLBP in primary care to provide a specific, updated, and evidence based overview of clinical recommendations. On review, again we see the juxtaposition of LBP in the title, for NSLBP in the method section, "Additionally, guidelines had to meet the following criteria for inclusion in the study: (a) addressed the clinical management of nonspecific CLBP in primary care" (p. 177).

They identified 13 CPGs and overall, Pillastrini et al. felt that the recommendations regarding the diagnosis and treatment of chronic LBP (note here again the use of LBP and not NSLBP), have not changed substantially compared to those included in the old CPGs and scientific literature identified by Furlan et al. (2001) about a decade ago. However in stark contrast to Furlan et al., and despite the CPGs being based on this same historic literature as highlighted in this chapter, Pillastrini et al. felt that sufficient refinements and valuable results had been obtained to confidently favour exercise therapy, and rule against traction.

Notwithstanding the confusion over LBP and NSLBP throughout the review, again this conclusion is incorrect. It has been demonstrated that the evidence is not good enough to rule against traction, and this myth that traction has been scientifically proven to be ineffective continues to be perpetuated. Pillastrini et al. conclude with the usual statement highlighting a weakness, in this case again requiring that CPGs should devote more attention to the definitions of chronic LBP itself (chronic, persistent, or recurrent), which in itself admits the past research to be deficient.

Madson and Hollman (2015) exclusively surveyed physical therapists who were members of the American Physical Therapy Association Orthopaedic Section. A majority of these respondents (76.6%) indicated that they used traction in their practices. It was also clear that respondents used traction as an adjunct incorporating multiple interventions.

They found;

- that a higher proportion of physical therapists with American Board of Physical Therapy Specialties orthopaedic certification used traction (88.6%), than did physical therapists without certification (73.0%)
- physical therapists with certification more commonly reported that patient positioning would be diagnosis specific (48.1%), than did respondents without certification (34.0%).

- a higher proportion of physical therapists with entry-level degrees at the masters or doctoral level reported using manual traction techniques (58.2% and 59.5%, respectively), than did those educated at the bachelors or certificate level (28.6% and 42.9%), respectively.

These results are very interesting. The more qualified physiotherapists either with certification, masters, or doctoral qualifications, were more likely to use traction in their clinical practice and be aware of the critical importance of patient positioning, despite the negative recommendations from SRs and CPGs.

The American College of Physicians guideline, released in 2007, addressing non-pharmacologic treatment options for LBP was discussed earlier. Chou et al. (2016) updated this with the current evidence on non-pharmacologic therapies for adults with LBP of any duration, categorized as acute (<4 weeks), subacute (4–12 weeks), and chronic (≥12 weeks), including non-radicular LBP, radicular LBP (e.g., due to herniated disc), and symptomatic spinal stenosis. To assess the quality of RCTs Chou et al. used criteria developed by the Cochrane Back Review Group (Furlan et al., 2009), for cohort studies the U.S. Preventive Services Task Force procedure manual (2015)[m] was utilised, and Shea et al. (2009) was used to assess SRs.

However, as in their earlier 2007 review, Chou et al. (2016) again unfortunately relied upon the methodology used in the previous SRs, and did not perform their own critique of the primary papers, failing again to determine the quality of the research. Only for the primary studies not included in the previous SRs did they consider study design, year, setting, country, sample size, eligibility criteria, population and clinical characteristics, intervention characteristics, and results. Here they synthesized the data qualitatively for each intervention, stratifying according to the duration of symptoms (acute, subacute, or chronic),

[m] https://www.uspreventiveservicestaskforce.org/Home/.../procedure-manual_2015/pdf

and the presence or absence of radicular symptoms. Chou et al. found little evidence to support the use of most passive physical therapies, such as traction (and interferential therapy, short-wave diathermy, ultrasound, lumbar supports, taping, and electrical muscle stimulation) for LBP.

However, within the review, there is an admission from the authors that the research into interventions for LBP is difficult and littered with controversy. Chou et al. confirm that attributing symptoms of LBP to a specific disease or spinal pathology is challenging, despite recent technological advances and imaging abnormalities. Degenerative disc disease, facet joint arthropathy, and bulging or herniated intervertebral discs, are extremely common in patients with or without LBP, particularly in older adults, and such findings are poor predictors for the presence or severity of LBP (Fardon et al., 2001, 2014; van Tulder, et al., 1997a).

Also radiculopathy from nerve root impingement (often due to a herniated intervertebral disc), but also radiculopathy from spinal stenosis (narrowing of the spinal canal) are each present in about 4 to 5 percent of patients with LBP and can cause similar neurological symptoms, such as lower extremity pain, paraesthesia, and weakness. Chou et al. conclude the natural history and response to treatment for these conditions may differ from back pain without neurological involvement. But as well as this, although they are both responsible for neurological involvement, each are pathoanatomically heterogenic, so each may respond differently to traction.

The three recent trials (Diab & Mostafa, 2012; Diab & Mostafa, 2013; Mostafa & Diab, 2012; Prasad et al., 2012) were identified (but in four publications) as not included in the Wegner et al. (2013) SR. They described using provisional key questions to ascertain the quality of these studies; populations, interventions, comparators, outcomes, timing, settings, and study designs (PICOTS), and any discrepancies were resolved by discussion and consensus.

However despite this they failed to identify that in the two publications of the same clinical trial, undertaken by Diab and Mostafa (2012, 2013), there are crucial methodological differences in the randomisation procedure they reported to carry out. In Diab and Moustafa (2012), randomisation was achieved by “using a role of the dice, the patients were randomly assigned to 1 of 2 equal groups, an experimental group (odd numbers) and a comparison group (even numbers)” (p. 247). In stark contrast the alternative publication Diab and Moustafa (2013) states that, “an independent person, blinded to the research protocol and not otherwise involved in the trial, operated the random assignment through picking one of the sealed envelopes which contained numbers chosen by a random number generator” (p. 214). These different descriptions of the randomisation procedures, despite it being the same trial, casts doubt on the overall methodological quality and validity of the results, as well as the depth of investigation of Chou et al. (2016), consequently both publications of Diab and Moustafa (2012, 2013) should be ignored.

On review of Mostafa and Diab (2012) they looked at using hot packs (15 minutes) and interferential therapy along with a lumbar extension traction system used to restore lumbar lordosis, on participants with chronic unilateral lumbosacral radiculopathy associated with L5–S1 lumbar disc prolapse on MRI. All had unilateral leg pain with mild to moderate disability according to the Oswestry Disability Index (up to 40% from Hagg, Fritzell, & Nordwall, 2003), and side-to side H-reflex latency differences of more than 1 ms. With duration of symptoms of more than three months, to avoid the acute stage of inflammation. Due to this criteria there was a greater chance of a homogeneous population, but apart from stating that participants were required to also have an absolute rotatory angle L1–L5 less than 39°, the full clinical examination is not included in the paper, meaning that there remains questions over their clinical diagnosis of unilateral lumbosacral radiculopathy and whether other potential contributors, such as SIJ and hip were assessed. Because of this, again this study should be excluded.

The study by Prasad et al. (2012) was a pilot study only randomising 24 patients (13 patients backswing inversion traction, 11 control), with single level unilateral lumbar disc protrusion, within 6 months of the first episode of symptoms, causing the appropriate nerve root impingement on MRI, and who were all on a waiting list for microdiscectomy.

Despite including this pilot trial, Chou et al. found that none of the three newly identified trials clearly stated the duration of LBP for each of the study participants, or the mean duration within groups, which should have immediately invalidated these trials from further analysis. In addition, they do not elucidate to the clinical assessment utilised and potential contributions from the SIJ or hip joint, and questions remain over the clinical relevance of the disc protrusion. Chou et al. agreed that overall the three newly identified trials had methodological shortcomings; describing unblinded design, and in the case of the Prasad et al., (2012), inadequate description of randomization and allocation concealment techniques, and incomplete follow-up.

Therefore, Chou et al. relied on the latest SR on traction (Wegner et al., 2013), which was critiqued earlier in section 4.3.1, and despite them noting low or insufficient evidence, they again stated that traction seemed to offer no benefit in the treatment of LBP.

As an indication that these methodological deficiencies were endemic in the treatment of chronic LBP and not just isolated to traction, Riley, Swanson, Brismée, and Sawyer (2016) performed a SR of the quality of recent clinical trials undertaken between 2010 and 2014 into orthopaedic manual therapy (OMT) interventions[n]. They observed that due to the paucity of high quality evidence, most meta-analyses arrive at an almost universal conclusion; that it is *impossible* to make definitive conclusions on anything. They also stated within their review that the suboptimal levels of reporting, and risk of bias, have been observed in RCTs published in medical journals across many other disciplines.

[n] OMT is based on clinical reasoning, using highly specific treatment approaches including manual techniques and therapeutic exercises

Their findings also collaborated that the current use of the CONSORT Statement and Cochrane Risk of Bias (RoB) tools is less than optimal; but even when followed that they still have a number of items that are unclear and unreliable (Turner, Shamseer, Altman, Schulz, Moher, 2012; Savović et al., 2014). Riley et al. (2016) stated that without a strong, reliable foundation of detailed reporting in the literature, progress may not be possible.

Their conclusion was as the quality of reporting and risk of bias has not improved, despite the introduction of the CONSORT and RoB tools to assist RCT design, it may be time to reassess the process. Also suggesting that medical journal editors needed to take further action to facilitate, endorse and implement the CONSORT and RoB tools to ensure accurate, transparent, and complete reporting of future trials.

This sentiment was echoed by Wong et al. (2017) who synthesized CPGs on the conservative (non-invasive) interventions for the management of acute and chronic LBP, published from 2005 to 2014. They too realised that in a general sense, concerns had been raised about the quality of many CPGs (Ransohoff, Pignone, & Sox, 2013), with methodological limitations (Shaneyfelt et al., 1999; Hasenfeld & Shekelle, 2003; Alonso-Coello et al., 2010; Knai et al., 2012). Common flaws identified included poor literature review methodology, limited involvement of stakeholders and unclear editorial independence (Alonso-Coello et al., 2010), lack of clarity of recommendation development, ambiguous recommendations, and inconsistent recommendations across CPGs (Cote et al., 2009). Therefore, valid concerns existed about the potentially negative impact of biased CPGs on the care and health outcomes of patients (Shaneyfelt & Centor, 2009; Alonso-Coello et al., 2010).

The poor methodological quality of CPGs may lead clinicians to consider interventions that are ineffective, costly, or harmful; or alternatively they may avoid using interventions which may be beneficial to the patient. These recommendations will also influence decision makers in the implementation of these ill-informed recommendations. Specifically with respect to traction Wong et al. (2017) found that CPGs of low methodological quality are still

being developed, and that the next generation of high-quality guidelines must focus on applicability to specific populations, and clear implementation strategies to promote adherence.

Wong et al. (2017) only identified one high-quality guideline for the noninvasive management of lumbar disc herniation with radiculopathy (Kreiner et al., 2014). Which found insufficient evidence to make any recommendation for the use of traction, (or ultrasound, and low-level laser therapy) in cases of radiculopathy. They were unable to present any conclusions regarding traction for any other forms of LBP however, as they felt that the different classifications used to make recommendations for the management of LBP complicated the evidence synthesis.

Qaseem, Wilt, McLean, & Forciea (2017) prepared a CPG on the efficacy, comparative effectiveness, and safety of non-invasive pharmacologic and non-pharmacologic treatments for acute (<4 weeks), subacute (4 to 12 weeks), and chronic (>12 weeks) non-radicular LBP, radicular LBP, and symptomatic spinal stenosis. Qaseem et al. found that for acute and sub-acute LBP, evidence was insufficient to determine the effectiveness of traction (also for transcutaneous electrical nerve stimulation (TENS), electrical muscle stimulation, inferential therapy, short-wave diathermy, superficial cold, motor control exercise (MCE), Pilates, tai chi, yoga, psychological therapies, multidisciplinary rehabilitation, ultrasound, and taping).

For chronic LBP, evidence was also insufficient to determine the effectiveness of traction (and electrical muscle stimulation, interferential therapy, short-wave diathermy, or superficial heat or cold). They concluded that for treatment of chronic LBP, clinicians should select therapies that have the fewest harms and lowest costs because there were no clear comparative advantages for most treatments compared with one another.

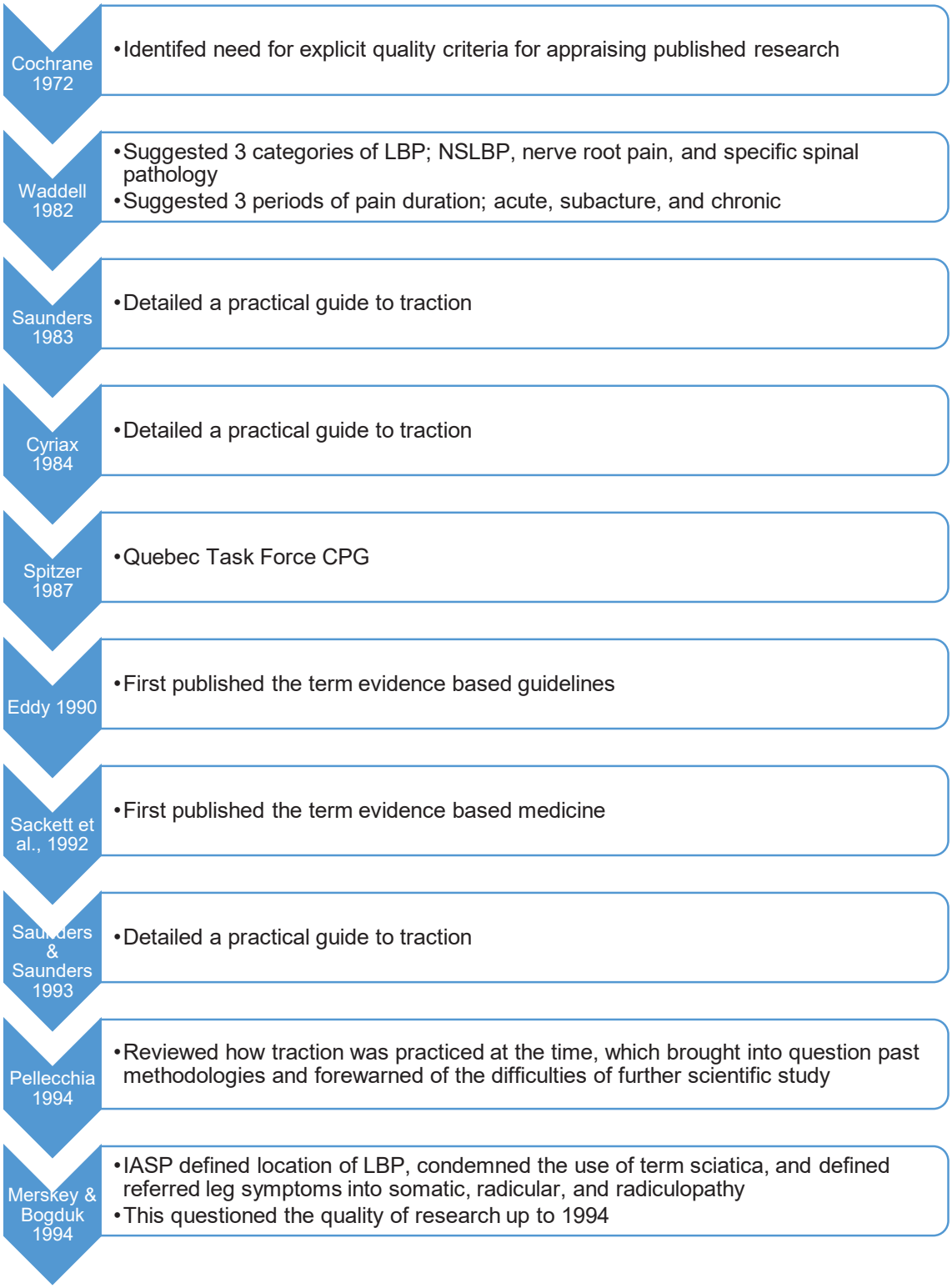
Finally Qaseem et al. agreed with the arguments within this thesis, that that evidence was again insufficient or lacking to determine the efficacy of treatments for radicular LBP, due to

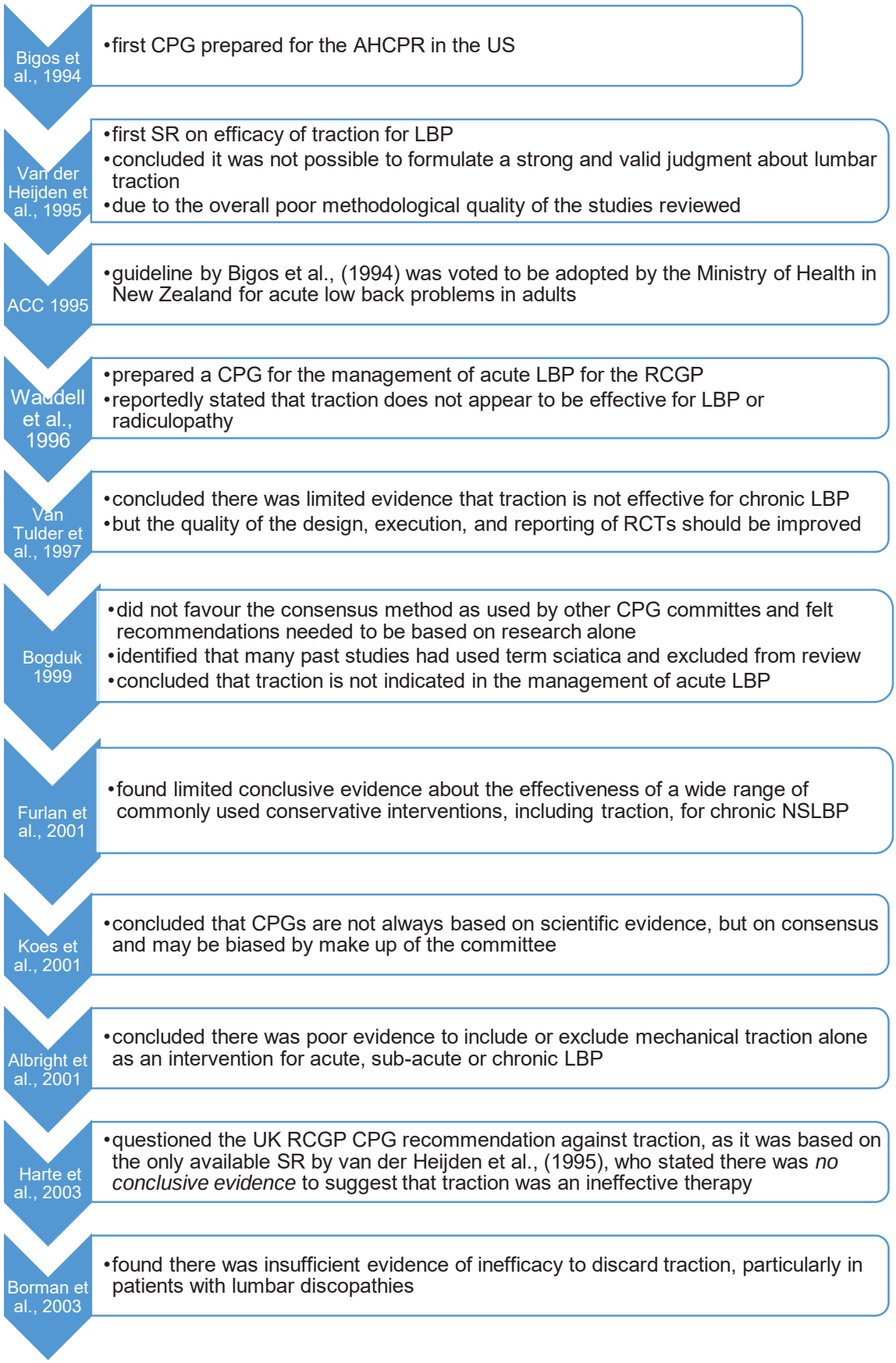
most RCTs enrolling a mixture of patients with acute, subacute, and chronic LBP, making it difficult to extrapolate the benefits of treatment compared with its duration.

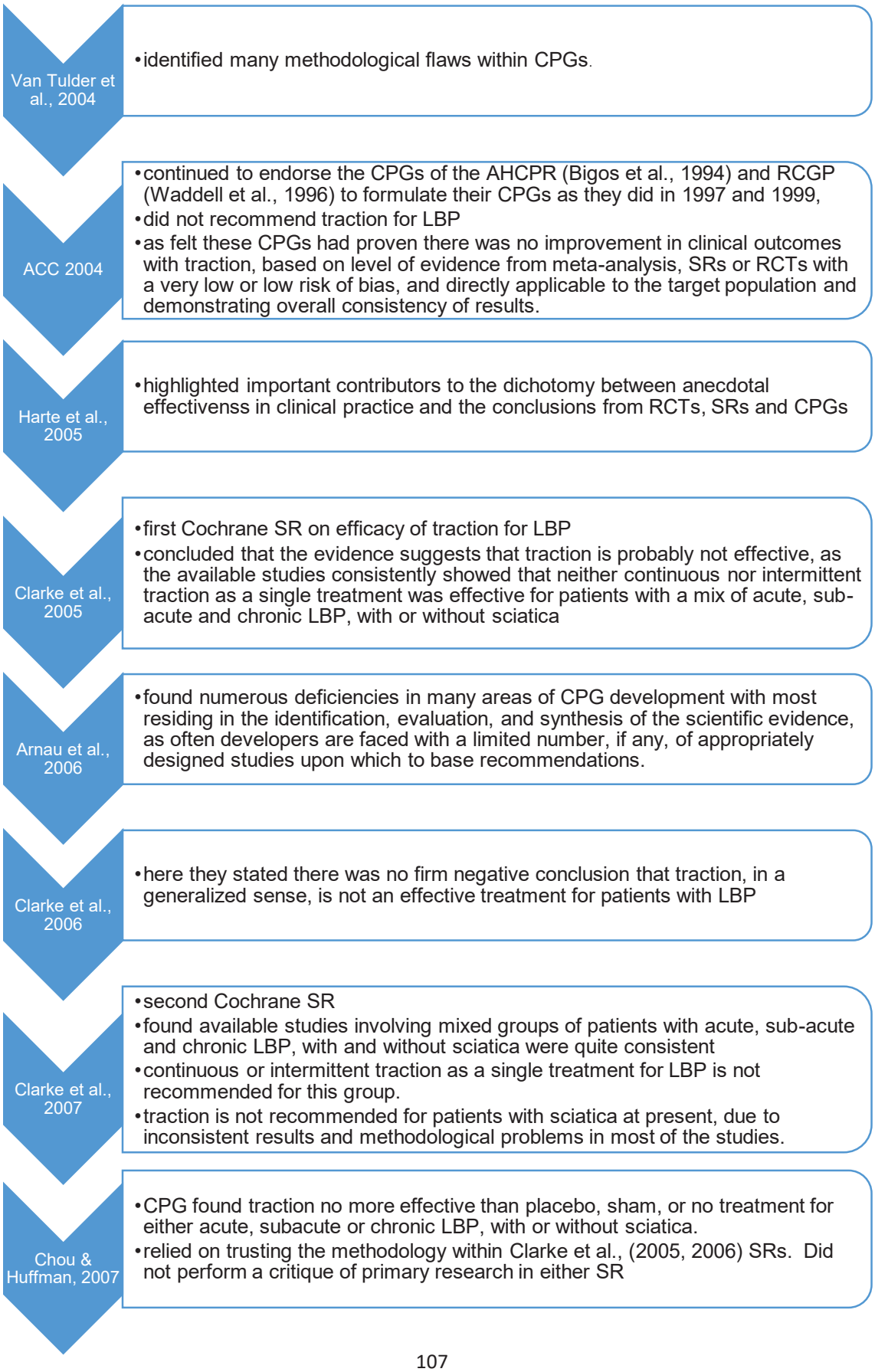
It seems clear that CPGs typically still fail to:

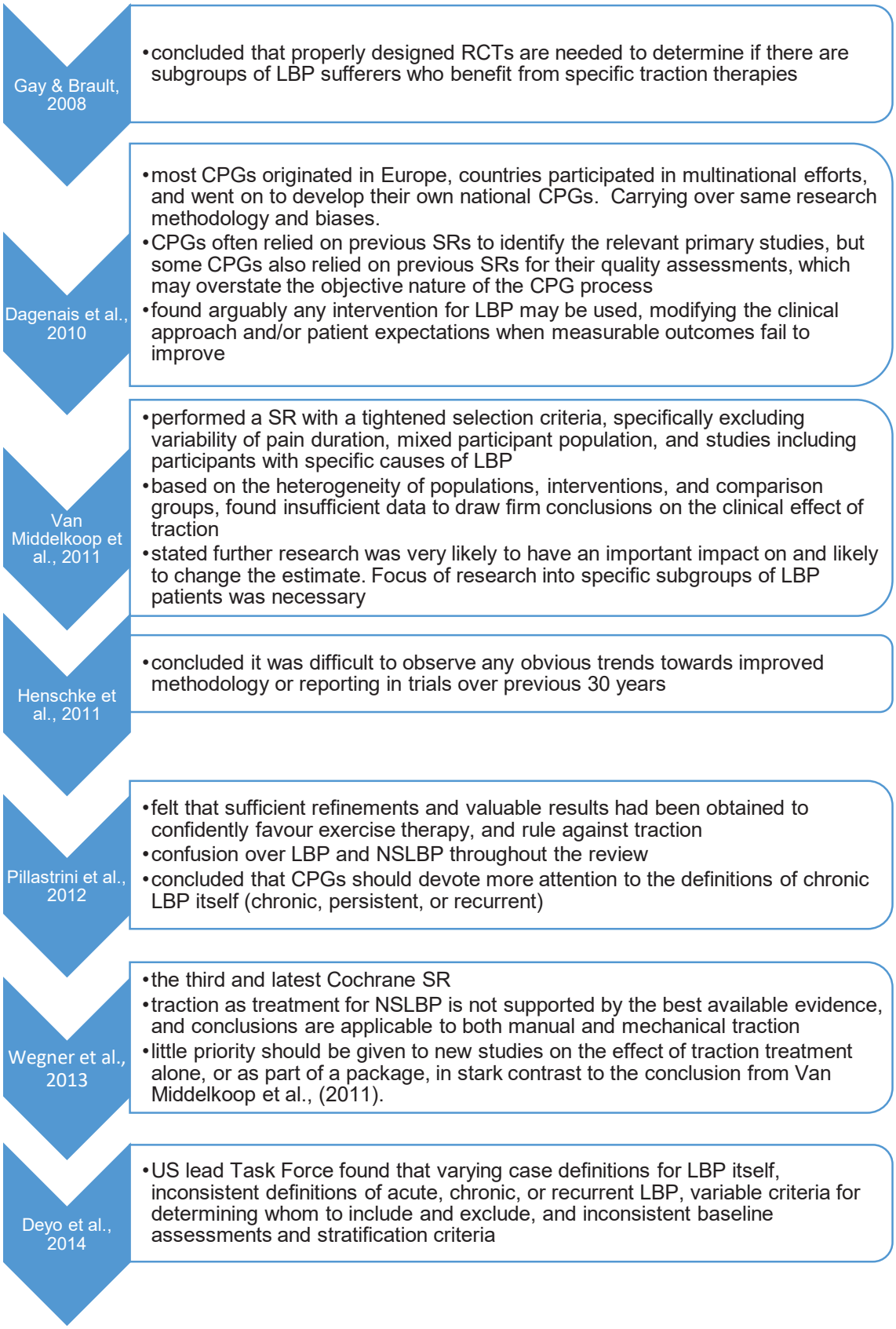
1. clearly outline selection criteria of the literature
2. adequately describe strengths and limitations of the literature
3. ensure homogeneous prognostic cohorts with respect to diagnosis, pain duration, and appropriateness of the intervention and methodological design
4. adequately describe the methods used to formulate recommendations
5. appreciate the bias and conflict of interest within committees, and from consensus opinion
6. integrate the views and preferences of the target population (patients, public) into guideline development

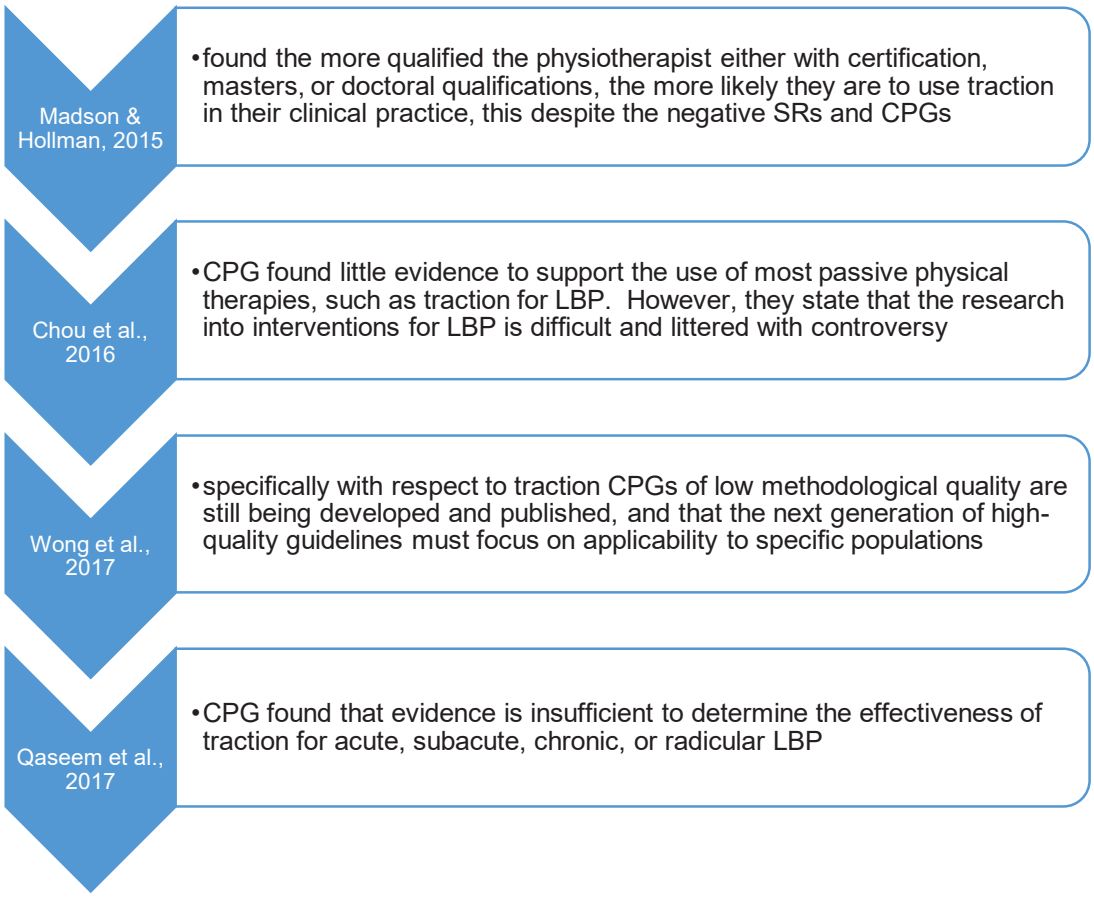
4.3.3 Summary, timeline of major historical literature referenced in Chapters 2, 3, and 4




Bigos et al., 1994
•first CPG prepared for the AHCPR in the US
Van der Heijden et al., 1995
•first SR on efficacy of traction for LBP
•concluded it was not possible to formulate a strong and valid judgment about lumbar traction
•due to the overall poor methodological quality of the studies reviewed
ACC 1995
•guideline by Bigos et al., (1994) was voted to be adopted by the Ministry of Health in New Zealand for acute low back problems in adults
Waddell et al., 1996
•prepared a CPG for the management of acute LBP for the RCGP
•reportedly stated that traction does not appear to be effective for LBP or radiculopathy
Van Tulder et al., 1997
•concluded there was limited evidence that traction is not effective for chronic LBP
•but the quality of the design, execution, and reporting of RCTs should be improved
Bogduk 1999
•did not favour the consensus method as used by other CPG committes and felt recommendations needed to be based on research alone
•identified that many past studies had used term sciatica and excluded from review
•concluded that traction is not indicated in the management of acute LBP
Furlan et al., 2001
•found limited conclusive evidence about the effectiveness of a wide range of commonly used conservative interventions, including traction, for chronic NSLBP
Koes et al., 2001
•concluded that CPGs are not always based on scientific evidence, but on consensus and may be biased by make up of the committee
Albright et al., 2001
•concluded there was poor evidence to include or exclude mechanical traction alone as an intervention for acute, sub-acute or chronic LBP
Harte et al., 2003
•questioned the UK RCGP CPG recommendation against traction, as it was based on the only available SR by van der Heijden et al., (1995), who stated there was *no conclusive evidence* to suggest that traction was an ineffective therapy
Borman et al., 2003
•found there was insufficient evidence of inefficacy to discard traction, particularly in patients with lumbar discopathies


Van Tulder et al., 2004
•identified many methodological flaws within CPGs.
ACC 2004
•continued to endorse the CPGs of the AHCPR (Bigos et al., 1994) and RCGP (Waddell et al., 1996) to formulate their CPGs as they did in 1997 and 1999,
•did not recommend traction for LBP
•as felt these CPGs had proven there was no improvement in clinical outcomes with traction, based on level of evidence from meta-analysis, SRs or RCTs with a very low or low risk of bias, and directly applicable to the target population and demonstrating overall consistency of results.
Harte et al., 2005
•highlighted important contributors to the dichotomy between anecdotal effectivenss in clinical practice and the conclusions from RCTs, SRs and CPGs
Clarke et al., 2005
•first Cochrane SR on efficacy of traction for LBP
•concluded that the evidence suggests that traction is probably not effective, as the available studies consistently showed that neither continuous nor intermittent traction as a single treatment was effective for patients with a mix of acute, sub-acute and chronic LBP, with or without sciatica
Arnau et al., 2006
•found numerous deficiencies in many areas of CPG development with most residing in the identification, evaluation, and synthesis of the scientific evidence, as often developers are faced with a limited number, if any, of appropriately designed studies upon which to base recommendations.
Clarke et al., 2006
•here they stated there was no firm negative conclusion that traction, in a generalized sense, is not an effective treatment for patients with LBP
Clarke et al., 2007
•second Cochrane SR
•found available studies involving mixed groups of patients with acute, sub-acute and chronic LBP, with and without sciatica were quite consistent
•continuous or intermittent traction as a single treatment for LBP is not recommended for this group.
•traction is not recommended for patients with sciatica at present, due to inconsistent results and methodological problems in most of the studies.
Chou & Huffman, 2007
•CPG found traction no more effective than placebo, sham, or no treatment for either acute, subacute or chronic LBP, with or without sciatica.
•relied on trusting the methodology within Clarke et al., (2005, 2006) SRs. Did not perform a critique of primary research in either SR


Gay & Brault, 2008
•concluded that properly designed RCTs are needed to determine if there are subgroups of LBP sufferers who benefit from specific traction therapies
Dagenais et al., 2010
•most CPGs originated in Europe, countries participated in multinational efforts, and went on to develop their own national CPGs. Carrying over same research methodology and biases.
•CPGs often relied on previous SRs to identify the relevant primary studies, but some CPGs also relied on previous SRs for their quality assessments, which may overstate the objective nature of the CPG process
•found arguably any intervention for LBP may be used, modifying the clinical approach and/or patient expectations when measurable outcomes fail to improve
Van Middelkoop et al., 2011
•performed a SR with a tightened selection criteria, specifically excluding variability of pain duration, mixed participant population, and studies including participants with specific causes of LBP
•based on the heterogeneity of populations, interventions, and comparison groups, found insufficient data to draw firm conclusions on the clinical effect of traction
•stated further research was very likely to have an important impact on and likely to change the estimate. Focus of research into specific subgroups of LBP patients was necessary
Henschke et al., 2011
•concluded it was difficult to observe any obvious trends towards improved methodology or reporting in trials over previous 30 years
Pillastrini et al., 2012
•felt that sufficient refinements and valuable results had been obtained to confidently favour exercise therapy, and rule against traction
•confusion over LBP and NSLBP throughout the review
•concluded that CPGs should devote more attention to the definitions of chronic LBP itself (chronic, persistent, or recurrent)
Wegner et al., 2013
•the third and latest Cochrane SR
•traction as treatment for NSLBP is not supported by the best available evidence, and conclusions are applicable to both manual and mechanical traction
•little priority should be given to new studies on the effect of traction treatment alone, or as part of a package, in stark contrast to the conclusion from Van Middelkoop et al., (2011).
Deyo et al., 2014
•US lead Task Force found that varying case definitions for LBP itself, inconsistent definitions of acute, chronic, or recurrent LBP, variable criteria for determining whom to include and exclude, and inconsistent baseline assessments and stratification criteria


Madson & Hollman, 2015
•found the more qualified the physiotherapist either with certification, masters, or doctoral qualifications, the more likely they are to use traction in their clinical practice, this despite the negative SRs and CPGs
Chou et al., 2016
•CPG found little evidence to support the use of most passive physical therapies, such as traction for LBP. However, they state that the research into interventions for LBP is difficult and littered with controversy
Wong et al., 2017
•specifically with respect to traction CPGs of low methodological quality are still being developed and published, and that the next generation of high-quality guidelines must focus on applicability to specific populations
Qaseem et al., 2017
•CPG found that evidence is insufficient to determine the effectiveness of traction for acute, subacute, chronic, or radicular LBP

4.4 Analysis

From the results of these chronological NRs on the pertinent literature, SRs, and subsequent CPGs on the efficacy of traction for treating LBP, recurrent themes are identified.

4.4.1 Interchanging of the terms nonspecific low back pain and low back pain, and use of sciatica

The most concerning is the confusion and apparent deviation from accepted definitions vis-à-vis LBP, such as the distinction between LBP and NSLBP as used within the primary literature and within Cochrane SRs. Moher et al. (2015) discussed how well designed SRs are assumed to be the reference standard for synthesizing evidence in health care because of their methodological rigor, and they are used in the development of CPGs to inform clinical decision making. However, to encourage reliability and ensure rigor, SRs should publish protocols clearly stating the pre-defined eligibility criteria along with the methodological approach used. When protocols are made available, they can be used to clearly identify deviations from the planned methods, and to determine whether these deviations bias the interpretation of the SR.

As Clarke et al. (2005) was the first review under the Cochrane umbrella, a review protocol was published by van Tulder et al. (2001). This protocol was entitled, 'Traction for low-back pain with or without *radiating symptoms'*. Within this protocol, van Tulder et al. (2001) state that they were to review RCTs that included subjects aged 18 years or older, who were treated for *low back pain* with or without *radiating symptoms* below the knee, and which also included *radicular or nerve root pain*. Although this is an extremely broad cohort, maybe 95-99% of all LBP (Waddell et al., 1996; Waddell, 2004; Greenhalgh & Selfe, 2006) if does fit within the accepted definitions of LBP and referred leg symptoms. With appropriate acknowledgment and distinction of isolated LBP, and LBP associated with radiating leg symptoms whether somatic, radicular, or nerve root in nature (presumably also including

radiculopathy), and avoids the term sciatica. However, despite this correct use of terminology, why they didn't specifically include the term radiculopathy is uncertain.

However this title was later changed in the SR published by Clarke et al. (2005) to, 'Traction for low-back pain with or without sciatica'. Why is not discussed but is important, as it may bias the results. Subsequent Cochrane reviews Clarke et al. (2007), and Wegner et al. (2013) continue to use this alternative title. Although this title still fits within the broad definition of LBP, the use of the term sciatica is controversial. Proving the point of Merskey and Bogduk (1994) that sciatica encapsulates all radiating leg symptoms, somatic, radicular, and radiculopathy (as discussed in section 3.2).

It becomes further complicated when reading within the method section of the Cochrane SRs. Where the inclusion criteria states RCTs examining any type of traction for the treatment of acute (less than four weeks duration), subacute (four to 12 weeks), or chronic (more than 12 weeks), *NSLBP* with or without *sciatica*. By changing LBP to NSLBP, but still including those with sciatica (radicular and / or radiculopathy) into a sentence alongside NSLBP is a misnomer. As according to the accepted classification triage, the presence of radicular or radiculopathy symptoms is caused by nerve root etiology, and this sits within its own distinct LBP category, and not within NSLBP (as discussed in section 3.2).

Within each of the three Cochrane SRs they define sciatica as "pain radiating down the leg(s) below the knee along the distribution of the sciatic nerve, usually related to mechanical pressure and / or inflammation of lumbosacral nerve roots" (Bigos et al., 1994, glossary). Bigos et al. (1994), clearly state that LBP should be categorised into the three distinct and accepted categories; potentially serious spinal conditions, sciatica, and NSLBP (Waddell, 1982).

Therefore to claim the existence of NSLBP with sciatica within a SR, would seem to be erroneous and nonsensical, and it may be presumed that the SR authors have had to adapt the original review protocol so that the research would fit within the review, as the cohorts

within the primary literature tended to be NSLBP with or without sciatica. This is an important point as the majority of the research Clarke et al. (2005, 2007), and Wegner et al. (2013) have included in their SRs have made the same basic logistical error of combining NSLBP with sciatica.

Highlighting this fundamental confusion on whether the intention of the primary researchers, and the systematic reviewers, was to make conclusions on traction for LBP, or for NSLBP, and pointing out the continued use of the term sciatica may seem overly pedantic. But the apparent innocuous interchangeability of the term LBP with NSLBP, and use of sciatica to describe any manner of radiating leg symptoms (section 3.2) results in heterogeneity, and casts doubt on the quality of the primary research as well as the SRs undertaken by Clarke et al. (2005, 2007), and Wegner et al. (2013). This provides overwhelming support to suggest that the methodological quality of the RCTs and SRs did not follow accepted definitions of the time. Meaning with respect to definitions of LBP and NSLBP alone, they were flawed.

4.4.2 Inconsistent definitions of pain duration and inappropriate cohorts of mixed pain duration

In addition to this the primary literature used variable temporal cut off points to distinguish acute, from sub-acute, or chronic pain, and often combined two, or all three in cohorts. These were then analysed by SRs as if they were homogeneous. This is clearly not so, and combined with inaccurate definitions of LBP cohorts (detailed in section 4.4.1 above), this introduces further heterogeneity into the studies and makes the results, conclusions, and recommendations unscientific and inappropriate to clinical practice.

4.4.3 Study designs fundamentally inappropriate to clinical practice

By committing these basic definitional errors and not ensuring homogeneity, or by following accepted clinical practice, the primary research, SRs, and CPGs have fundamentally misrepresented the actual clinical application of traction as forewarned by Saunders (1983).

It is perhaps pertinent that although referred to in many articles, Saunders (1983) does not make the reference list within any of the Cochrane reviews.

4.4.4 Poor methods for appraising quality of the primary research

The fact that Koes et al. (1995), van der Heijden et al. (1995), van Tulder et al. (1997), and Clarke et al. (2005) decided to appraise the quality of trials each following their own predetermined assessment criteria, by simply scoring a trial out of 100 (Table 3), or Clarke et al. (2007) accepting a 'yes, no or don't know' (Table 4), gives an indication of how the importance of homogeneity in term of cohort selection and equivalence of prognosis was undervalued.

By offering points, and not a definitive decision to include or exclude studies based on the equivalance of diagnosis, prognosis, and appropriatness of traction, they have all fatally under-rated the importance of them. The weighted rating system as described is arguably poorly informed. It is extremely concerning that the authors have developed a scoring system in itself, believing it to be a measure of a study's quality. Never mind that it only awards homogeneity a maximum of two, and comparability of prognosis at baseline five or ten points.

The decision to award points to determine the value of the homogeneity of the cohort, and the comparability of the prognosis at baseline, to a maximum of 12, seems questionable. These are the defining features of any study or SR. If a study does not ensure homogeneity of the chosen study cohort, with clear definitions and accepted inclusion and exclusion criteria, and diagnostically appropriate participants selected for the studied intervention, with equivalent pathology in terms of pain radiation into the legs, duration of pain, and a comparable prognosis, it should be immediately excluded. Subjecting it further along the rating system becomes superfluous. Enabling a study to 'fail' these two defining criteria, and yet possibly still score 88 out of 100 and be ranked high quality will colour any analyses and conclusions obtained from the study due to the heterogeneity of the cohort studies.

The total score is irrelevant, it is already suffering from fatal heterogeneity. Enabling a study to completely 'fail' these two defining criteria, and yet possibly still score 88 out of 100 and be ranked high quality, is completely irrational. This fundamental ommission supercedes any other methodological factors, and how a study may rank on other criteria such as, method of randomisation, number of participants, absence of blinding, the outcome measures or statisitical methods used, and the absence of a control group or placebo, become superfluous. It is dissapointing that the importance of ensuring homogeneity was not realised within early RCTs, and was not given sufficent emphasis and demanded their exclusion from SRs, as this will have prevented their unwarranted negative influence over later CPGs.

Despite the earlier comments made by Bloch (1987), it seems that reviews using this rating criteria have not appreciated that these mixed characterisitics will introduce extreme heterogeneity, immediately questioning the fundamental design, conclusions, and credibility of trials. Wegener et al. (2013) supposedly followed the latest guidelines from the Cochrane Back Review Group;

> The Editorial Board recommends that reviews focus specifically on (sub)acute or chronic back or neck pain. It is also recommended that reviews focus separately on nonspecific back or neck pain, sciatica or radicular symptoms, or specific causes (Furlan et al., 2009, p. 1930)

It is clear that although this may have been the intention, Wegner et al. (2013) did not follow this.

4.4.5 Overlooking pertinent research describing the poor methodological quality of RCTs and negative effects of historical CPGs

Various authors were expressing their opinions and critique on the inappropriateness of the primary research (Albright et al., 2001; Borman et al., 2003; Furlan et al., 2001; Harte et al., 2005; Riley et al., 2016; Saunders, 1983, 1998). But Cochrane SRs and various CPGs were

either not cognizant of these opinions, or they were ignored, as poor methodologically designed trials continued to be used as evidence to support the ineffectiveness of traction for LBP.

Critically examining this process has illuminated how previously identified population heterogeneity and methodological flaws in study design, as well as within SRs, have contributed to the damning and inaccurate conclusions regarding the efficacy of traction as an intervention for LBP. These inaccurate conclusions have informed CPGs worldwide, and as a consequence the clinical application of traction has waned, which seems unwarranted.

4.4.6 Process of undertaking SRs and CPGs

It is evident that authors of SRs and committees responsible for CPGs have used poor processes to arrive at their conclusions and recommendations. Often relying on the findings of previous SRs, or previous CPGs to inform them, without performing their own detailed critique (Dagenais et al., 2010). In addition they were formed by consensus opinion, and that this was affected depending on the bias of each particular committee (Arnau et al., 2006; Bogduk, 1999; Koes et al., 2001; Rosner, 2001; van Tulder et al., 2004), which meant that they were not dictated by inconclusive scientific evidence as envisioned.

4.4.7 Current utilisation of Traction

Despite these negative conclusions from the primary studies, SRs, and CPGs it seems that traction continues to utilised, albeit sporadically. Studies have shown that 41% (Harte et al., 2005), and 76.6% (Madson & Hollman, 2015) of physiotherapists have continued to use traction within their clinical practice, no doubt remaining anecdotally certain of its effectiveness when set amongst meticulous clinical reasoning skills, within an effective EBP paradigm. Harte et al. (2005) who looked at the use of traction amongst all physiotherapists, leaves a great number who no longer use traction. As opposed to Madson and Hollman (2015), who demonstrated that you may have to study to masters level to have the time, ability, and 'right' to question and fully appreciate the existence of this poorly informed

evidence, and so the fortitude to continue to use traction. Due to the preponderance of research, it is an impossible task for busy practicing clinicians to perform their own critique of primary research, SRs or CPGs. Many only have access to the abstract, conclusions, clinical pearls, or SR and CPG recommendations, and with respect to traction it can be seen that these are all extremely misleading.

Chapter 5. Discussion

The burden of LBP is growing and many physiotherapeutical interventions, such as traction, have been found to be ineffective. This has seen a shift away from such 'passive' modalities into more active management of LBP, with patients being asked to take more responsibility for their own recovery. Although this is a positive development, it seems that it may have accidentally evolved from within an environment of unsubstantiated negative conclusions surrounding passive interventions, due to the preponderance of poorly designed studies into passive modalities, which is fortuitous. Historically there have been a large number of physiotherapeutical interventions used to treat LBP, many with anecdotal clinical support, which have been discontinued due to such negative scientific recommendations.

Physiotherapists use CPGs to inform their clinical practice and these are determined from primary research and SRs. Traction has been removed from CPGs as an intervention for LBP. This research study has investigated the pertinent research that informed the removal of traction from clinical practice to identify if the conclusions and CPG recommendations were valid.

This chapter will be outlined with a summary of the findings of this research (section 5.1), heterogeneity in past research (section 5.2), inherent variability within nonspecific low back pain (section 5.3), limitations of this research (section 5.4), and recommendations for research (section 5.5).

5.1 Summary of the findings of this research

From the arguments detailed within this thesis, specifically the first NRs to collate pertinent studies chronologically, it is evident that past research into the efficacy of traction for LBP suffers from numerous flaws within cohort selection and methodological designs. The inconsistent importance and interpretation of definitions such as what is LBP, the variable, interchangeable, erroneous use of terms with respect to the pathophysiology of LBP and

referred leg symptomology, the lack of distinction between acute, subacute and chronic LBP, and the appropriateness of traction as an intervention for the selected cohorts, and the contribution from other methodological flaws within the study design, were highlighted in Chapters 2 - 4.

These errors have made it impossible to compare studies of similar or competing interventions, to replicate findings, to pool data from multiple studies, to confidently resolve conflicting conclusions, or develop multidisciplinary consensus, or even be able to achieve consensus within a single discipline of musculoskeletal medicine. The development, publication, and dissemination of CPGs is fundamental toward evidence based practice. But it is crucial that the efficacy of various physiotherapeutical interventions are based on results of clinical studies with sound methodologic quality (Koes et al., 2001).

The findings in this research study show that researchers overlooked, or misapplied population selection criteria, in terms of diagnosis, pain duration, and equivalence of prognosis, as well as the overall poor methodological designs. These fundamental requirements are necessary for the clinical appropriateness and homogeneity of the chosen cohort, to ensure that the randomised groups have equivalent pathoanatomical and prognostic characteristics.

The poor quality of analysis and reporting also within subsequent SRs on the efficacy of traction, has meant that the previously identified poor research concerning LBP in general, extends to traction. The resultant heterogeneity within and between studies causing the various conclusions drawn from this primary research to be inconsistent, contradictory, and not valid to everyday clinical practice.

5.2 Heterogeneity in past research

Many researchers have stated that due to heterogeneity it is difficult to compare past studies of similar, or competing interventions for LBP (Bogduk, 2009; Borman et al., 2003; Brennan et al., 2006; Chanda et al., 2011; Childs et al., 2004; Clarke et al., 2005, 2007; Deyo et al.,

2014; Fardon et al., 2001; Fardon et al., 2014; Fritz et al., 2000; Fritz et al., 2007; Henschke et al., 2012; Itz et al., 2013; Kamper et al., 2011; Koes et al., 1995; Lin et al., 2014; Manchikanti et al., 2010; Merskey & Bogduk, 1994; Pellecchia 1994; Qaseem et al., 2017; Riley et al., 2016; Schäfer et al., 2014; Shultz et al., 2015; Stanton et al., 2009; Sweetman et al., 1993; van der Heijden et al., 1995; van Middelkoop et al., 2011; Wong et al., 2017; Wegner et al., 2013).

The inconsistencies amongst studies on the efficacy of traction therapy may be explained by the differences in the diagnostic categories of LBP, particular traction techniques, and methodological design (Borman et al., 2003; Gay & Brault 2008; Harte et al., 2003; Koes et al., 1995; Krause et al., 2000; Macario & Pergolizzi, 2006; Pellecchia 1994; Qaseem et al., 2017; van der Heijden et al., 1995a; van Middelkoop et al., 2011; Wong et al., 2017). These authors agree that the literature on the efficacy of traction in the treatment of LBP is conflicting and that there is no compelling evidence that lumbar traction is clinically effective, but also there is insufficient evidence of inefficacy to discard traction either.

Despite this, traction was not found to be an effective intervention within any Cochrane SRs (Clarke et al., 2005, 2007; Wegner et al., 2013) albeit they recognised the methodological flaws within the studies investigated. The underappreciation of this heterogeneity has led to the unwarranted removal of traction from CPGs for use in treatment of LBP, as the results of the NRs has demonstrate that the SRs conclusion of traction being ineffective in treating LBP, cannot be supported by the historical primary research. Therefore these interventions may have been incorrectly disbanded, and the hesitancy in the uptake of CPGs by some practitioners may be justified and applauded.

It is encouraging that finally after many years of authors expressing concern and identifying methodological weaknesses within LBP research in general and traction in particular, that the resultant heterogeneity, which makes it impossible to determine the effectiveness of traction (as well as a large range of other clinical physiotherapeutical interventions), has now become accepted (Deyo et al., 2014).

5.3 Inherent variability within nonspecific low back pain

Even if future researchers obey contemporary definitions regarding correct triaging of LBP into specific spinal pathology, nerve root involvement, or NSLBP, the difficulty of ensuring homogeneity is further complicated when consideration is given to the size of the NSLBP population (95 – 99 % of LBP cases), and the range and variety of pathophysiological causes of NSLBP (section 3.2). Even if we could ensure careful equivalence of pain duration into acute, subacute, and chronic pain, it is still very unlikely that any given cohort within or between studies will be the same. Each made up of different combinations and percentages of the various causes of NSLBP, some causes of which would not even be suitable for and may be exacerbated by traction. Consequently it would not be undertaken or repeated in everyday clinical practice, and would be found to be ineffective for that particular diagnosis, but it is inappropriate to extrapolate that out to LBP in general.

At present the research, as historically undertaken, can only provide the misleading conclusion that traction is ineffective for LBP (or NSLBP with the juxtaposition inherent) in general, with mixed pathology with and without sciatica, and variable pain duration. This has been taken out of context to mean that traction is not effective for any type of LBP. But this is plainly incorrect, the past research cannot even reveal if traction may be an effective intervention for LBP with respect to broad pathological classifications (NSLBP, or nerve root pain) and duration, when each is studied in isolation, never mind following further classification into various sub-groups of NSLBP. As an example, the work of Harte et al. (2005) suggested that traction is most commonly used within clinical practice on a sub-group of patients presenting with sub-acute LBP with nerve root involvement. Also Gudavalli et al. (2006) found evidence that their subgroup analysis may help explain contrasting outcomes among previous trials of chronic LBP treatments.

It is not surprising that traction is ineffective for LBP in general, as practicing clinicians would agree that traction is not an appropriate intervention for every patient with LBP regardless of

pain duration. The decision to apply it on an individual with LBP is determined by clinical assessment, clinical experience of the clinician, and preference of the patient; with how (what type, in what position, how long, how often) to apply traction informed and directed by effective clinical reasoning skills.

Crucially, this decision on how traction will be utilised is also fluid, dependent on clinical reasoning, as well as based on the individual patients experience within the session, and response between sessions. Clinically it will not be considered or continued for a predetermined number of weeks if it is quickly found to be inappropriate. As with all physiotherapeutic interventions it should be thought of as one tool, and its use quickly curtailed and replaced by another if it does not achieve the desired result.

Historic scientific research has been undertaken within an environment ripe with heterogeneity, making results within and between studies, down to chance combinations of infinite variabilty. Extroadinarily large cohorts, complicated and intensive correlation analyse would be required to arrive at any meaningful conclusions due to the size of the NSLBP (or LBP) cohorts.

As this poorly informed and undertaken research has suggested that traction is ineffective, it has been removed, concurrently there has been a paradigm shift away from such ‘passive modalities’, towards the recommendation of general exercise, and psychosocial support to help patients take responsibility for and cope with the pain, averting fear avoidance behaviour, and pain catastrophizing.

It should be noted that this thesis does not downplay, underestimate, or question the undoubted importance of exercise or psychosocial support. These are essential. Rather it questions whether passive modalities, as used in the clinic and not as studied within historic research, provided a valid option to manage LBP. This intervention perhaps helping avoid negative psychosocial influences due to chronicity, and asks whether a perfect marriage exists between effective passive modalities and psychosocial pain management.

5.4 Limitations of this research

This thesis was driven by the need to question the conclusions of SRs and the recommendations of CPGs on the inefficacy of traction, which seemed likely, based on past studies on LBP to be informed by poorly designed primary literature. This resulted in the need to search for pertinent literature to investigate whether this was so.

It must be stressed that although a practicing clinician for 25 years, the author has no bias towards traction and, due to the recommendations of CPGs, has not used traction as an intervention for LBP in clinical practice.

It is felt therefore that there were no pre-conceived opinions regarding traction research and that this was prepared and grew organically on the discovery of the methodological flaws. It would be worthwhile if another researcher repeated the NRs for verification and this would be encouraged.

5.5 Recommendations for future research

It may be possible that in the process of scientifically deconstructing and isolating the practice of traction to allow empirical, quantitative measurement, researchers have removed the very essence of its actual clinical applicability. The clinical application of traction was fundamentally fluid depending on individual presentation and reaction, and not fixed or rigidly applied, identically to all LBP patients. It is arguable that this in itself, and regardless of weaknesses also identified in population selection criteria and study methodology, would result in conclusions not valid to actual clinical practice.

These arguably poorly informed recommendations from within SRs and CPGs has had a deleterious knock on effect to clinical practice, intra- and inter- professional relationships, and undergraduate educational facilities. The inappropriate negative conclusions have dictated interventions utilised by EBP clinicians, taught by tutors, and funded by governmental health legislators and insurance policy writers. So consequently traction

remains unsupported, despite seemingly anecdotally effective within clinical practice, and not being proved to be ineffective by scientific studies.

There remains a great need for better study designs to determine more accurate diagnostic methods to identify and delineate the various conditions that present as LBP with or without leg symptomology into more concise sub-groups. As well as a method to accurately delineate the duration of pain to ensure homogeneity.

In summary, LBP is a very common and costly condition, we owe it to our patients to determine;

- better specificity and sensitivity of clinical assessments to differentiate LBP from hip or SIJ pathoanatomical structures
- agreed diagnostic and / or prognostic sub-groups of LBP which are studied in isolation
- clear delineation and utmost importance given to preparing and following agreed terminology with respect to low back related leg symptoms,
- an alternative or at least agreed, definition of acute, sub-acute, and chronic pain. Which may or may not remain time dependent, but could involve other ways of categorising pain. Maybe we look to divide LBP into 'simple' and 'complex' and decide on the clinical parameters which determine this which may not be temporal, but include scoring above a certain score in a psychosomatic questionnaire, the presence of comorbidities, the number of medications taken, and the inability to work due to pain, amongst others. For example the expected recovery following anterior cruciate reconstruction surgery, is accepted to be 1 to 2 years, but this must not always be viewed as a chronic pain syndrome. Although in some individuals there may be a chronic pain or 'complex' psychosocial element, this is not differentiated by temporal factors, but by other innate factors which would require added interventions from a wider multi-disciplinary team

- that within any study cohort there will be a natural history of spontaneous recovery of LBP, which may also be set within a framework of intermittent or recurrent exacerbation

Arguably even the results of meticulously and judiciously designed RCTs, as they by definition remain undertaken within the scientific demands of rigid and sterile controlled conditions, may not demonstrate external validity to clinical practice. Meaning they may never be applicable to the variable, tailored, fluid, and responsive environment evident and fundamental to clinical practice. To obtain more meaningful and applicable data it may be necessary to use more pragmatic RCT methods, or alternatively qualitative, mixed method, comparative, or observational studies, which may be best undertaken within the clinically relevant environment itself with outcomes that are of importance to the patient (Kamper, Stanton, Williams, Maher & Hush, 2011; McPherson & Kayes, 2012; Magilvy & Thomas, 2009; Neergaard, Olesen, Andersen, & Sondergaard, 2009; Petty et al., 2012; Sandelowski, 2000).

Since surgery is not a fix-all approach as studies have shown that conservative care is at least equivalent to surgery at one to two years (Jacobs et al., 2011), and failed back surgery is a common occurrence; we need to ensure that cases are thoroughly worked-up and all avenues of conservative care and interventions are exhausted, to filter out those who do not respond and leaving those who may be more likely to have a successful outcome from appropriate surgery (Gibson, Grant, & Waddell, 1999; Willems, 2013).

An interesting study provides an insight on how when traction might be effective. Swanson et al. (2016) looked at patients between the ages of 18 and 75 years, with complaints of non-radicular LBP. Non-radicular LBP they defined as pain in the lumbar area that did not extend below the knee. Participants were excluded if they presented with advanced pathology including tumor, fracture, infectious disorder, central nervous system involvement, presence of medical red flags, absence of LBP, radicular leg pain (below the knee),

pregnancy, epidural steroid injection within 4 weeks before study involvement, previous back surgery, workers compensation involvement, or active litigation.

Patients were assessed with a manual unloading test in their most provocative position followed by a single application of intermittent mechanical traction. Post traction, pain in the provocative position was reassessed and utilized as the outcome criterion.

Swanson et al. (2016) concluded that a manual unloading test appeared to be a reliable, and had a moderate to strong correlation with pain relief that exceeded the minimal clinically important difference (MCID) following traction, which supported the validity of this test and deserved more research into the effect of traction on similar more homogeneous cohorts.

Chapter 6. Conclusion

Despite historical literature highlighting the poor methodological quality of the research studies into physiotherapeutical interventions in general, and in doing so questioned our understanding of the clinical assessment, diagnosis, treatment, and management of LBP, these inconsistent definitions and methodologically poor study designs, seem to have been largely ignored or overlooked. Consequently many interventions, such as traction, have been portrayed as being ineffective for LBP and not recommended by CPGs.

However these conclusions are from poorly undertaken primary studies, SRs, and CPGs therefore past and current beliefs and recommendations concerning LBP in general, and traction interventions in particular, are incorrect. The consequence today is that this poorly informed historical process has resulted in inappropriate negative recommendations on the effectiveness of traction, which have ensured the unwarranted demise of traction within physiotherapy clinics.

Some studies have shown that, despite these negative recommendations, 41% (Harte et al., 2005), and 76.6%, (Madson & Hollman, 2015) of physiotherapists have continued to use traction within their clinical practice. No doubt remaining anecdotally certain of its effectiveness when set amongst meticulous clinical reasoning skills, within an effective EBP paradigm. But in the case of Harte et al. (2005) who looked at utilisation amongst all physiotherapists especially, it leaves a great percentage of physiotherapists who no longer use traction. Madson and Hollman (2015) demonstrated that you may have to study to masters level to have the time, ability, and 'right' to critique and question, and fully appreciate the existence and consequences of this poorly informed evidence. As perhaps counterintuitively, they found greater utilisation of traction within this postgraduate populace. It seems that undergraduates and newly qualified physiotherapists, are at the mercy of their tutors and employers respectively. Who with the best intentions, erroneously rely on SRs

and CPGs to flavour their curriculum and clinical practice, ironically still echoing the "if….then" statement of Eddy (1984), although now at least 'evidence' informed.

Future researchers must acknowledge these past failings, develop, agree, and abide by contemporary definitions, and arrive at quantitative methodological paradigms which mirror accepted clinical practice. There should also be more consideration given to using mixed method, qualitative designs, or case studies and case series. To help specify the accumulated knowledge about psychosocial experiences of chronic LBP, to further illuminate the contribution of qualitative research, and together inform the development of specific interventions and management strategies (Snelgrove & Liossi, 2013).

This will establish accurate and scientifically justified conclusions on the efficacy of traction for clinically appropriate sub-groups of LBP patients, and facilitate EBP to the betterment of patients suffering from LBP.

6.1 Clinical Pearl

This thesis gives justification to the case that historical research within LBP in general, and traction in particular, has truly been flawed and therefore unable to support the negative conclusions and recommendations within SRs and CPGs. This historical synthesis of pertinent literature should finally settle the debate and confirm the need to acknowledge the heterogeneity rampant within LBP research, and the inappropriateness of the supposed validity to clinical practice.

Importantly, it should spark debate amongst the clinical and scientific communities on whether traction should be reinstated as a physiotherapeutic intervention for patients presenting with LBP in the clinic; provided it is used within an effective EBP model, inclusive of a biopsychosocial framework.

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Appendices

Appendix A. Critique of primary literature referenced in SRs, and CPGs

Review and critique of primary literature referenced within three systematic reviews, van der Heijden et al., (1995), Clarke et al., (2007), and Wegner et al., (2013). Clarke et al., (2005) omitted as Clarke et al., (2007) repeated 2005 and included one extra study.

		van der Heijden et al., (1995)	Clarke et al., (2007)	Wegner et al., (2013)	According to the primary literature	Comments and critiques	From reviews and primary literature, and considering only the homogeneity of the population studied and pain duration, should it have been considered as evidence of efficacy of traction?
Author(s)	Year						
Lidström and Zachrisson	**1970**						
DEFINITION OF LBP AND PAIN REFERRAL		62 patients LBP, sciatica	62 participants selected from an orthopaedic outpatient clinic. Participants had LBP and sciatic pain radiating down 1 leg	62 participants selected from an orthopaedic outpatient clinic. Participants had LBP and sciatic pain radiating down 1 leg	62 participants selected from an orthopaedic outpatient clinic. Participants had LBP and sciatic pain radiating down 1 leg	Definition of LBP or sciatica not stated in r/vs. Sciatica defined in article as pressure on the nerve root is the most accepted cause of sciatic pain and also that palpation, the mobility tests and the possible neurological findings are put in relation to the verbal statements of the patient to reach a comprehensive judgement. This is, of course, a subjective estimation. To-day, however, the only possible one. So likely to include somatic, radicular and radiculopathy	
TYPE OF LBP (acute, subacute, chronic, recurrent)		chronic	Radiating pain for more than one month's duration. 32 patients had a history of pain > 1year	Radiating pain for more than one month's duration. 32 patients had a history of pain > 1year	Radiating pain for more than one month's duration. 32 patients had a history of pain > 1year	Definition not stated in VD Heijden r/v, but is in other sources. Mix of acute, sub-acute and chronic group heterogeneity	

NEUROLOGIC DEFICIT AND OTHER	not stated	not stated	not stated	Neurological loss symptoms were present in single cases, Irradiating pain down to below knee level and positive Lasègue's sign were recorded.	Not stated in r/vs but from original article some including neurologic deficit. group heterogeneity - mixed somatic and radicular and radiculopathy	
OTHER CONDITIONS INCL/EXCL	Not stated	Patients strongly suspicious of the presence of a disc prolapse were not accepted.	Patients strongly suspicious of the presence of a disc prolapse were not accepted.	Patients strongly suspicious of the presence of a disc prolapse were not accepted.	What clinical criteria did they use to decide this. Unsure of other non-mechanical pathology. unsure of other non-mechanical pathology	NO poor summary in vd Heijden r/v, from original article still questions over definition LBP, mixed referred pain, mixed pain duration, group heterogeneity
Weber **1973**						
DEFINITION OF LBP + PAIN REFERRAL	72 patients prolapsed lumbar disc, sciatica	72 patients admitted to neurology department. All had radiating pains and neurological signs	72 patients admitted to neurology department. All had radiating pains and neurological signs	72 patients admitted to neurology department. all hospitalised on bed rest, all had radiating pains & neurological signs from a prolapsed intervertebral disc, all hospitalised on bed rest	All had radiating pains and neurological signs suggest possibility of ensuring radiculopathy. However this and diagnosis of a prolapsed intervertebral disc is very reliant on diagnostic accuracy as well as terminology in 1973, and clinical examination not discussed in paper	
TYPE OF LBP (acute, subacute, chronic, recurrent)	not stated	not stated	not stated	not stated	unsure as to duration of pain	
NEUROLOGIC DEFICIT AND OTHER	included	All had neurological signs L5 or S1, positive radiculogram.	All had neurological signs L5 or S1, positive radiculogram.	All had neurological signs L5 or S1, positive radiculogram.	All having neurological signs so maybe suggestive of group homogeneity, radiculopathy group possible. Dependent on diagnostic accuracy of radiculogram and terminology in 1973	
OTHER CONDITIONS INCL/EXCL	not stated	Excluded were patients with bladder paresis, strong persistent pains, acutely occurring paresis and/or considerable constraint of the spinal column.	Exclusion criteria: people with bladder paresis, strong persistent pains, acutely occurring paresis or considerable constraint of the spinal column (or both).	Excluded were patients with bladder paresis, strong persistent pains, acutely occurring paresis and/or considerable constraint of the spinal column.	positive radiculogram (x-ray), red flags excluded, unsure of ability to distinguish metastatic disease at time, as 1 patient discontinued due to discovery of prostate cancer	NO, although good attempt to ensure some homogeneity with diagnosis, but still questions over investigation & relevance of prolapsed lumbar disc, considering 1 had cancer, pain duration not stated, likely group heterogeneity

Lind (thesis) 1974	not in r/v			can't source		
DEFINITION OF LBP + PAIN REFERRAL	not in r/v	45 participants from waiting list of orthopaedic surgery department.	45 participants from waiting list of orthopaedic surgery department.	can't source	patients awaiting surgery so reasonably narrow population	
TYPE OF LBP (acute, subacute, chronic, recurrent)	not in r/v	Recurrent pain, All had several periods of attack, mean no. 3.5.	Recurrent pain, All had several periods of attack, mean no. 3.5.	can't source	All had recurrent pain, so again reasonably narrow population, although definition of recurrent is questionable. Not stated but a mix of acute, sub-acute and chronic possible	
NEUROLOGIC DEFICIT AND OTHER	not in r/v	Included patients with or without neurological signs	Included participants with or without neurological signs	can't source	group heterogeneity - mixed somatic and radicular and radiculopathy	
OTHER CONDITIONS INCL/EXCL	not in r/v	All had had some previous non-surgical therapy. Pts with serious disorders (e.g. arteriosclerosis hypertension) excluded.	Participants with serious disorders (e.g. arteriosclerosis, hypertension) excluded. All had had some previous non-surgical therapy	can't source	good that other conservative therapy tried and as failed on to surgery	NO, from r/vs alone there are questions over definition of recurrent and unsure of duration of pain in each episode or prior to study, with or without neurological deficit, likely group heterogeneity.
Matthews and Hickling 1975						
DEFINITION OF LBP + PAIN REFERRAL	27 patients LBP, not stated if includes radiating pain	27 patients had sciatica or cruralgia, with or without back pain	27 patients had sciatica or cruralgia, with or without back pain	27 patients had sciatica or cruralgia, with or without back pain	Radiating pain status omitted from VD Heijden r/v, but is in other sources. Article defines sciatica as taken to be severe and well delineated pain, posterior in the leg and radiating distal to the knee, and cruralgia a similar pain, anterior in the thigh or shin They also admit that traction has not been applied to a specific condition but to a defined syndrome	

TYPE OF LBP (acute, subacute, chronic, recurrent)	not stated	at least 3 wks duration	of at least 3 wks duration	at least 3 weeks	Duration omitted from VD Heijden r/v. Other sources state at least 3 weeks in text but appears 1.5 - 46 weeks in Table 1? Mixed acute, sub-acute, chronic - group heterogeneity	
NEUROLOGIC DEFICIT AND OTHER	not stated	excl recently acquired neurological deficit	excl recently acquired neurological deficit	excl recently acquired neurological deficit	neurological status omitted from VD Heijden r/v, but excl in other sources, question over definition of recently acquired	
OTHER CONDITIONS INCL/EXCL	unsure of what else	Back movement was required to be limited in at least one direction and either the sciatic or femoral nerve stretch test positive. All had root pain. excl a psychological disturbance, pregnant, radiological evidence of sacro-iliitis or osteoporosis, previous traction	Back movement was required to be limited in at least 1 direction and either the sciatic or femoral nerve stretch test positive. All had root pain. Exclusion criteria: a recently acquired neurological deficit, psychological disturbance, were pregnant, a radiological evidence of sacro-iliitis or osteoporosis, previous traction	Back movement limited in at least one direction and either the sciatic or femoral nerve stretch test positive. Excluded if had recently acquired a neurological deficit, twinging leg pain, a psychological disturbance, pregnant, radiological evidence of sacro-iliitis or osteoporosis, previous traction, worked in hospital, travelling long distance. All patients radiograph of the lumbar spine and ESR **estimation,** allowed only paracetamol.	No definition of recently acquired neurological deficit, was sciatic nerve stretch Lasègue's, reliability of femoral nerve stretch since found to be poor. Unsure of other non-mechanical pathology. Cross over design	NO term sciatica, cruralgia, variable pain duration, likely group heterogeneity, accuracy of femoral nerve stretch
Bihaug (in Norwegian) 1978				can't source		
DEFINITION OF LBP + PAIN REFERRAL	42 patients LBP, not stated if includes radiating pain	42 participants referred from secondary care setting. All had radicular pain; in 32 radiating pain was below the knee.	42 participants referred from secondary care setting. All had radicular pain; in 32 radiating pain was below the knee.	can't source	VD Heijden r/v omitted that all patients had radicular pain, but r/vs by Clarke and Wegner state all had radicular pain and some radiating to below the knee. Definition of radicular or radiating was not stated in any r/v	

TYPE OF LBP (acute, subacute, chronic, recurrent)	chronic	Pain duration was 3 to 52 weeks	Pain duration was 3-52 wks (mean 9.7 wks), 25 participants were on sick leave at baseline (1-24 wks, mean 5.1 wks)	can't source	definition not stated in VD Heijden r/v, but r/vs by Clarke and Wegner more info and range from acute, sub-acute to chronic	
NEUROLOGIC DEFICIT AND OTHER	not stated	some had neurological deficits	27 had neurological deficits (figures not given for the 2 different groups)	can't source	definition not stated in VD Heijden r/v, but r/vs by Clarke and Wegner neurological symptoms	
OTHER CONDITIONS INCL/EXCL	unsure of what else	unsure of what else	unsure of what else	can't source	unsure of other non-mechanical pathology	NO from r/vs alone, there are questions over definition of radicular and radiating pain, mixed duration of pain, with/without neurological deficit - group heterogeneity. Unsure of excl criteria.
Larsson et al 1980						
DEFINITION OF LBP + PAIN REFERRAL	82 patients LBP, not stated if includes radiating pain	82 participants in 6 departments of orthopaedic surgery in Sweden, with lumbago-sciatica with or without symptoms of neurological deficit.	82 participants in 6 departments of orthopaedic surgery in Sweden, with lumbago-sciatica with or without symptoms of neurological deficit.	82 participants in 6 departments of orthopaedic surgery in Sweden, with lumbago-sciatica with or without symptoms of neurological deficit.	VD Heijden r/v omitted that patients admitted with/without neurological deficit as according to other sources. unsure as definition of sciatica-lumbago but as can be with or without neurologic deficit, will include somatic, radicular and radiculopathy - group heterogeneity	
TYPE OF LBP (acute, subacute, chronic, recurrent)	acute	Duration of current episode at least 2 wks and not more than 3.5 mos.	Duration of current episode at least 2 wks and not more than 3.5 mths	Duration of the current episode > 2 weeks and < 3 1/2 months.	Contradiction as VD Heijden r/v claimed acute but other sources confirm a mixture of acute, sub-acute and chronic LBP	
NEUROLOGIC DEFICIT AND OTHER	excluded	with or without neurological deficit, has positive SLR	with or without neurological deficit, has positive SLR	with or without neurological deficit, has positive SLR	Contradiction as VD Heijden r/v claimed neurological deficit were excluded but other sources say otherwise. group heterogeneity - mixed somatic and radicular and radiculopathy	

OTHER CONDITIONS INCL/EXCL	not stated	not stated	not stated	not stated	unsure of other non-mechanical pathology	NO poor summary in vd Heijden r/v, but still questions over definition of LBP and referred pain, mixed duration of pain, with or without neurological deficit, likely group heterogeneity
Coxhead et al 1981						
DEFINITION OF LBP + PAIN REFERRAL	334 patients LBP, sciatica	334 participants referred to the outpatient department with sciatic pain at least as far as the buttock crease, with/without back pain.	334 participants referred to the outpatient department with sciatic pain at least as far as the buttock crease, with/without back pain.	334 participants referred to the outpatient department with sciatic pain at least as far as the buttock crease, with/without back pain.	From original article is a very good factorial study design looking at tru-trac traction, exercises, manipulation and corset - alone or in combination for a total of 16 groups, definition of sciatica not stated in r/vs or article. group heterogeneity of somatic, radicular and radiculopathy	
TYPE OF LBP (acute, subacute, chronic, recurrent)	acute	Average duration of symptoms 14.3 weeks	Mean duration of symptoms 14.3 wks	av duration 14.3 weeks	Contradiction as VD Heijden r/v claimed acute but other sources confirm a mixture of acute, sub-acute and chronic LBP	
NEUROLOGIC DEFICIT AND OTHER	not stated	not stated	not stated	not stated	unsure if including neurologic deficit	
OTHER CONDITIONS INCL/EXCL	unsure of what else	Excl malignant or infective disease, gynaecological disorders, sacroiliac disease, vertebral collapse, or gross structural abnormality.	Pain not due to malignant or infective disease, gynaecological disorders, sacroiliac disease, vertebral collapse or gross structural abnormality.	excl malignant, infective, gynaecological, SIJ disease, vertebral collapse, gross structural abnormality, spinal surgery, pregnant &post-partum women	unsure of other non-mechanical pathology	NO poor summary in vd Heijden r/v, but still questions over definition of LBP, sciatica and referred pain, mixed duration of pain, neurological deficit not stated, group heterogeneity, clinical diagnosis of SIJ, numbers small when split over 16 groups

Walker et al 1982

DEFINITION OF LBP + PAIN REFERRAL	LBP, sciatica	29 patients with NSLBP and radiating pain chosen by a specialist in neurology at the Department of Neurology.	29 patients with NSLBP and radiating pain chosen by a specialist in neurology at the Department of Neurology.	in Norwegian	No definition of LBP or sciatica in VD Heijden r/v, or of NSLBP and radiating pain in other sources. May include somatic, radicular and radiculopathy	
TYPE OF LBP (acute, subacute, chronic, recurrent)	acute	mixed duration (18 subjects with pain >12 weeks; 11 with <12 weeks)	mixed duration (18 subjects with pain >12 weeks; 11 with <12 weeks)	in Norwegian	definition not stated in r/v	
NEUROLOGIC DEFICIT AND OTHER	not stated	neurological deficit not stated	neurological deficit not stated	in Norwegian	unsure if including neurologic deficit	
OTHER CONDITIONS INCL/EXCL	not stated	not stated	not stated	in Norwegian	unsure of other non-mechanical pathology	NO despite not sighting original question over definition of LBP or NSLBP or sciatica or radiating pain, likely group heterogeneity

Weber et al 1984

DEFINITION OF LBP + PAIN REFERRAL	94 patients prolapsed lumbar disc, sciatica	94 patients, All had sciatica, radiating pain, neurological symptoms and signs	94 patients, All had sciatica, radiating pain, neurological symptoms and signs	215 patients, all had herniated lumbar intervertebral discs, sciatica and radiating pain and neurological symptoms and signs, hospitalised on bed rest. Actually 4 trials within the one paper	No definition of prolapsed/herniated lumbar disc or sciatica, or neurological deficit stated in vd Heijden r/v, but in other sources all have neurological signs. Definition of sciatica and radiating pain and clinical diagnosis of neurological symptoms and signs not stated. However try to suggest homogeneity of radiculopathy. Dependent on diagnostic accuracy and terminology in 1984, all on bed rest	
TYPE OF LBP (acute, subacute, chronic, recurrent)	not stated	duration unknown	duration unknown	The age of the patients and duration of the illness were similar in the treated and control groups	definition of duration not stated in article, so likely combination of acute, sub-acute and chronic	

NEUROLOGIC DEFICIT AND OTHER	not stated	All incl neurological symptoms, a lesion of the L5 or S1 root and positive radiculogram.	All incl neurological symptoms, a lesion of the L5 or S1 root and positive radiculogram.	All incl neurological symptoms corresponding to a lesion of the L5 or S1 root and positive radiculogram.	From VD Heijden r/v unsure if including neurologic deficit, from other sources clear that all patients had it. As all needed to have neurological signs suggestive of radiculopathy but dependent on clinical diagnosis and accuracy of radiculogram at time. Later 3 patients excluded, 1 for extradural tumour, 1 as no disc prolapse found on operation, 1 as spontaneous recovery	
OTHER CONDITIONS INCL/EXCL	Not stated	Exclusion: spondylolisthesis or previous operations of the spine, root entrapment caused mainly by hypertrophic facet joints or a narrow bony canal in the last three studies.	Exclusion criteria: spondylolisthesis or previous operations of the spine, root entrapment caused mainly by hypertrophic facet joints or a narrow bony canal in the last 3 studies.	Exclusion: spondylolisthesis or previous operations of the spine, root entrapment caused mainly by hypertrophic facet joints or a narrow bony canal in the last three studies.	unsure of other non-mechanical pathology, infection, inflammatory	NO question over definition of sciatica, radiating pain and prolapsed disc and investigation & relevance of this, unsure of duration of pain, group heterogeneity. However a good attempt to have group homogeneity with all having radiating pain and neurological signs
Ljunggren et al 1984						
DEFINITION OF LBP + PAIN REFERRAL	52 patients prolapsed lumbar disc, sciatica	52 hospitalized participants with lumbago-sciatica and prolapsed lumbar intervertebral discs, admitted to neurological department, and considered for operation.	52 hospitalized participants with lumbago-sciatica and prolapsed lumbar intervertebral discs, admitted to neurological department, and considered for operation.	52 hospitalized participants with lumbago-sciatica and prolapsed lumbar intervertebral discs, admitted to neurological department, and considered for operation.	unsure of definition of prolapsed intervertebral disc or sciatica dependent on accuracy and relevance of clinical examination at this time, some patients only had pain for 9 weeks and arguably soon to already consider surgery	
TYPE OF LBP (acute, subacute, chronic, recurrent)	not stated	not stated	not stated	chronic 18-190 weeks (auto traction), 9-46 (manual traction)	Pain duration not stated in r/vs but from article, although auto-traction population is strictly chronic, manual traction group mixed sub-acute and chronic; also large difference in baseline characteristics of pain duration between groups.	

NEUROLOGIC DEFICIT AND OTHER	included	Incl criteria included: radicular signs L5 and/or S1 nerve root; symptoms aggravated or unchanged in last 2-4 weeks	Inclusion criteria: radicular signs L5 or S1 (or both) nerve root; symptoms aggravated or unchanged in last 2-4 weeks	According to authors from a patho-anatomical point of view the patients may be considered a homogeneous group. radicular signs and symptoms L5 and/or S1 nerve root, radiculographical findings in conformity with the clinical ones, indicating disc prolapse, positive Lasègue's sign, symptoms aggravated or unchanged during the last 2-4 weeks, no previous lumbar spine surgery. all on bed rest	All hospitalised patients with prolapsed intervertebral disc awaiting surgery. Only question is over known uncertainty over clinical diagnosis, for example 1 patient excluded as later surgery revealed a ganglion and another excluded as no disc prolapse was found during surgery, but fair attempt to be a homogenous group, albeit restricted to those awaiting surgery, than some other studies.	
OTHER CONDITIONS INCL/EXCL	not stated	not stated	not stated	not stated	unsure of other non-mechanical pathology	No still likely to be a group heterogeneity, questions over clinical diagnosis, investigation & relevance of prolapsed intervertebral disc and use of sciatica, mixed pain duration, unsure of other non-mechanical pathology, bed rest
Pal et al 1986						
DEFINITION OF LBP + PAIN REFERRAL	39 patients LBP, sciatica	39 patients admitted to hospital for back pain and sciatica.	39 participants were admitted to hospital for back pain and sciatica	39 patients admitted to hospital for back pain and sciatica. also on bed rest	definition sciatica not stated in r/vs or article	
TYPE OF LBP (acute, subacute, chronic, recurrent)	acute	average duration of pain intervention = 42 days Control = 56 days	Mean duration of pain: T) 42 days, C) 56 days.	Average duration of pain intervention is 42 days. Control is 56 days	Definition not stated in VD Heijden r/v, and only average duration stated in article. Still seems patients at best could only be considered sub-acute, thereby time period still allowing for spontaneous recovery	
NEUROLOGIC DEFICIT AND OTHER	not stated	incl neurological deficits	incl neurological deficits	incl neurological deficits	not stated in VD Heijden r/v, but from other sources incl neurological deficits	

OTHER CONDITIONS INCL/EXCL	not stated	not stated	not stated	not stated	unsure of other non-mechanical pathology	NO questions over definition of LBP and sciatica, duration of pain, likely group heterogeneity, unsure of other non-mechanical pathology
Matthews et al 1987						
DEFINITION OF LBP + PAIN REFERRAL	143 patients LBP	143 patients with low backache or pain, referred from a rheumatology clinic or general practitioner were included.	143 patients with low backache or pain, referred from a rheumatology clinic or general practitioner were included.	143 patients with low back pain and sciatica referred from a rheumatology clinic or general practitioner were included.	This is very likely to be a heterogeneous group of somatic and radicular referred pain, as the criteria was LBP and sciatica, and no definition of sciatic is acknowledged.	
TYPE OF LBP (acute, subacute, chronic, recurrent)	acute	within the past 3 months	within the past 3 months	entry criteria required onset of the most recent feature within 3 months; intervention grp median = 3 weeks (o days to 3 mths), control grp median = 4 weeks (1 day to 13 weeks)	According to VD Heijden r/v it was restricted to an acute group. However later reviews state most recent feature within last 3 months, and the primarily article states control group had symptom duration of up to 13 weeks - so wide variation and acute, sub-acute and chronic pain durations, and question over definition of most recent feature	
NEUROLOGIC DEFICIT AND OTHER	not stated	had local tenderness, asymmetrical restriction of movement, limited SLR and root pain	local tenderness, asymmetrical restriction of movement, limited straight leg raise and root pain	local tenderness, asymmetrical restriction lumbar movements, asymmetrical SLR or +ve femoral nerve stretch, nerve root pain (NB they did not have uniradicular neurological deficit)	Neurologic criteria - not stated in VD Heijden r/v but is in other sources, attempt to identify group homogeneity by incl only those with radicular signs and symptoms, excl radiculopathy. However dependent on clinical diagnosis definition and relevance at time	
OTHER CONDITIONS INCL/EXCL	unsure of what else			Radiographs of the lumbar spine, blood count, erythrocyte sedimentation rate, alkaline phosphatase and routine urine test. Patients with abnormalities or complicating problems were excluded from study	good	NO use of LBP and sciatica, heterogeneous so dependent on clinical diagnosis, also relevance at time (femoral nerve stretch since found to be unreliable), excl radiculopathy, also variation in pain duration, group heterogeneity.

Reust et al

1988

DEFINITION OF LBP + PAIN REFERRAL	LBP, sciatica	60 participants hospitalized for back pain	60 participants hospitalized for back pain	(in Swiss German)	unsure of definition of LBP or sciatica	
TYPE OF LBP (acute, subacute, chronic, recurrent)	not stated	Duration of back pain unknown	Duration of back pain unknown	(in Swiss German)	unsure as to duration of pain	
NEUROLOGIC DEFICIT AND OTHER	not stated	with or without neurological deficits	with or without neurological deficits	(in Swiss German)	neurologic criteria - not stated	
OTHER CONDITIONS INCL/EXCL	not stated	Exclusion criteria: previous traction, fast progressing neurological deficit, behavioural problems, or bone aliments that may have caused the back pain.	Exclusion criteria: previous traction, fast progressing neurological deficit, behavioural problems, or bone aliments that may have caused the back pain	(in Swiss German)	unsure of other non-mechanical pathology	NO despite not sighting original, from SRs question over definition of LBP, sciatica, and also participants with/without neurological deficits, likely group heterogeneity

Konrad et al

1992 not in r/v

DEFINITION OF LBP + PAIN REFERRAL	170 participants from 3 factories in Budapest, with NSLBP localized to the lumbosacral region, with or without radiation to the thigh	170 participants from 3 factories in Budapest, with NSLBP localized to the lumbosacral region, with or without radiation to the thigh	170 participants from 3 factories in Budapest with NSLBP localized to the lumbosacral region, with or without radiation to the thigh	NSLBP and radiation dependent on definition and clinical assessment, patient population only recruited from and so restricted to 3 different factories in Budapest	

TYPE OF LBP (acute, subacute, chronic, recurrent)			at least 1 month, but no longer than three months	Duration of pain at least 1 month, but no longer than 3 months	at least one month, but no longer than three months	Duration mixed acute, sub-acute depending on definition of acute pain as less than 4 weeks or less than 6 weeks?	
NEUROLOGIC DEFICIT AND OTHER			not stated	not stated	not stated	mixed somatic, radicular and radiculopathy	
OTHER CONDITIONS INCL/EXCL			excl pts with pregnancy, back surgery, spondylolisthesis, infections, tumours, fractures, ankylosing spondylitis, osteoporosis, and structural scoliosis	Exclusion criteria: participants with pregnancy, back surgery, spondylolisthesis, infections, tumours, fractures, ankylosing spondylitis, osteoporosis and structural scoliosis.	exclusion of patients from the trial were pregnancy, back surgery, spondylolisthesis, infections, tumours, fractures, ankylosing spondylitis, senile osteoporosis, structural scoliosis.	good	NO, questions over definition of NSLBP and radiation, unsure if neurological deficit are included or not so likely mix of somatic and radicular and radiculopathy, mixed duration of pain - group heterogeneity
Ljunggren et al	1992	not in r/v					
DEFINITION OF LBP + PAIN REFERRAL			50 patients admitted to the Department of Neurology with radiating pain, neurological symptoms	50 participants admitted to the department of neurology	51 (nb 1 drop-out) in-patients with lumbago-sciatica due to a proven herniated intervertebral lumbar disc admitted to the Department of Neurology were originally included in the study. The patients were all considered potential candidates for disc surgery.	Sciatica seemed to indicate radiating pain and neurological symptoms in surgical candidates, however one patient was excluded due to spontaneous improvement following lumbar myelography, leaving 50 patients to be randomised. So question over accuracy of diagnosis and also chance of spontaneous recovery	
TYPE OF LBP (acute, subacute, chronic, recurrent)			The males had a mean duration of symptoms for 4.8mths, and the females for 5.3 mths	males had a mean duration of symptoms for 4.8 months, and the females for 5.3 months	The traction grp had a mean duration of symptoms for 4.8 months, and the isometric for 5.3 months in the table	Discrepancy between r/vs (ref to sex) and article (ref to group). Duration would suggest possibly chronic but is mean only, and they state that random allocation to the treatment groups was performed regardless of age, sex or duration of symptoms	

NEUROLOGIC DEFICIT AND OTHER			Incl radiating pain, neurological symptoms signs confirmed by a myelogram	Incl radiating pain, neurological symptoms and signs confirmed by a myelogram.	Inclusion radiating pain, neurological symptoms and signs corresponding to a lesion of the L5 and/or S1 nerve root confirmed by a lumbar myelogram in conformity with the clinical findings.	All hospitalised patients with prolapsed intervertebral disc awaiting surgery. Only question is over known uncertainty over clinical diagnosis, for example 1 patient spontaneously recovered, but fair attempt to be a homogenous group, albeit restricted to those awaiting surgery, than some other studies.	
OTHER CONDITIONS INCL/EXCL			Patients with previous spinal surgery, spondylolisthesis, and root entrapment were excluded.	Participants with previous spinal surgery, spondylolisthesis and root entrapment were excluded	Patients with previous spinal surgery, spondylolisthesis, root entrapment caused mainly by hypertrophic facet joints or narrow bony canal, cauda equina were excluded.	unsure of other non-mechanical pathology	No still likely to be group heterogeneity, questions over definition of sciatica and clinical diagnosis, investigation & relevance of herniated intervertebral disc, considering spontaneous recovery in 1 patient, only mean duration of pain presented, uncertainty over excl criteria
Letchuman R, Deusinger RH.	1993	not in r/v			can't source		
DEFINITION OF LBP + PAIN REFERRAL			26 subjects referred from physicians. Participants with LBP with/without lower extremity pain	26 subjects referred from physicians. Participants with LBP with/without lower extremity pain	can't source	with or without lower extremity pain so dependent on definition and clinical assessment is likely group heterogeneity	
TYPE OF LBP (acute, subacute, chronic, recurrent)			not stated	not stated	can't source	unsure of pain duration	
NEUROLOGIC DEFICIT AND OTHER			with/without neurological signs	with/without neurological signs	can't source	group heterogeneity - mixed somatic and radicular and radiculopathy	

OTHER CONDITIONS INCL/EXCL			Cough, sneeze or deep breath does not cause severe pain, radiographs, MRI or CT scan of lumbar spine taken within past 6 mths	Cough, sneeze or deep breaths did not cause severe pain, x-rays, MRI or CT scan of lumbar spine taken within past 6 months	can't source	unsure of diagnostic significance in terms of specificity and sensitivity of these clinical findings, unsure of other non-mechanical factors	NO, from r/v alone there are questions over definition of LBP and lower extremity pain, unsure of duration of pain, with or without neurological deficit - group heterogeneity. Clinical significance of diagnostic findings
Sweetman et al	1993	not in r/v					
DEFINITION OF LBP + PAIN REFERRAL			LBP, 400 participants referred from general practice.	400 participants referred from general practice with LBP of sufficient severity to warrant PT	400 participants referred from general practice with LBP of sufficient severity to warrant PT	definition in article, in agreement with IASP, bounded by inferior costal margins above, gluteal folds below, and mid axillary lines laterally	
TYPE OF LBP (acute, subacute, chronic, recurrent)			pain for >1 wk,	pain for >1 wk,	pain for >1 wk, categorised as < 5wks, 5 wks plus, 10 mths plus	mix of acute, sub-acute and chronic group heterogeneity	
NEUROLOGIC DEFICIT AND OTHER			neurological deficit not stated		incl sciatica and cruralgia and neurological deficit	mix of somatic, radicular and radiculopathy - group heterogeneity	

OTHER CONDITIONS INCL/EXCL			Exclusion criteria: serious causes for back pain including fractures, infection and malignancy, pregnancy, inflammatory arthritis, bone diseases, where physician suspected that treatments may precipitate or exacerbate spinal cord or nerve root compromise, when other therapy was specifically indicated, recent steroid injections, intercurrent treatment other than routine oral medication	Exclusion criteria: serious causes for back pain including fractures, infection and malignancy, pregnancy, inflammatory arthritis, bone diseases, where physician suspected that treatments may precipitate or exacerbate spinal cord or nerve root compromise, when other therapy was specifically indicated, recent steroid injections, intercurrent treatment other than routine oral medication	Inclusion: pain caused by low back musculoskeletal problems incl disc disease care taken to specifically excl pain from abdominal viscera. Exclusion criteria: serious causes for back pain including fractures, infection and malignancy, pregnancy, inflammatory arthritis, bone diseases, where physician suspected that treatments may precipitate or exacerbate spinal cord or nerve root compromise, metal in the area (SWD) when other therapy was specifically indicated, recent steroid injections, intercurrent treatment other than routine oral medication	Authors identified within the original article that previous therapeutic trials seemed to indicate little evidence as they were inadequate in selecting patient populations where little or no effort was made to distinguish between the different types of LBP. When they sub-classified LBP into 7 patterns of LBP, dependent upon recorded signs and symptoms and presumed diagnosis, they found significant effects of various forms of treatment, 'hidden' within the original broad sample.	NO, although they are the only study to have clearly identified the need for greater care in sub-classifying types of LBP into diagnoses, they seem to still have a group heterogeneity according to pain duration. Trial good in that it tries to sub-group based on signs/symptoms and outcomes and finds differences hidden within these sub-groups
Tesio & Merlo	1993	not in r/v					
DEFINITION OF LBP + PAIN REFERRAL			44 patients referred from an outpatient service, with or without radiation, herniation. protrusion	44 participants referred from an outpatient service with LBP with or without radiation, herniation or protrusion,	44 LBP patients referred from an outpatient service, with or without radiation, herniation. Protrusion on CT or MRI	from r/vs unsure of diagnosis of herniation, protrusion, from original article had CT or MRI but questions over clinical significance and relevance of this	
TYPE OF LBP (acute, subacute, chronic, recurrent)			duration > 1mth	duration > 1mth	duration > 1mth	mix of acute, sub-acute and chronic pain - group heterogeneity	

NEUROLOGIC DEFICIT AND OTHER			neurological deficit not stated		incl neurological deficit	mix of somatic, radicular and radiculopathy group heterogeneity	
OTHER CONDITIONS INCL/EXCL			Inclusion criteria, failure of one or more conservative approaches. Exclusion criteria: neoplastic, inflammatory or metabolic causes of back pain, or indication for urgent surgery	Inclusion criteria failure of 1 or more conservative approaches. Exclusion criteria: neoplastic, inflammatory or metabolic causes of back pain, or indication for urgent surgery	Inclusion criteria: failure of one or more conservative approaches. Exclusion criteria: neoplastic, inflammatory or metabolic causes of back pain, or indication for urgent surgery	good	NO, definition of LBP, herniation, protrusion dependent on clinical diagnosis and significance of CT or MRI changes, mixed duration of pain, likely group heterogeneity
Beurskens et al	1995	n/a after r/v					
DEFINITION OF LBP + PAIN REFERRAL			151 participants with chronic nonspecific LBP, recruited by physiotherapists and general practitioners in the Netherlands	151 participants with chronic nonspecific LBP, recruited by physiotherapists and general practitioners in the Netherlands	151 participants with chronic NSLBP, with or without radiation, recruited by physiotherapists and general practitioners in the Netherlands. The traction group contained a few more patients with pain radiating below the knee	Termed NSLBP but diagnostic criteria not stated, NSLBP +/- radiation, no definition of radiation, group heterogeneity - mixed somatic and radicular and radiculopathy possible.	
TYPE OF LBP (acute, subacute, chronic, recurrent)			with at least 6 wks of subacute and chronic	with at least 6 wks of subacute and chronic	suffered for at least six weeks	the duration of NSLBP was a mixture of acute, subacute, chronic, group heterogeneity	
NEUROLOGIC DEFICIT AND OTHER			not stated	not stated	not stated	neurologic criteria - not stated	
OTHER CONDITIONS INCL/EXCL			never had any form of lumbar traction treatment	never had any form of lumbar traction treatment	Those with evidence for underlying disease or anatomical abnormalities (such as rheumatic diseases, previous surgery or fracture, herniated disc) were excluded. Patients were also excluded if they were receiving treatment (other	They state in their conclusion that the ambiguity in diagnosis of LBP is enormous and they made no distinction between patients with discus, facet joint or muscular problems. Their diagnostic criteria to differentiate radicular from somatic pain is not specified. They specifically excluded herniated disc - arguably what traction is best for? how	NO definition of NSLBP or radiating pain, mixed duration of pain, with or without radiation, unsure of neurological deficit, basis for excluding herniated discs group heterogeneity

					than medication) or had had lumbar traction	they clinically attempted to differentiate symptomatic from asymptomatic discs not specified	
van der Heijden et al	1995a	n/a after r/v					
DEFINITION OF LBP + PAIN REFERRAL			25 participants from hospital setting, with or without radiation	25 participants from hospital setting, with or without radiation	Pilot trial, 25 participants persistent NSLBP with/without sciatica or radiating pain	Actually a pilot trial; their definition of NSLBP is there was no evidence for underlying systemic disease or anatomic abnormalities. Unsure of definition of sciatica or radiating pain, but nonsensical to have NSLBP and sciatica	
TYPE OF LBP (acute, subacute, chronic, recurrent)			duration T)18% <6 mo, 82% >24 mo; C) 17% <6 mo, 83% >24 mo	duration: T) 18% < 6 months, 82% > 24 months; C) 17% < 6 months, 83% > 24 months	Duration > 3 mths. T)18% <6 mths, 82% >24 mths; C) 17% <6 mths, 83% >24 mths	duration consistent with chronic pain	
NEUROLOGIC DEFICIT AND OTHER			neurological deficit not stated	neurological deficit not stated	not explicitly stated	mix of somatic, radicular and radiculopathy - group heterogeneity	
OTHER CONDITIONS INCL/EXCL			not stated	not stated	excl systemic disease, anatomic abnormalities, previous traction experience, inguinal hernia, pregnancy, cardiovascular, respiratory disorder, hemiplegia, malignancy, previous prolapse of nucleus pulposus, pain, numbness on cough/sneeze, spondylolysis, spondylolisthesis, hemilumbarisation hemisacralisation, congenital hip dysplasia, Bechterew syndrome, Scheuermann's Disease, Ehlers Danlos syndrome, osteoporosis, previous related fracture, infection, leg length difference	definition not in r/v but is in article	NO, pilot trial, definition of NSLBP, sciatica/radiating pain, group heterogeneity, possible psycho-social effects of chronic pain

Werners et al 1999	n/a after r/v			can't source		
DEFINITION OF LBP + PAIN REFERRAL		147 LBP patients low back pain severe enough to warrant seeking the help of an orthopaedic general practitioner. Incl patients with sciatica	147 LBP patients low back pain severe enough to warrant seeking the help of an orthopaedic general practitioner. Incl patients with sciatica	can't source	unsure of definition of sciatica, likely to include patients with somatic, radicular and dependent on clinical examination radiculopathy	
TYPE OF LBP (acute, subacute, chronic, recurrent)		not stated	not stated	can't source	not sure of duration	
NEUROLOGIC DEFICIT AND OTHER		No patient had objective neurology	No patient had objective neurology	can't source	mix of somatic and radicular referred pain - group heterogeneity	
OTHER CONDITIONS INCL/EXCL		Exclusion: age <20, >60 yrs, previous surgery, significant medical condition, and spinal disorder demonstrable on plain radiograph	Exclusion: age <20, >60 yrs, previous surgery, significant medical condition, and spinal disorder demonstrable on plain radiograph	can't source	unsure of other non-mechanical pathology	NO, despite not sighting original, questions over definition of sciatica, unsure of pain duration, group heterogeneity
Güvenol et al 2000	n/a after r/v					
DEFINITION OF LBP + PAIN REFERRAL		LBP + lower extremity pain. lumbar disc herniation diagnosed by CT.	29 participants with LBP and lower extremity pain and lumbar disc herniation diagnosed by CT. Disc pathology at 2 levels was present in 10 subjects, 5	LBP + sciatica due to lumbar disc herniation diagnosed by CT. All had disc pathology at 1 or both levels of L4-L5 (6 in each group), L5-S1 (4 inv & 3 conventional), or both levels (5 in each grp)	LBP +/- sciatic pain, no definition of sciatic pain, a very heterogeneous group - mixed somatic and radicular and radiculopathy possible. Accuracy and relevance of CT changes?	

				from each treatment group			
TYPE OF LBP (acute, subacute, chronic, recurrent)			not less than 1 month	not less than 1 month, Mean duration of pain: T1) 28.5 ± 26.5 months, T2) 39.3 ± 39.2 months	not less than 1 month, Mean duration of pain: inv) 28.5 ± 26.5 months, horiz) 39.3 ± 39.2 months	duration mixed sub-acute and chronic	
NEUROLOGIC DEFICIT AND OTHER			not stated	not stated	neurological deficits included	includes radiculopathy which by definition should be in separate population category to the systematic reviews who wished to look at NSLBP	
OTHER CONDITIONS INCL/EXCL			None had history of spinal surgery. Pain not due to disease such as malignant, inflammatory, infectious, metabolic, congenital or developmental disorders	None had history of spinal surgery. Pain not due to disease such as malignant, inflammatory, infectious, metabolic, congenital or developmental disorders	Excluded those with history of spinal surgery, cerebrovascular accident, thyroid disorder, hiatus hernia, glaucoma, detachment of retina, hypertension, cardiac disorders, chronic obstructive & restrictive lung disorders, osteoporosis, excessive joint laxity. in addition ESR, FBC, routine biochem tests, urine analysis, CRP, group agglutination tests and lumbosacral radiograms were taken to rule out malignancy, inflammatory, infectious, metabolic, congenital, and developmental disorders of the spine	good	NO, mix of somatic and radicular and radiculopathy, mixed duration of pain, group heterogeneity. Accuracy of CT diagnosis. Difference in lower leg positon extended vs flexed. Bed rest.
Sherry et al	2001	n/a after r/v					
DEFINITION OF LBP + PAIN REFERRAL			44 patients with associated leg pain and confirmed disc protrusion or	44 participants recruited through advertisements in local newspapers with associated leg pain and	44 patients with chronic low back pain and associated leg pain, and a confirmed disc protrusion or herniation on CT Scan or MRI	Good exclusive category, however question clinical diagnosis and investigations and relevance of disc protrusion or herniation on CT / MRI. But may also have somatic and radicular symptoms	

	herniation on CT scan or MRI.	confirmed disc protrusion or herniation on CT scan or MRI			
TYPE OF LBP (acute, subacute, chronic, recurrent)	pain of >3 months duration	pain of > 3 months' duration, chronicity (mean/range years) T) 8.4/0.25-30, C) 6.2/0.5-28	greater than 3 months in duration	Good that chronic but very wide range 0.25 years to 30 years. Need to consider any psychosomatic influences here	
NEUROLOGIC DEFICIT AND OTHER	not stated if neurological deficits incl or excl	not stated if neurological deficits incl or excl	not stated if neurological deficits incl or excl	Mix of somatic, radicular and radiculopathy. not stated if had neurological deficit group heterogeneity	
OTHER CONDITIONS INCL/EXCL	not stated	not stated	candidates must live within 45 minutes of the clinic location; Exclusion criteria were: osseous stenosis; unstable spine (bilateral pars defect or Spondylolisthesis of Grade II or greater); spinal surgical implants; shoulder problems which prevent compliance with VAX-D therapy; spinal pain due to tumor, infection, or inflammatory disease; pregnancy; and previous VAX-D therapy	good	NO question over definition of LBP and disc protrusion and clinical diagnosis and relevance of changes on CT or MRI, uncertainty of incl/excl of neurological symptoms, although duration all chronic mean duration very long - group heterogeneity

Borman et al	2003	n/a after r/v				
DEFINITION OF LBP + PAIN REFERRAL		NSLBP with/without radiation	42 participants NSLBP with/without radiation, outpatients in physical medicine and rehabilitation department of large hospital. All patients received instruction on correct posture, ergonomic principles in ADLs, associated with descriptions of recommended therapeutic exercises. Pain medications were not allowed during the treatment period	42 participants NSLBP with/without radiation, outpatients in physical medicine and rehabilitation department of large hospital.	No definition of radiating pain, group heterogeneity, as may have depending on clinical examination included radicular pain with somatic pain	
TYPE OF LBP (acute, subacute, chronic, recurrent)		persistent > 6 mths and or recurring	persistent > 6 months or recurring , or both	At least 6 weeks stated in abstract, but pain for longer than 6 months, and/or recurrent in methods	Uncertainty of the duration of LBP studied. According to the abstract 'at least 6 weeks' under materials & methods 'pain longer than 6 mths'	
NEUROLOGIC DEFICIT AND OTHER		Excluded those with neurological deficits	Excluded those with neurological deficits.	excluded those with neurological defects	leaves mixed somatic and radicular so heterogeneous group	
OTHER CONDITIONS INCL/EXCL		not stated	not stated	Patients with inflammatory, infectious, malignant, or metabolic disease of the spine, pregnancy, osteoporosis, and those with spinal operations, and severe orthopaedic, cardiovascular, or metabolic disorders excluded	Good exclusion category ruled out non-mechanical conditions and neurological deficits/radiculopathy. Clinical diagnostic criteria not stated	NO NSLBP still with or without radiating pain, may include somatic and radicular, diagnostic criteria not stated, uncertainty of pain duration and recurrent, group heterogeneity

Ozturk et al	2006	n/a after r/v	not in r/v				
DEFINITION OF LBP + PAIN REFERRAL				46 participants (24 in the traction group, 22 in the control group) hospitalized with the diagnosis of lumbar disc herniation. Participants had LBP or sciatica	46 hospitalised patients all with lumbar disc herniation, traction group (24 patients), and the control group (22 patients). Participants had LBP or sciatica due to lumbar disc herniation	Patients had LBP or sciatica due to lumbar disc herniation, definition of lumbar disc herniation was that it was verified by CT scan. Question here is uncertainty over clinical significance of CT and with/without back pain or sciatica as depends on these definitions and so could be mix of somatic, radicular and radiculopathy	
TYPE OF LBP (acute, subacute, chronic, recurrent)				duration < 6 months	duration < 6 months	mix of acute, sub-acute and chronic - a heterogeneous group	
NEUROLOGIC DEFICIT AND OTHER				not stated	included: L3-S1 radiculopathy; consistency in the pattern of pain complaint, neurological, and radiological findings; no history of previous physical therapy in the past;	good but dependent on clinical examination investigations and relevance of CT scan	
OTHER CONDITIONS INCL/EXCL				Excl LBP due to neoplastic, inflammatory, infectious or metabolic causes were excluded.	Exclusion LBP due to neoplastic, inflammatory, infectious, or metabolic causes; indication of urgent surgery (Cauda equina syndrome or progressive motor deficit); spinal stenosis; pregnancy, postpartum period, and postoperative 3 months; previous vertebral surgery; gross structural abnormalities (e.g. spondylolisthesis); being unable to tolerate physical therapy due to cardiovascular reasons; presence of significant degenerative changes in lumbosacral vertebrae on X-rays;	good	No, questions over definition of LBP, sciatica, and clinical diagnosis, significance and relevance of CT changes, mix of pain durations - group heterogeneity

Gudavalli et al	2006	n/a after r/v	not in r/v			
DEFINITION OF LBP + PAIN REFERRAL				235 participants (123 in the flexion-distraction group, 112 in the active trunk exercise programme) all with LBP, some with sciatica	235 participants (123 in the flexion-distraction group, 112 in the active trunk exercise programme) all with LBP some subjects had symptoms below the knee.	also performed subgroup analysis and division was based on recurrent versus chronic pain, and pain severity at study onset and evidence of radiculopathy (yes/no) was included
TYPE OF LBP (acute, subacute, chronic, recurrent)				duration of at least 3 months	> 3 months, differences in number of recurrences some first episode, up to 4 or more across groups	chronic pain but actually recurrent, question over time of each episode of LBP, ?acute, subacute but subgroup analysis performed
NEUROLOGIC DEFICIT AND OTHER				not stated	some patients had radiculopathy	mix of somatic, radicular and radiculopathy, but subgroup analysis performed

		included; primary complaint of LBP from L1 to SI joint inclusive, palpatory tenderness over one or more lumbar Zygapophyseal joints, forego narcotic use during treatment phase, forego NSAID use and/or muscle relaxant use for 24 h prior to baseline or outcome measure assessment excluded; evidence of central nervous system disease, severe osteoporosis, lumbar fracture, systemic disease potentially affecting the musculoskeletal system, failed fusion surgery with unstable components, inability to undergo physical therapy or flexion–distraction therapy for any other reason, psychiatric illnesses or lack of cognitive abilities that would potentially modify true responses on primary outcomes, current and known substance abuse, not fluent and/or illiterate in the English language, morbidly obese (40% over ideal body weight), pregnant, currently receiving care for LBP from any other provider, treated by chiropractor or physical therapist in the past 6 months, New York Heart Association Classification of grade III or IV (marked limitation or inability to carry on any physical activity without discomfort)		
OTHER CONDITIONS INCL/EXCL	not stated		Patients also received $75.00 compensation at the completion of active care and an additional $75.00 upon completion of the 1-year follow-up.	POSSIBLY, although pain duration gives chance of spontaneous reduction in LBP, also set amongst differences in the number of recurrences,- some group heterogeneity, also participants paid

Harte et al	2007	n/a after r/v	n/a after r/v			
DEFINITION OF LBP + PAIN REFERRAL				30 participants (16 in the traction group and 14 in the manual therapy group) with acute or subacute LBP accompanied with radiculopathy	30 LBP patients (16 in the traction group and 14 in the manual therapy group) with acute/subacute LBP all with 'nerve root' radiculopathy involvement.	Good categorisation of LBP all with Radiculopathy or 'nerve root' was identified by the presence of: dermatomal pain distribution radiating below the knee (one or both limbs), of a sharp/severe quality, often worse in the leg than back (leg pain threshold of 3/10 VAS). With at least one of the following signs and symptoms: pins and needles in the distal dermatome (where this was present patients with leg pain were accepted even if not extending below the knee), Increased pain in the leg on coughing, sneezing or straining, Neurological deficit i.e. decreased muscle strength/sensory loss/reflex loss. positive straight leg raise test i.e. limb symptoms reproduced on SLR test below 90 degrees
TYPE OF LBP (acute, subacute, chronic, recurrent)				Duration of complaints: T) 6.5 wk, C) 6 wk	Acute/subacute LBP, defined as LBP of less than 12 weeks duration, or a recurrent episode with a pain free period of at least three months prior to the onset of this episode. Also after 4 weeks of onset of leg pain, The mean duration of the current episode of LBP was 7 weeks (SD 2.7 weeks; range 4 – 12 weeks).	mix of acute and sub-acute, open to spontaneous resolution of symptoms
NEUROLOGIC DEFICIT AND OTHER				incl of radiculopathy	all had radiculopathy	seems reasonable considering the clinical diagnosis but also dependent on whether there may be coexisting pathologies

OTHER CONDITIONS INCL/EXCL	Exclusion in case of previous spinal surgery, co-existing conditions interventions within the last 3 months	Excluded if patients were not literate with English as their first language. Previous spinal surgery; therapeutic or medical intervention within the last three months (eg epidural injection, facet joint block, physiotherapy etc); Co-existing conditions (ankylosing spondylitis, rheumatoid arthritis, spinal stenosis (diagnosed), spondylolisthesis, recent spinal fracture, spinal tumor or a patient where secondary metastases was suspected); Concomitant severe medical problem preventing participation in the trial (cardiac condition, respiratory conditions, neurological disorder or organ disease); Long term oral steroid intake (due to the risk of osteoporosis); Current anti-coagulant therapy or blood clotting disorders, Pregnancy; History of major psychiatric illness; Roland Morris disability questionnaire score of below 4, and/or a VAS score of less than 3 on a 10 point scale for leg pain (to avoid floor effects).	Good, extensive and well justified	NO, although aware of previous issues with group heterogeneity and looking at radiculopathy in isolation, but may have included those with co-existing pathologies, and mixed duration of pain from acute to sub-acute, and under 12 weeks not allowing for spontaneous resolution in symptoms

Fritz et al	2007	n/a after r/v	n/a after r/v				
DEFINITION OF LBP + PAIN REFERRAL				64 participants (33 in the extension group, 31 in the traction plus extension group) with pain or numbness (or both) extending distal to the buttocks. All had LBP, 76.5% sciatica	64 subjects with low back and leg pain and signs of nerve root compression and/or radiculopathy, recruited from 4 outpatient physical therapy clinics, Followed McKenzie rationale regarding promoting exercises which caused centralisation and avoiding those leading to peripheralisation of symptoms.	good attempt for a population homogeneity in terms of presentation, also sub-grouping analysis performed. And mechanical traction was provided using an adjustable table allowing for modifications of a subject's position in flexion/extension, rotation or side-bending according to centralisation position.	
TYPE OF LBP (acute, subacute, chronic, recurrent)				Duration of complaints: 47.5 days	Median symptom duration of 47.5 days (range 2–761 days).	range indicating a mix of acute, sub-acute and chronic - group heterogeneity	
NEUROLOGIC DEFICIT AND OTHER				nerve root compression in the past 24 hours	Symptoms of pain and/or numbness extending distal to the buttock in the past 24 hours. signs of nerve root compression positive straight leg raise - reproduction of symptoms at 45°, or reflex, sensory, or muscle strength deficit	wide duration of pain, and the need for radiculopathy type signs within 24hrs,	
OTHER CONDITIONS INCL/EXCL				Exclusion criteria included non-mechanical LBP and previous spinal fusion or spine surgery in the past 6 months.	excluded based on any of the following; medical red flags indicative of non-mechanical LBP, previous spinal fusion or spine surgery in the past 6 months (some had had surgery prior), current pregnancy, or the absence of any symptoms while sitting. Took into account work history	mixed group as some, but not all, had previous spinal surgery albeit > 6 mths prior	NO, despite their clear identification for the need for better research into the efficacy of traction, and that sub-groups may respond differently, and pragmatic allowance for traction position – there remains question of group heterogeneity in terms of wide pain duration and spontaneous resolution, and that some had prior spinal surgery

Unlu et al	2008	n/a after r/v	n/a after r/v				
DEFINITION OF LBP + PAIN REFERRAL				60 participants (20 in the traction group, 20 in the ultrasound group and 20 in the low power laser group) with acute LBP and leg pain that was definitely being caused by lumbar disc herniation.. All participants had complaints of sciatica	60 patients who presented with acute low back and leg pain that was definitely diagnosed as being caused by lumbar disc herniation, all patients had sciatica or femoral neuralgia symptoms	Despite statement is difficult to be certain that patients had a lumbar disc herniation which was solely responsible for their pain. Definition and diagnosis of sciatica and femoral neuralgia. Use of sciatica, mix of somatic, radicular and radiculopathy possible	
TYPE OF LBP (acute, subacute, chronic, recurrent)				mean symptom duration: T) 47.9 days, C1) 36.8 days, C2) 49 days	less than 3 month's duration	mix of acute and sub-acute	
NEUROLOGIC DEFICIT AND OTHER				not stated	neurological deficit included	mix of somatic, radicular and radiculopathy possible and co-existing pathologies	
OTHER CONDITIONS INCL/EXCL				not stated	incl: herniation of one or more lumbar discs, verified by MRI, and consistency in the pattern of pain complaint, neurologic, and radiologic findings. excl: pregnant, no previous spinal surgery, patients with abnormal laboratory findings, systemic and psychiatric illnesses, lumbar spinal stenosis or spondylolisthesis were excluded from the study by radiographs.	good, but dependent on clinical examination	NO although good attempt to look at group homogeneity, still questions over clinical significance and relevance of MRI changes, definitions of sciatica and femoral neuralgia, mix of acute and sub-acute likely group heterogeneity, chance of spontaneous resolution

Schimmel et al	2009	n/a after r/v	n/a after r/v				
DEFINITION OF LBP + PAIN REFERRAL				60 participants (31 to the traction group, 29 to the sham group)	60 subjects with chronic LBP were recruited, 31 randomized to the IDD and 29 to the SHAM protocol.	since chronic LBP was associated with cognitive and emotional factors, a psychological examination was also completed at baseline	
TYPE OF LBP (acute, subacute, chronic, recurrent)				All participants had LBP for > 3 months	all subjects known to have had lumbar back pain for at least 1 year , episode LBP for more than 3 months	so seems chronic definition but also includes recurrent episodes of LBP	
NEUROLOGIC DEFICIT AND OTHER				not stated	not stated	not stated if they checked for radiculopathy signs and symptoms	
OTHER CONDITIONS INCL/EXCL				Exclusion criteria were radicular leg pain, previous surgical treatment	incl bulging disc, symptomatic lumbar degenerative disc disease; place of residence within 25 km from the hospital, All patients underwent one or more non-surgical treatment modalities before starting with the investigated treatment Exclusion criteria were previous surgical treatment with dynamic stabilization, fusion or disc replacement; radicular pain, malignancy; pregnancy; osteoporosis.	Excluding radicular pain will depend on definition and accuracy of clinical differential diagnosis, so may include somatic, radicular and radiculopathy as not stated. The subjects use the VAS scale to rate their leg pain so this must be assumed to be somatic	NO, although they identified the psychosocial factors associated with chronic LBP it is not clear that they treated this clinically; duration of LBP chronic and recurrent, not sure of clinical assessment of radicular and radiculopathy - group heterogeneity

Simmerman et al	2011	n/a after r/v	n/a after r/v			
DEFINITION OF LBP + PAIN REFERRAL				61 participants randomly allocated to 2 treatment groups (31 in the land-based supine flexion first group, 30 to the aquatic vertical traction first group). All participants had LBP and sciatica	61 participants with LBP and/or numbness that extended distal to the buttock in the past 24 hours, pain level 7/10 on the Numerical Rating Scale, signs of nerve root compression, randomly allocated to 2 treatment groups, cross-over design (31 in the land-based supine flexion first group, 30 to the aquatic vertical traction first group). All participants had LBP and sciatica	Mix of somatic, radicular and radiculopathy, but also note crossover design
TYPE OF LBP (acute, subacute, chronic, recurrent)				Mean duration of pain complaints: T)1.7 years, C)8.9 years	Mean duration of pain complaints: aquatic traction first 1.7 years, land based traction first 8.9 years	mean duration of pain ranges from 1.7 yrs to 8.9 yrs between the 2 groups which may affect response to initial randomised group,
NEUROLOGIC DEFICIT AND OTHER				not stated	incl neurological deficit	Potential for mix of somatic, radicular and radiculopathy and mixed pathology, but with being a cross-over design this is mitigated to some extent.

OTHER CONDITIONS INCL/EXCL	excl vertebral fractures, neurological disorders	incl: which consisted of any of the following: intensification or reproduction of more distal symptoms with extension testing of the lumbar spine in a standing position, positive SLR raise (reproduction of more peripheral symptoms), reflex changes of the Achilles or patella tendons, sensory loss in the symptomatic lower extremity, or symptomatic lower extremity muscle strength deficit. If bilateral symptoms, the most symptomatic side only was included in the study, excl: unable to walk for a minimum of 15 consecutive minutes, sit for a minimum of 5 minutes, or lie supine for a minimum of 15 minutes; fear of water or unwillingness to enter into a deep pool; allergy to chlorine; neurologic disorders that include multiple sclerosis, spinal cord injury, or spinal tumors; incontinence; spinal fusion; inability to elevate either shoulder above 90°, pregnancy; vertebral fractures; pain level reported above 7/10 or at 0/10 on a numerical rating scale (NRS)	good	NO, large LBP population incl term sciatica, potential for mixed pathology, variation and mixed duration of pain affecting similarity of prognosis at baseline, also psycho-social effects probable - group heterogeneity

Trials undertaken subsequent to the reviews of VD Heijden et al (1995), Clarke et el (2007) and Wegner et al (2013)

							HAS THE HOMEOGENEITY OF THE STUDY POPULATION IMPROVED?
Prasad et al	2012	n/a after r/v	n/a after r/v	n/a after r/v			
DEFINITION OF LBP + PAIN REFERRAL					24 patients (13 patients backswing inversion traction, 11 control) with a single level unilateral lumbar disc protrusion causing the appropriate nerve root impingement on MRI. All patients on a waiting list for microdiscectomy	Don't actually state in article the clinical symptoms or diagnosis are for the patients in the study. Use of MRI with usual doubt over clinical significance and relevance and clinical diagnosis	
TYPE OF LBP (acute, subacute, chronic, recurrent)					within 6 months of the first episode of symptoms	don't state in article the range of the duration of pain, so possible that have acute, sub-acute and chronic - group heterogeneity	
NEUROLOGIC DEFICIT AND OTHER					incl as long as not increasing	somatic, radicular and radiculopathy possible - group heterogeneity	
OTHER CONDITIONS INCL/EXCL					excl any red flag features, increasing neurological deficits, significant cardio-respiratory disorder, pregnancy, weight more than 20% of ideal norms for height and age or more than 140 kg. Magnetic resonance imaging (MRI) evidence of a large sequestrated disc fragment	unsure of other non-mechanical factors	NO, despite the seemingly narrow population still questions over clinical diagnosis and definitions, mixed pain duration - group heterogeneity
Diab and Mustafa	2012, 2013	n/a after r/v	n/a after r/v	n/a after r/v			
DEFINITION OF LBP + PAIN REFERRAL					Chronic Mechanical LBP, conveniently selected from an institution's outpatient	No definition of mechanical LBP or specific diagnostic criteria to differentiate	

					clinic, traction group (n = 40), control group (n = 40)	SIJ of hip pain for example. Small population source. Not randomised	
TYPE OF LBP (acute, subacute, chronic, recurrent)					with symptoms longer than 3 months to avoid the acute stage of inflammation	chronic pain, no indication of mean or median values between groups. No indication if they performed any psycho-somatic testing. Variable influence of psychosocial factors.	
NEUROLOGIC DEFICIT AND OTHER					not stated specifically	critically there is no indication from the article if they included/or excluded radiculopathy, or radicular referred pain - mixed population also including somatic and visceral referral possible	
OTHER CONDITIONS INCL/EXCL					Exclusion criteria included spinal canal stenosis, rheumatoid arthritis, osteoporosis, inability to tolerate the lumbar extension position, scoliotic deformity and any lower extremity deformity that may interfere with global alignment	no in-depth inclusion criteria, dependent on their definition of mechanical LBP and diagnostic criteria	NO, there are still questions over definition and clinical diagnosis of mechanical LBP, use and relevance of investigations, and uncertainty of classification of referred leg pain - group heterogeneity. Uncertainty in pain duration. Also methodological differences in randomisation between 2012 and 2013 versions – more doubt.
Moustafa and Diab	2012	n/a after r/v	n/a after r/v	n/a after r/v	vertical load applied by a posterior padded strap between the upper torso and lower pelvis, while the upper torso and femur are stabilized by other straps chronic unilateral lumbosacral radiculopathy associated with L5–S1 32 patients were allocated to each group. Control group (n = 32) received hot packs and interferential therapy, whereas the traction group (n = 32) received lumbar extension traction in addition to hot packs and interferential therapy.	3 point bending lumbar extension traction (Vertical traction to lumbar lordosis in horizontal position)	
DEFINITION OF LBP + PAIN REFERRAL						no explanation of clinical diagnosis of unilateral lumbosacral radiculopathy, or specific clinical diagnostic criteria to differentiate SIJ pain or hip pain for example.	

TYPE OF LBP (acute, subacute, chronic, recurrent)	duration of symptoms more than three months, to avoid acute stage of inflammation	Uncertainty over extent of chronic pain duration, mean or median in each group, variety of psychosocial contributions	
NEUROLOGIC DEFICIT AND OTHER	Needed to have chronic unilateral lumbosacral radiculopathy associated with L5–S1 lumbar disc prolapse. They all had side-to side H-reflex latency differences of more than 1 ms Inclusion, absolute rotatory angle L1–L5 less than 39°. MRI detected disc lesions of the S1 nerve root. All patients had unilateral leg pain with mild to moderate disability according to the Oswestry Disability Index (up to 40%). Exclusion criteria included previous history of lumbosacral surgery, metabolic system disorder, cancer, cardiac problems, peripheral neuropathy or history of upper motor neuron lesion, spinal canal stenosis, rheumatoid arthritis, osteoporosis, inability to tolerate lumbar extension position, spondylolisthesis, scoliotic deformity and any deformity of lower extremity that may interfere with global alignment	No clinical examination provided	
OTHER CONDITIONS INCL/EXCL		Adequate but no consideration of SIJ or hip as no clinical diagnosis provided	POSSIBLY, there is a greater chance of a homogeneous population, but there are still questions over definition and clinical diagnosis of unilateral lumbosacral radiculopathy and other contributors such as SIJ and hip. As well as uncertainty over duration of LBP.

Kim et al	2013	n/a after r/v	n/a after r/v	n/a after r/v			
DEFINITION OF LBP + PAIN REFERRAL					47 women volunteers from Hanseo University Hospital, suffering NSLBP in everyday life for 23.0 ± 5.45 weeks, after completing the clinical examinations, randomized supine group (n = 15), inversion, −30◦ group (n = 18), and inversion −60◦ group (n = 14).	definition of LBP defined as pain localized between the 12th rib and the inferior gluteal folds, with or without leg pain, and in 90% of cases it is nonspecific, do not give details of the clinical examination apart from checked by a specialist through X-ray, CT and MRI scans, and then diagnosed with LBP. Only rate back pain with VAS, and leg pain (if any) no measured	
TYPE OF LBP (acute, subacute, chronic, recurrent)					more than 12 weeks. Average duration 22.73 ± 4.45 (sup grp), 23.94 ± 6.77 (−30◦ group) , 22.07 ± 4.65 (−60◦ group)	Good, >12 weeks, average duration equivalent but still possibility in variation in psychosocial contribution	
NEUROLOGIC DEFICIT AND OTHER					Excl if had past or present neurological disease	Neurological disease was not defined, leg pain may be somatic, radicular, or radiculopathy, depending on this definition and clinical examination	
OTHER CONDITIONS INCL/EXCL					self-assessed questionnaire designed to identify subjects with CLBP. exclusion criteria, hypertension, or cardiopulmonary diseases, chronic disease, and operation for LBP, abnormal ophthalmic artery pressure during inversion from this study	definition of chronic LBP	No again questions over terminology they use NSLBP and LBP, and neurological diseases, and did they exclude radiculopathy, considering interchangeably within the article. From pain duration would seem chronic population, therefore group heterogeneity. Limited to women also