CONSERVATIVE MANAGEMENT OF LUMBAR DISC HERNIATION WITH ASSOCIATED RADICULOPATHY

Submitted by
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LIST OF ABBREVIATIONS

95% CI:	95% confidence interval
AIC:	Aikaike's Information Criteria
AU$	Australian dollars
CONSORT:	Consolidated Standards of Reporting Trials
CT:	Computerised tomography
DHR:	Disc herniation with associated radiculopathy
DP:	Directional preference
DPM:	Directional preference management
EuroQol-5D:	EuroQol-5 dimensions (quality of life questionnaire)
FR:	Functional restoration
K:	Kappa statistic
LBD:	Low back disorder
LBP:	Low back pain
MCID:	Minimum clinically important difference
MRI:	Magnetic resonance imaging
n:	Number of participants
NNT:	Number needed to treat
NRS:	Numerical rating scale
NSAIDs:	Non-steroidal anti-inflammatory drugs
Orebro:	Orebro musculoskeletal pain questionnaire
Oswestry:	Oswestry Disability Index (Version 2.1)
p:	Probability (of a Type I error associated with a significance test)
PEDro:	Physiotherapy Evidence Database
QUOROM:	Quality of Reporting of Meta-analyses
RCT:	Randomised controlled trial
SD:	Standard deviation
SE:	Standard error
SLR:	Straight-leg-raise test
SMD:	Standardised mean difference (in this thesis the Hedges-g SMD is used which includes an adjustment for bias resulting from small sample sizes)
TENS:	Transcutaneous electrical nerve stimulation
US$	American dollars
VAX-D:	Vertebral-axial decompression therapy

GLOSSARY OF TERMS

Behavioural modification:	The use of positive and negative reinforcement to increase desirable behaviour and reduce undesirable behaviour based on the principles of operant conditioning.
Catastrophizing:	The irrational thought that a situation is worse than it actually is, or that the worst possible outcomes will eventuate in the future.
Cognitive-behavioural approach:	The application of psychological treatment strategies based on theories of human cognition and behaviour.
Cognitive restructuring:	The identification of unhelpful beliefs and development of more accurate and productive beliefs.
Discectomy:	A surgical procedure involving the removal of a portion of disc material.
Disc bulge:	A generalised displacement of disc material involving at least 180° of the disc circumference.
Disc degeneration:	Typical age-related changes that occur in discs over time.
Disc degradation:	Abnormal pathological changes in the structure and function of a disc as a result of an injury, usually to the vertebral endplate or the annulus fibrosus.
Disc herniation:	A localised displacement of intervertebral disc material beyond the normal margins of the disc space (involving less than 180° of the disc circumference). The terms protrusion, prolapse, extrusion and sequestration are all synonymous with, or types of, disc herniations.
Disc herniation with associated radiculopathy:	A condition where clinical evidence of radiculopathy corresponds to radiological visualisation of a disc herniation that could realistically be expected to be the cause of the radiculopathy.
Directional preference:	The direction of movements or positions that leads to a positive benefit (centralisation of pain, reduced pain intensity by at least 1/10 on a 0-10 numerical rating scale, or improved range-of-motion).
Fear avoidance beliefs:	The belief that physical activities should be avoided due to a fear of causing pain or re-injury.
Functional restoration:	A multimodal pain management program that employs a comprehensive cognitive behavioral treatment orientation to help patients better cope with, and manage, their pain . . . while undergoing the sports medicine physical approach to correct functional deficits.

Glossary of terms continued

Low back disorder:	Any disorder where pain and activity limitation result from a disorder of the lumbar spine (includes referred leg pain and radiculopathy).
Low back pain:	Pain perceived in an area between the inferior costal margin and the inferior gluteal fold.
Natural history:	The degree and duration of recovery without treatment for a certain disorder.
Nerve root impingement:	Any contact with a nerve root, including contact, displacement or compression.
Phenomenology	A qualitative analysis approach concerned with the study of "the lived experience", where situations are described from the perspectives of the person experiencing them.
Radicular pain:	Pain arising from irritation of a damaged spinal nerve or its roots, typically described as shooting pain travelling along a narrow band in the leg.
Radiculopathy:	A conduction blockage of a spinal nerve or its roots, typically resulting in a collection of clinical features such as paraesthesia, motor weakness, and depression of reflexes corresponding to the affected nerve root.
Saturation:	In qualitative data analysis, refers to the point where no new information emerges from additional transcripts, which in this thesis was considered likely when three consecutive interviews were coded without any new themes being identified.
Sciatica:	Pain perceived along the course of the sciatic nerve.
Sensitivity:	In diagnostic testing, the proportion of people with the target condition who are correctly identified by a positive test (the true positive rate). A negative test result on a highly sensitive test rules the condition out.
Somatic referred pain:	Pain that is perceived in an area of the body that is separate to the source of the pain.
Specificity:	In diagnostic testing, the proportion of people free of the target condition who are correctly identified by a negative test (true negative rate). A positive test result on a highly specific test rules the condition in.

SUMMARY

This thesis explores the conservative management of people with a clinical and radiological diagnosis of lumbar disc herniation with associated radiculopathy (DHR). Background research summarises the epidemiology, pathophysiology and diagnosis of this condition. A systematic review examines the effectiveness and safety of conservative treatments for DHR. The review found that no conservative treatment has demonstrated clear superiority over others in this population. Physiotherapy functional restoration is then proposed as a potential treatment option for people with DHR. The remainder of the thesis outlines the development and evaluation of a physiotherapy functional restoration protocol for people with DHR. A case series is presented involving 95 participants with DHR who undertook a physiotherapy functional restoration program, with positive outcomes and a low rate of adverse events resulting. A pilot randomised controlled trial is then outlined comparing physiotherapy functional restoration to advice for people with DHR. The pilot study found moderate effect sizes in favour of functional restoration on a range of outcome measures at 10 week and 6 month follow-ups. A low rate of minor adverse events was also noted. On this basis a larger trial appears warranted in the future if challenges to the recruitment of people with DHR can be overcome. The thesis then presents a qualitative study investigating the self-described outcomes and perspectives of the participants in the randomised controlled trial who received the functional restoration intervention. Participants described several additional outcomes that were not assessed in the randomised controlled trial. Avenues for improving the functional restoration program were also suggested by some participants. In an area of research where few existing treatments are known to be effective, functional restoration emerges as a new treatment for DHR that has considerable potential to benefit this population. Further research involving larger samples is required before functional restoration can be widely recommended for the conservative management of DHR.

STATEMENT OF AUTHORSHIP

Except where reference is made in the text of the thesis, this thesis contains no material published elsewhere or extracted in whole or in part from a thesis submitted for the award of any other degree or diploma.

No other person's work has been used without due acknowledgment in the main text of the thesis.

This thesis has not been submitted for the award of any degree or diploma in any other tertiary institution.

The scope of the randomised controlled trial in this thesis (Chapter 6) required some collaboration with other members of the Low Back Research Team at La Trobe University. Fellow PhD candidates Luke Surkitt, Matthew Richards, Alexander Chan and Sarah Thompson assisted with the implementation of the marketing campaign, along with the screening and enrolment of participants.

While the planning, implementation, interpretation and writing of the statistical analyses utilised in this thesis was undertaken by myself, Dr. Siew-Pang Chan (Biostatistician) confirmed that these were appropriate.

All research procedures in this thesis were approved by University Ethics Committees: Health Sciences Human Ethics Committee, The University of Melbourne (#0718601); and Faculty of Health Sciences Human Ethics Committee, La Trobe University (#08/196).

Signed: **Date:**

LIST OF PUBLICATIONS AND PRESENTATIONS RESULTING FROM THIS THESIS

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Conference presentations

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CHAPTER 1: GENERAL INTRODUCTION

1.1 Low back disorders: a major health problem

Low back pain (LBP) has been defined as pain perceived in an area between the inferior costal margin and the inferior gluteal folds (Koes, van Tulder, & Thomas, 2006; van Tulder, Becker et al., 2006). As structures within the lumbar spine can also produce referred pain into the legs (Bogduk, 2005), this thesis adopts the broader term of low back disorders (LBDs) to encompass pain and activity limitations resulting from a disorder of the lumbar spine (McGill, 2007).

Low back disorders affect a large number of people throughout the world (Hoy, Brooks, Blyth, & Buchbinder, 2010; Leboeuf-Yde & Lauritsen, 1995; Loney & Stratford, 1999; Louw, Morris, & Grimmer-Somers, 2007; Walker, Muller, & Grant, 2004b). On any given day, up to 33% of the adult population will experience pain related to LBDs (Loney & Stratford, 1999; Walker, 2000), including approximately five million Australians (Walker et al., 2004b). The lifetime prevalence of LBDs has been estimated at 80% (Friedly, Standaert, & Chan, 2010; Walker, 2000; Walker et al., 2004b).

Despite its high prevalence, many LBD episodes result in only minor pain or activity limitation (Dunn & Croft, 2004; Kent & Keating, 2005b). More severe episodes are of primary concern and in this regard a study showed that approximately 10% of the Australian population had experienced a LBD that resulted in significant activity limitation or time off work in the six months preceding the survey (Walker et al., 2004b). Other studies have shown that approximately one in two people with LBDs seek healthcare (Carey et al., 1996; Kent & Keating, 2005b; Walker, Muller, & Grant, 2004a). In addition to pain and activity limitation, LBDs can result in psychosocial distress and reduced quality of life (Bogduk, 2004b; Ehrlich, 2003; Friedly et al., 2010).

The natural history (recovery without treatment) and the clinical course (recovery with treatment) of LBDs have often been reported as favourable, with 80-90% of individuals purported to recover within six weeks of pain onset (van Tulder, Becker et al., 2006; Waddell, 1987). However, reviews of epidemiological studies have suggested that

these estimates may be overly optimistic, as studies with the highest methodological standards have shown lower rates of recovery (Hayden, Dunn, van der Windt, & Shaw, 2010; Hestbaek, Leboeuf-Yde, & Manniche, 2003). For people who seek healthcare for an acute LBD episode, as many as 60% will still have pain one year later and 16% of those off work initially due to a LBD will remain off work six months later (Hayden et al., 2010; Henschke et al., 2008; Hestbaek et al., 2003; Kent & Keating, 2005b). In addition, LBDs are known to recur at a high frequency, with an estimated 60% recurrence rate for pain and a 33% rate of repeated work absence within a one to five year period following recovery (Hayden et al., 2010; Hestbaek et al., 2003; Waddell, 1987). It has therefore been proposed that the prognosis of LBDs is less favourable than some guidelines and individual studies have reported (Henschke et al., 2008).

The economic burden associated with LBDs is reportedly very high in several Western regions including The United States of America, The United Kingdom, Australia and Europe (Dagenais, Caro, & Haldeman, 2008; Frymoyer & Cats-Baril, 1991; Kent & Keating, 2005b; Maniadakis & Gray, 2000; Stewart, Ricci, Chee, Morganstein, & Lipton, 2003; Walker, Muller, & Grant, 2003). The total economic burden comprises direct costs (spending on healthcare intervention) and indirect costs (production losses to industry and insurance payments) (Dagenais et al., 2008; Kent & Keating, 2005b). The direct cost of treating LBDs in Western countries accounts for between 0.19% and 0.42% of Gross Domestic Product (GDP), or between 1.65% and 3.22% of all health expenditure (Kent & Keating, 2005b). The indirect costs attributable to LBDs are known to be much higher, typically comprising an estimated 78% of the total economic burden (Dagenais et al., 2008). In Australia, it was estimated that AU$1 billion was spent treating LBDs in 2001, with an additional AU$8 billion of indirect costs (Walker et al., 2003). In the United States of America, annual healthcare spending on LBDs between 1996 and 2002 has been estimated at US$24 billion (Dagenais et al., 2008; Frymoyer & Cats-Baril, 1991; Luo, Pietrobon, Sun, Liu, & Hey, 2004; Martin et al., 2008), with indirect cost estimates ranging from US$19.8 billion to US$28 billion annually (Dagenais et al., 2008; Rizzo, Abbott, & Berger, 1998; Stewart et al., 2003). In the United Kingdom, direct and indirect costs associated with LBDs were estimated to be £1.6 billion and £5 billion respectively in 1998 (Maniadakis & Gray, 2000). While the accuracy of the financial data presented above can be challenged, it appears clear that LBDs impose a significant economic burden on many countries around the world (Dagenais et al., 2008).

In summary, LBDs are highly prevalent and carry a significant risk of persistent or recurrent pain. Low back disorders can result in considerable physical and psychosocial dysfunction for a proportion of individuals, while also posing a significant economic burden to society. For these reasons, LBDs are considered to be a major international health problem and it has been proposed that this condition should become a national health priority area in Australia (Briggs & Buchbinder, 2009).

1.2 Treatment of low back disorders

Given the significance of LBDs as a health problem, effective treatments have potential to substantially reduce the burden of LBDs on individuals and society (Fletcher & Fletcher, 2005; Frank et al., 1996). A variety of treatments have been developed and evaluated for people with LBDs. While randomised controlled trials (RCTs) have shown that some interventions are slightly superior to placebo or no treatment, comparisons between treatments have typically resulted in either no difference or modest effect sizes that are below the magnitude of clinical significance (Chou, Atlas, Stanos, & Rosenquist, 2009; Foster, Hill, & Hay, 2010; Keller, Hayden, Bombardier, & van Tulder, 2007; van Middelkoop et al., 2010; van Tulder, Malmivaara, Hayden, & Koes, 2007; van Tulder, Koes, & Malmivaara, 2006).

One potential explanation for the lack of strong evidence to support the effectiveness of interventions for LBDs is the heterogeneity of participants recruited into RCTs (Atlas, Deyo, Patrick et al., 1996; Ford, Story, O'Sullivan, & McMeeken, 2007; Foster, Hill et al., 2010; Fritz, Cleland, & Childs, 2007; Kent & Keating, 2004). Recruitment of heterogenous samples is thought to occur based on an assumption that all LBDs are comparable, or due to difficulties identifying homogenous groups of participants (Ford et al., 2007; Foster, Hill et al., 2010; McCarthy & Cairns, 2005). This results in a sample of participants who have different types of LBDs that may all respond variably to a particular treatment approach (Foster, Hill et al., 2010). Trials that do not account for sample heterogeneity therefore risk a diminished likelihood of detecting a significant treatment effect due to the reduced proportion of the sample for whom the treatment is appropriate (Ford et al., 2007; Foster, Hill et al., 2010; Fritz et al., 2007).

1.2.1 Classification of low back disorders

In order to overcome the negative implications that sample heterogeneity can have on RCT results, it has been suggested that subgroups of LBDs should be identified that might respond more predictably to specific treatments (Billis, McCarthy, & Oldham, 2007; Ford et al., 2007). Researchers have recommended that future RCTs should recruit from homogenous LBD subgroups to maximise the chance of detecting larger effect sizes (Delitto, 2005; Ford et al., 2007; Foster, Dziedzic, van der Windt, Fritz, & Hay, 2009). This approach is consistent with clinical practice where most clinicians aim to identify subgroups and provide a tailored treatment program (Foster, Thompson, Baxter, & Allen, 1999; Kent & Keating, 2004).

The process of identifying and ordering entities such as LBDs into subgroups (or categories) that have maximum within group homogeneity and between group heterogeneity is known as classification (Bailey, 1994). In order for a person to qualify for membership to a particular subgroup, they must meet certain selection criteria (Ford et al., 2007; Riddle, 1998). Classification research relating to LBDs has been identified as an important research priority (Borkan, Koes, Reis, & Cherkin, 1998; Ford et al., 2007; Foster et al., 2009; Fritz et al., 2007; Henschke, Maher, Refshauge, Das, & McAuley, 2007). Review articles have shown that a number of LBD classification systems have been developed and evaluated for research and clinical purposes using various validation methods (Billis et al., 2007; Ford et al., 2007). A brief description of existing classification approaches for LBDs follows, along with a description of the methods used in their development and validation. Guidelines relating to the categorisation, development and validation of classification systems for LBDs have been proposed previously (Bogduk, 2005; Buchbinder, Goel, Bombardier, & Hogg-Johnson, 1996; Feinstein, 1972; Ford et al., 2007) and these have been used as a framework for discussing the various elements of classification research.

1.2.1.1 Dimensions of low back disorders that are represented in classification systems

Low back disorders affect a number of different aspects of a person's health and functioning (Ford et al., 2007; Waddell, 1998). These can include negative impacts upon all major domains of the World Health Organisation's International Classification of Functioning, Disability and Health (ICF); body structures, body functions, activities & participation and environmental factors (Cieza & Stucki, 2008; World Health Organisation, 2011). A number of bodily structures have been hypothesised or proven

as a source of LBDs, including the intervertebral discs, vertebral endplates, zygapophyseal joints, sacroiliac joints, muscles and neural tissues (Bogduk, 2005; Hancock et al., 2007; Schwarzer et al., 1994, 1995). Damage to any of these structures can interfere with bodily functions such as spinal joint range of motion and muscle strength, while a variety of physical symptoms have been reported by people with LBDs include back pain and referred leg pain (Cassisi et al., 1993; Deyo et al., 1998; Koes et al., 2006; Lindstrom, Ohlund, Eek, Wallin, Peterson, & Nachemson, 1992). Impaired psychological function is also associated with LBD's, including depression, anxiety and fear avoidance beliefs (Cairns, Foster, Wright, & Pennington, 2003; Cassisi et al., 1993; Deyo et al., 1998; Foster, Thomas, Bishop, Dunn, & Main, 2010). Low back disorders can lead to limitations in the performance of specific activities such as sitting, standing, walking and dressing, as well as reduced participation in occupational, leisure and social activities (Cassisi et al., 1993; Deyo et al., 1998). Furthermore, environmental factors can have an additional impact on people with LBDs including social isolation, stigma and strain on relationships (Cairns et al., 2003; Cassisi et al., 1993; Deyo et al., 1998; Foster, Thomas et al., 2010; Slade, Molloy, & Keating, 2009c).

Classification systems for LBDs have incorporated criteria representative of a number of dimensions that relate to the ICF domains (Bailey, 1994; Dankaerts & O'Sullivan, 2010; Ford et al., 2007). The criteria representing the pathoanatomical dimension of LBDs relate to pathological processes occurring in lumbar spine structures, such as a disc herniation depicted on radiological imaging which identifies an injured disc (Dankaerts & O'Sullivan, 2010; Ford et al., 2007; Riddle, 1998). Other criteria that appear in classification systems relate to the psychological and social (or environmental) dimensions of LBDs (Dankaerts & O'Sullivan, 2010; Ford et al., 2007; Riddle, 1998). A further dimension of LBDs that is reflected in some classification systems relates to signs and symptoms such as reduction in muscle strength or range of motion (consistent with the bodily functions domain of the ICF) (Dankaerts & O'Sullivan, 2010; Ford et al., 2007; Riddle, 1998). The majority of classification systems published to date have been unidimensional, containing criteria representing only one of these dimensions (Ford et al., 2007). The pathoanatomical dimension is the most commonly used basis for LBD classification systems both in the research field (Ford et al., 2007) and in clinical practice (Kent & Keating, 2005a; Miller Spoto & Collins, 2008). In addition, pathoanatomical classification systems lend themselves to

the development of specific treatments that target the causal mechanism of the condition (Ford et al., 2007; Hancock et al., 2007; Miller Spoto & Collins, 2008). For these reasons, this thesis considers a pathoanatomical subgroup of LBDs. Classifying a person to a pathoanatomical subgroup is synonymous with the process of diagnosis (Feinstein, 1972), hence the terms diagnosis and classification are used interchangeably in this thesis.

1.2.1.2 Development of classification systems

Classification systems can be developed using two main methods; statistical and judgemental (Feinstein, 1972; Ford et al., 2007; Riddle, 1998). Statistical approaches can be employed to develop statistically homogenous subgroups (Feinstein, 1972; Ford et al., 2007; Riddle, 1998). The development of clinical prediction rules that aim to identify characteristics of participants who respond most favourably to a particular treatment is one example of a statistical approach (Beattie & Nelson, 2006; Fritz et al., 2007; Hancock, Herbert, & Maher, 2009; May & Rosedale, 2009; Stanton, Hancock, Maher, & Koes, 2010). A disadvantage of this method of developing a classification system is the potential for the resultant subgroups to be artificial and lacking in clinical meaningfulness. This can make it difficult to develop new treatments for the identified subgroups based on mechanisms of effect (Feinstein, 1972; Ford et al., 2007; Heinrich, O'Hare, Sweetman, & Anderson, 1985). The second method of developing classification systems uses a judgemental approach (Feinstein, 1972; Ford et al., 2007; Riddle, 1998). This relies on the use of clinician or researcher judgement to identify homogenous subgroups, usually in conjunction with an interpretation of literature relating to the mechanisms of effect (Bogduk, 2005; Feinstein, 1972; Ford et al., 2007). While it could be argued that judgemental processes allow greater opportunity for bias to influence the development of classification systems, this can be reduced by using standardised procedures such as expert panels and systematic literature reviews (Ford et al., 2007). Judgemental approaches are the most commonly used means of developing or identifying pathoanatomical subgroups (Ford et al., 2007).

One judgemental method of developing pathoanatomical subgroups of LBDs based on mechanisms of effect has been suggested by Bogduk (2005). In a modification of Koch's postulates for bacterial diseases, Bogduk proposed four criteria that should be met for a pathoanatomical condition to be considered as a potential source of pain (Bogduk, 2005). These criteria serve as a standard by which all pathoanatomical

conditions can be evaluated to determine whether they have sufficient evidence of causal mechanisms. Bogduk's postulates are outlined in Table 1.1.

Table 1.1: Bogduk's postulates for identifying a pathoanatomical subgroup of low back disorders (adapted from Bogduk, 2005)

1. The hypothesised causal structure must have a nerve supply
2. The structure must be capable of causing pain that is seen clinically
3. The structure should be prone to injury or disease that is known to be painful
4. It should be possible to identify the structure as a cause of pain based on valid and reliable diagnostic testing

1.2.1.3 Validation of classification systems

Once a classification system has been identified or developed, there are various methods for evaluating its validity and reliability (Anastasi & Urbina, 1997; Buchbinder et al., 1996; Ford et al., 2007; Portney & Watkins, 2009). Some of the main types of validity and reliability that can be used for this purpose are defined in Table 1.2.

Table 1.2: Types of validity and reliability relevant for classification system evaluation

Measurement type	Definition in relation to classification system or subgroup validation
Criterion validity	
Concurrent validity	Comparison of the classification system or subgroup selection criteria to established reference standards that have already been validated
Predictive validity	Evaluation of the classification system's ability to predict a future outcome (such as recovery)
Construct validity	
Discriminant validity	The degree to which a subgroup can be discriminated from others based on variables that measure constructs relevant to LBDs
Reliability	Repeatability of the classification system, or of the criteria used to classify people with LBDs to a subgroup
Intraobserver	Repeatability of the classification system or its criteria when measured by the same observer on multiple measurement occasions
Interobserver	Repeatability of the classification system or its criteria when measured by different observers

It may be difficult to fully establish some types of reliability and validity for a LBD subgroup. For example, it is difficult to definitively establish concurrent validity for LBDs because no ideal reference standards exist against which subgroup criteria can be compared (Carragee, Haldeman, & Hurwitz, 2007; Carragee, Lincoln, Parmar, & Alamin, 2006; Deyo, Haselkorn, Hoffman, & Kent, 1994; Ford et al., 2007; Lauder et al., 2000; Saal, 2002; van der Windt et al., 2010). Given the difficulty in achieving unequivocal validation of LBD subgroups using any one method, it has been proposed that subgroup validity can be demonstrated by the accumulation of evidence from various studies that use different evaluation methods (Dankaerts & O'Sullivan, 2010; Ford et al., 2007; George & Delitto, 2005; Reitsma, Rutjes, Khan, Coomarasamy, & Bossuyt, 2009). This concept has been labelled "convergence of validity" (George & Delitto, 2005; Reitsma et al., 2009).

1.3 Disc herniation with associated radiculopathy as a pathoanatomical subgroup of low back disorders

It has been proposed that LBDs are a significant problem for which few treatments have proven to be highly effective. Identification of homogenous subgroups is one strategy aimed at facilitating the development of treatments that might produce larger effect sizes in RCTs. To develop and validate an entire classification system containing several subgroups is beyond the scope of this doctoral thesis. As such, one pathoanatomical LBD subgroup is the focus of this thesis. While the validity and reliability of this subgroup is thoroughly evaluated in Chapter 2 using the framework described above, a brief introduction to the subgroup is firstly presented in the lead-up to the thesis aims at the conclusion of this chapter.

Disc herniation with associated radiculopathy (DHR) (Chou, Loeser et al., 2009; Thomas et al., 2007; van der Windt et al., 2010) is a widely accepted subgroup of LBDs (Bartram, 2005; Ford, 2005; Genevay, Atlas, & Katz, 2010; Koes et al., 2010; Martin et al., 2008; Mooney, 1987; Rhee, Schaufele, & Abdu, 2006). Almost all clinical practice guidelines recommend that DHR should be considered separately from other LBDs (Koes et al., 2010). This distinction is warranted, as DHR has a different pain source and unique treatment options compared to other LBDs (Bogduk & McGuirk, 2002; Deyo, 2007). In addition, the presence of referred leg symptoms as a key feature of DHR is associated with delayed recovery, persistent activity limitation, higher pain intensity, slower return to work, increased healthcare utilisation and a higher economic burden compared to LBDs without radiation (Cherkin, Deyo, Street, & Barlow, 1996; Loisel et al., 2002; O'Hearn, 1997; Selim et al., 1998; van der Weide, Verbeek, Salle, & van Dijk, 1999; Waddell, Burton, & Main, 2003).

In addition to its widespread acceptance, unique pain mechanisms and poorer prognosis, literature relating to the cost of treating LBDs suggests that further research into conservative treatments for DHR may be particularly important. A report from the Australian Institute of Health and Welfare (2009) showed that AU$156.2 million was spent on total healthcare expenditure in the 2004-05 financial year for the management of disc herniation in Australia. The most significant costs were inpatient hospital services, accounting for 77% of the expenditure, compared to chronic back pain where inpatient costs accounted for 50% of expenditure. The cost per person for the inpatient management of disc herniation was AU$5,250, compared to AU$4,037 per person for

chronic back pain. The most substantial contributor to inpatient costs was surgery, with discectomy and/or fusion surgery costing between $16,300 and $29,500 per procedure (Australian Institute of Health and Welfare, 2009). The high cost of treating DHR is mirrored in other countries too, with one report from 2007 estimating that US$5 billion was spent annually on discectomy surgery in the United States of America (Deyo, 2007). While the cost of hospital based management for one person with DHR is substantial, the frequency of hospital admissions for this population also appears high. A Finish survey estimated that one-third of adults with signs consistent with DHR had previously been admitted to hospital, while one-fifth had undergone surgery for this condition (Heliovaara et al., 1987). Data from Australia showed that 2% of people in the population who were thought to have DHR were admitted to hospital in the 2004-05 financial year. These data indicate that opportunity exists to reduce the total cost of managing DHR if the rate of expensive surgical interventions and hospitalisation can be minimised.

An obvious way to minimise the rate of hospital admissions and surgical procedures for DHR is through effective outpatient conservative management. One explanation for high surgical rates and hospital admissions may be that people with DHR do not commonly undertake conservative management prior to being admitted to hospital. There is however considerable research that disputes this hypothesis. Clinical practice guidelines recommend that surgical management of DHR should only be considered when either conservative measures have failed, or in the presence of acute cauda equina syndrome (Health Council of the Netherlands, 1999; Wong et al., 2000). Surveys from Australia, the United States of America and The Netherlands confirm that at least 50% of people with DHR receive physiotherapy prior to consideration of surgical intervention (Australian Institute of Health and Welfare, 2009; Cummins et al., 2006; Luijsterburg et al., 2005). Aside from physiotherapy, approximately 50% of people with DHR presenting for surgery in the United States of America have previously received an epidural injection (Cummins et al., 2006). The average cost of conservative treatments for one person with DHR in the 90 days prior to surgery in the United States of America has been estimated at US$2,537 (Daffner, Hymanson, & Wang, 2010). The progression of people with DHR from conservative to surgical management is therefore not explained by lack of access to, or under-utilisation of, conservative management prior to surgery.

Given that conservative treatments for DHR are commonly attempted prior to consideration of surgery, another hypothesis that would explain the high rate of hospitalisation and surgical management is that conservative treatments commonly applied to people with this condition are not effective. While previous systematic reviews have evaluated the effectiveness and safety of surgery and injections for people with verified DHR (Abdi et al., 2007; Armon, Argoff, Samuels, & Backonja, 2007; DePalma, Bhargava, & Slipman, 2005; Gibson & Waddell, 2007), no such reviews could be located relating to conservative and non-injection treatments. It is therefore unclear whether any conservative and non-injection treatments are effective for people with DHR or not, so the hypothesis posed above cannot be answered. On this basis, further research focussing on the effectiveness of conservative management for DHR has been recommended (Chou & Huffman, 2007). If future research can identify conservative treatments for DHR that are effective and safe, and then if these treatments become widely utilised in this population, there would be significant potential to reduce the proportion of people who progress to inpatient services such as surgery with their high associated costs.

1.4 Thesis aims and outline

The broad aim of this thesis is to evaluate the conservative management of DHR. The content of each thesis chapter is outlined below.

Chapter 2 provides background information relevant to the studies in this thesis. This chapter summarises literature regarding the terminology relating to DHR, as well as the anatomy, pathophysiology and healing mechanisms involved in DHR. This information is then used in a discussion of literature relating to the development and validation of DHR as a subgroup of LBDs. An estimate of the prevalence of DHR diagnosed in accordance with validated criteria is then made.

The aim of Chapter 3 is to determine the effectiveness and safety of conservative and non-injection treatments for DHR. This involves a systematic review of RCTs focussing specifically on people with clinical and radiological evidence of DHR.

Chapter 4 introduces physiotherapy functional restoration as a potential treatment for the conservative management of DHR. Existing literature relating to functional restoration is reviewed and the proposed mechanisms by which functional restoration

could assist people with DHR are discussed. A case series then collates the outcomes and adverse events reported by participants with DHR who were treated with physiotherapy functional restoration.

Chapter 5 describes and justifies a standardised functional restoration protocol for people with DHR, to be applied by physiotherapists in a RCT.

Chapter 6 investigates the feasibility of conducting a large-scale RCT comparing physiotherapy functional restoration to advice for people with DHR. This pilot RCT utilises the standardised treatment protocol outlined in Chapter 5.

Chapter 7 presents the qualitative outcomes and the perspectives of participants who undertook the functional restoration program in the RCT. This qualitative study utilises semi-structured interviews and a phenomenological analysis method.

Chapter 8 provides conclusions and suggestions for future research relating to the conservative management of DHR.

CHAPTER 2: INTRODUCTION TO LUMBAR DISC HERNIATION WITH ASSOCIATED RADICULOPATHY

In commencing this thesis on the conservative management of DHR, pertinent background information is required. This chapter defines terminology relating to DHR so that this can be applied consistently throughout the thesis. A brief description of the anatomy, pathophysiology and healing mechanisms relevant to DHR is then presented and this is applied later in the thesis when developing a treatment protocol for a RCT that targets the pathophysiological mechanisms involved in DHR. An evaluation of the development and validation of DHR as a subgroup of LBDs is made by following the framework outlined in Chapter 1 relating to classification of LBDs. The features with the highest validity and reliability for diagnosing DHR are then used as selection criteria in the remaining studies. An estimate of the prevalence of DHR diagnosed in accordance with the validated features is made at the end of this chapter.

To assist with identifying appropriate references for this chapter and for those that follow, a general search of Medline (Ovid SP) and CINAHL (EBSCO) was undertaken (see Appendix B for full search strategy). Multiple relevant references were identified for the topics covered in this chapter, so only those considered to be of greatest relevance were cited. Sources were considered most relevant if they were published systematic reviews, recently published primary studies, articles utilising the highest methodological standards, or seminal original sources.

2.1 Definitions and terminology

The definitions of key terms that are relevant to DHR need to be clarified, as there is considerable variation in this terminology in the literature (Bogduk, 2009; Genevay et al., 2010; Tarulli & Raynor, 2007; Van Boxem et al., 2010). Definitions of all key terms also appear in the glossary of terms (Pages xv-xvi).

The definition of disc herniation used in this thesis is based on the terminology proposed by Fardon and Milette, who defined disc herniation as a "localised displacement of disc material beyond the normal margins of the intervertebral disc space" (Fardon & Milette, 2001, p. E107). The term herniation is an umbrella term that encompasses disc protrusions, extrusions and sequestrations (see Figure 2.1). Disc herniation excludes disc bulging, which involves at least 180° of the disc circumference and hence is not localised (Fardon & Milette, 2001).

a) protrusion **b) extrusion** **c) sequestration**

In a disc protrusion, the base of the herniated disc material (in contact with the disc) is greater in diameter in any plane compared to the herniated material away from the base. In a disc extrusion, the disc material distant from the base is greater in diameter than the base itself in at least one plane. In a sequestration, part of the herniated disc material looses continuity with the base and a free fragment of disc material results (Fardon & Milette, 2001).

Figure 2.1: Diagram showing the types of disc herniations (adapted from Fardon & Milette, 2001)

A further grading system has been established for the degree of nerve root impingement depicted on magnetic resonance imaging (MRI) or computerised tomography (CT) (Lurie et al., 2008; Pfirrmann et al., 2004). This has been graded as "no contact", "contact" of the nerve, "displacement" of the nerve from its usual position and "compression" of the nerve (reduction in its cross sectional area). The terms nerve root impingement or nerve root compromise are umbrella terms that cover all degrees of contact with a nerve root by other structures such as a herniated disc.

With any compromise of a nerve root, radiculopathy can result. Radiculopathy refers to a conduction blockage of a spinal nerve or its roots (Bigos, Bowyer, & Braen, 1994; Bogduk, 2005, 2009). It typically leads to a collection of clinical symptoms and signs such as paraesthesia, motor weakness and depression of reflexes corresponding to the affected nerve root (Bigos et al., 1994; Bogduk, 2005, 2009). While a herniated disc is the most common cause of radiculopathy (Frymoyer, 1988; Gibson & Waddell, 2007; Tarulli & Raynor, 2007), there are many other causes including spinal stenosis, spondylolisthesis, spinal cysts and tumours (Bejia, Younes, Zrour, Touzi, & Bergaoui, 2004; Tarulli & Raynor, 2007). This thesis focuses on radiculopathy most likely caused by a herniated disc, hence the term "disc herniation with associated radiculopathy" (DHR) (Chou, Loeser et al., 2009; Thomas et al., 2007; van der Windt et al., 2010).

While DHR does occur in the cervical and thoracic spine, for the purposes of this thesis the term relates to lumbar DHR.

While radiculopathy is not always associated with pain, it is commonly accompanied by referred leg pain (Bogduk, 2005, 2009; Van Boxem et al., 2010). Referred leg pain can be categorised into two types based on different mechanisms. Radicular pain arises from a damaged spinal nerve or its roots, and is typically described as shooting pain travelling along a narrow band in the leg (Bogduk, 2005, 2009). Radicular pain is one type of peripheral neurogenic pain (more commonly termed peripheral neuropathic pain in cases of sustained damage to a peripheral nerve) (International Association for the Study of Pain, 1994; Merskey & Bogduk, 1994). Somatic referred pain is a type of nociceptive pain perceived in an area of the body that is separate to the source of the pain (Bogduk, 2005, 2009). Somatic referred pain is typically described as having a dull and aching quality, and usually covers a diffuse area (Bogduk, 2005, 2009). Unlike radicular pain, somatic referred pain does not involve irritation of spinal nerves or its roots, rather it results from convergent sensory nerve pathways that are shared by the source of nociceptive stimulation and the site of referred pain (Bogduk, 2005, 2009; International Association for the Study of Pain, 1994). The term sciatica is defined as pain perceived along the course of the sciatic nerve (Bigos et al., 1994; Rebain, Baxter, & McDonough, 2002; Stafford, Peng, & Hill, 2007). This term is often used interchangeably to describe radicular and somatic referred pain (Andersson & Deyo, 1996; Stafford et al., 2007; Valat, Genevay, Marty, Rozenberg, & Koes, 2010) and on this basis has been criticised for its lack of precision (Andersson & Deyo, 1996; Fairbank, 2007). Accordingly, this thesis avoids the use of the term sciatica in favour of more specific terminology such as DHR. Exceptions to this are made in marketing and treatment related information for the RCT (Chapter 6) where the term sciatica would be better recognised by participants (Stafford et al., 2007).

2.2 The normal intervertebral disc

Having defined key terminology for this thesis, the anatomy and physiology of the normal intervertebral disc is now considered. This material aids understanding of the pathophysiology of DHR that follows.

The lumbar intervertebral discs are comprised of three main components (see Figure 2.2). The nucleus pulposus is located in the centre of the disc and is comprised of a

semi-fluid material containing a low concentration of collagen fibres and a high concentration of water (70-90%) held in proteoglycan molecules (Bogduk, 2005; Rhee et al., 2006). The annulus fibrosus consists of a series of collagenous rings (or lamellae) that surround the nucleus, with the fibres of one layer orientated at a 90° angle to the next (Bogduk, 2005; Raj, 2008; Rhee et al., 2006). The fibres of the annulus are thinnest in the posterior aspect of the disc but they are reinforced somewhat by the posterior longitudinal ligament that runs through the vertebral canal (Bogduk, 2005; Moore, 1992). The fibres of the posterior longitudinal ligament are thinnest over the posterolateral aspect of each intervertebral disc, hence this part of the disc has the least support (Moore, 1992). The discs are joined to the vertebral bodies by a superior and inferior cartilaginous vertebral endplate (Bogduk, 2005; Raj, 2008).

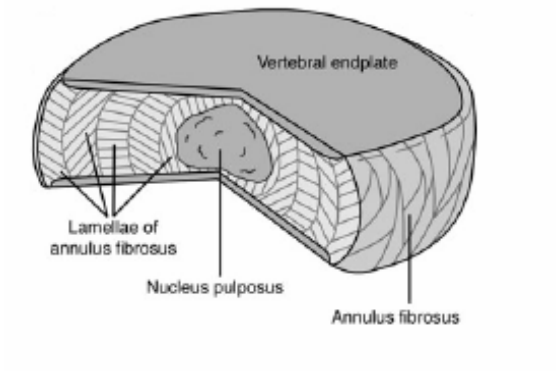


Figure 2.2: The normal intervertebral disc (adapted from Raj, 2008)

The intervertebral discs contain active cells, hence they require a source of nutrition (Bogduk, 2005). The periphery of the annulus fibrosus receives some direct vascular supply from small blood vessels (Adams & Roughley, 2006; Beattie, 2008; Bogduk, 2005; Rhee et al., 2006). The remainder of the annulus and the nucleus depend on diffusion of substances from the outer annulus and the vertebral endplates for their nutritional supply (Adams & Roughley, 2006; Beattie, 2008; Bogduk, 2005; Hadjipavlou, Tzermiadianos, Bogduk, & Zindrick, 2008; Rhee et al., 2006). Research has shown that normal movement and compression forces that lead to dispersion of fluid around the disc may potentially be an additional means of aiding the transport of nutrients within the disc (Adams & Roughley, 2006; Beattie, 2008; Bogduk, 2005; Hadjipavlou et al., 2008; Holm & Nachemson, 1983; Kraemer, Kolditz, & Gowin, 1985).

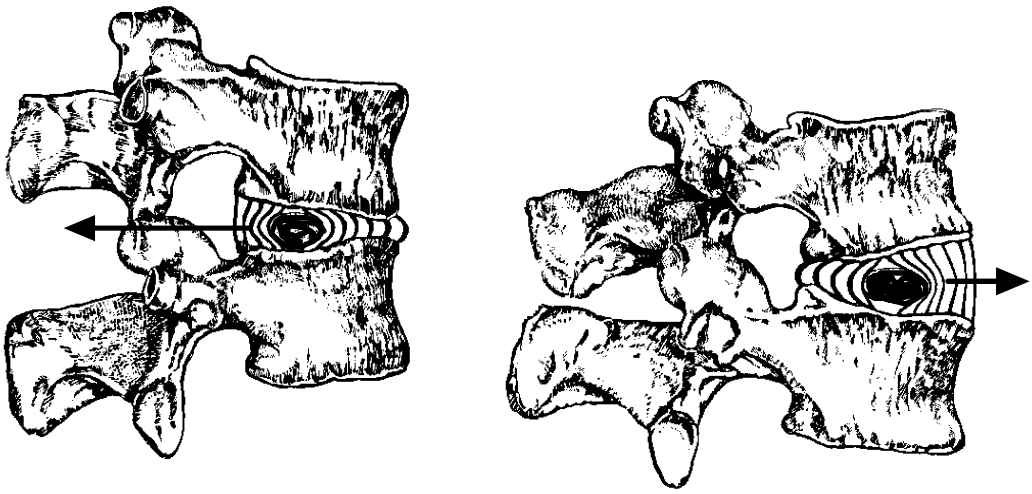
The outer one-third of the annulus is innervated by abundant nerve endings (Adams & Roughley, 2006; Bogduk, 2005; Rhee et al., 2006), of which a proportion are likely to have a nociceptive function (Adams & Roughley, 2006; Bogduk, 2005). The nucleus pulposus and inner aspects of the annulus fibrosus are not innervated in normal discs (Adams & Roughley, 2006; Bogduk, 2005; Vora, Doerr, & Wolfer, 2010).

The lumbar intervertebral discs are in close proximity to major neural structures. The spinal cord in most adults terminates at the level of the L1/2 disc and continues caudally as the cauda equina (Bogduk, 2005; Louis, 1978; Moore, 1992). At each vertebral level, a dorsal and ventral spinal nerve root on each side of the spine course laterally towards the intervertebral foramen where they unite to form a spinal nerve (Bogduk, 2005; Moore, 1992). Particularly in the lower lumbar spine, each dorsal root begins to course obliquely towards its exiting intervertebral foramen from at least one vertebral segment superior, requiring it to cross the posterolateral aspect of the intervertebral disc located superiorly to its exiting intervertebral foramen (Bogduk, 2005; Bose & Balasubramaniam, 1984; Moore, 1992). Just prior to the formation of the spinal nerve in the intervertebral foramen, the dorsal root contains a swelling called the dorsal root ganglion where the cell bodies of the sensory fibres of the dorsal nerve roots are contained (Bogduk, 2005; Moore, 1992).

The primary functions of the lumbar intervertebral discs are to assist with weight-bearing and to facilitate movement of the spine (Adams & Roughley, 2006; Bogduk, 2005; Raj, 2008). The annulus fibrosus is a relatively stiff structure that can assist with weight bearing and transmission of forces from one vertebra to the next (Bogduk, 2005; Vora et al., 2010). This weight bearing role is shared by the nucleus pulposus which develops high levels of hydrostatic pressure in response to mechanical loading, allowing forces to be dispersed in all directions to the annulus and the vertebral endplates (Bogduk, 2005; Podichetty, 2007; Vora et al., 2010).

While movements of the lumbar spine are also influenced by the zygapophyseal joints, the discs play a critical role in allowing movement to occur. The primary movements in the lumbar spine are flexion and extension in the sagittal plane, lateral-flexion in the frontal plane and a small amount of rotation in the transverse plane (Bogduk, 2005; Taylor & Twomey, 1980). Movements of the lumbar spine in the sagittal and coronal planes result in narrowing of one side of the disc and thickening of the opposite side

(Bogduk, 2005). This process is facilitated by internal distortion of the annulus fibrosus and nucleus pulposus (Bogduk, 2005; Vora et al., 2010). For example, during flexion the fibres in the anterior aspect of the annulus and nucleus are compressed, while the posterior annulus and nucleus are stretched (Bogduk, 2005; Snijders, Hermans, Niesing, Spoor, & Stoeckart, 2004). As the anterior aspect of the fluid-filled nucleus becomes compressed during flexion, intradiscal pressure increases and the nucleus temporarily distorts posteriorly until the movement is reversed, in a process known as nuclear migration (see Figure 2.3) (Bogduk, 2005; Kolber & Hanney, 2009). Nuclear migration has been demonstrated to consistently occur in normal discs during flexion and extension movements (Alexander, Hancock, Agouris, Smith, & MacSween, 2007; Bogduk, 2005; Kolber & Hanney, 2009; Wetzel & Donelson, 2003). Although the process of nuclear migration allows intradiscal pressure to be spread throughout the disc, studies have shown that there is typically a net increase in nuclear pressure during movements, possibly due to the additional forces transmitted through the discs by activity of the posterior spinal muscles (Bogduk, 2005; Ortengren, Andersson, & Nachemson, 1981). For rotary movements in the transverse plane, as one vertebrae is twisted upon another, half of the layers of the annulus are stretched to resist the movement while the other half (with oppositely orientated fibres) are slackened (Bogduk, 2005; Vora et al., 2010). During rotation in the opposite direction, the roles of the annular layers are reversed with the other half of the fibres now stretching to resist the movement.



Posterior nuclear migration during flexion. **Anterior nuclear migration during extension.**

Figure 2.3: Nuclear migration of the nucleus pulposus within an intervertebral disc during flexion and extension movements of the lumbar spine: adapted from (McKenzie, 1990)

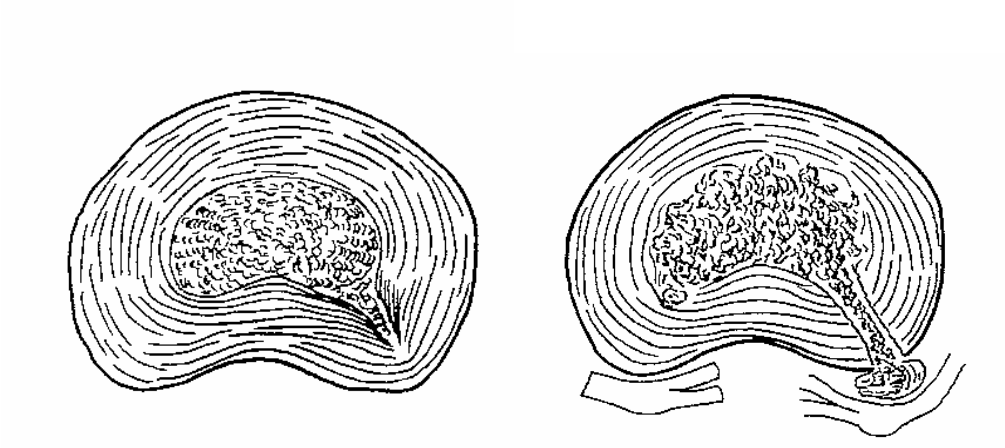
2.3 Pathophysiology of disc herniation with associated radiculopathy

Having briefly discussed the anatomy and physiology of normal lumbar intervertebral discs, the pathophysiology of DHR can now be understood. This information is utilised later in the chapter to justify the validation of DHR as a pathoanatomical subgroup of LBDs. The pathophysiological information also informs the development and justification of a treatment protocol based on causal mechanisms that is evaluated in the RCT that follows later in the thesis (Chapters 5 & 6).

It is very difficult for a normal disc to herniate, even when high compression and flexion forces are applied to it (Adams & Hutton, 1985; Bogduk, 2005; Brinckmann, 1986). When disc herniations have been induced experimentally by combining compressive loading with flexion and/or rotation of the spine, the required forces have exceeded normal physiological conditions (Adams & Hutton, 1982, 1985; Adams & Roughley, 2006; Hadjipavlou et al., 2008). Herniations therefore tend to occur in discs that are structurally and functionally compromised (Adams & Hutton, 1985; Bogduk, 2005; Brinckmann, 1986). Disc degeneration refers to typical age-related changes that occur in most individuals over time (Adams & Roughley, 2006; Bogduk, 2005; Raj, 2008). For example, all aging discs show a reduction in water content leading to

reduced ability to absorb and distribute forces (Adams & Roughley, 2006; Bogduk, 2005; Raj, 2008). Disc degradation, or internal disc disruption, refers to abnormal pathological changes in the structure and function of a disc as a result of physical trauma, usually to the vertebral endplate or the annulus fibrosus (Bogduk, 2005; Crock, 1986). It can be difficult to distinguish between disc degeneration and degradation (Adams & Roughley, 2006; Raj, 2008) and the terms are often used interchangeably (Bogduk, 2005). However, the typical pathogenesis of a disc herniation is more consistent with a process of degradation as it most commonly commences with trauma to the endplate or annulus either months or years prior to the herniation occurring (Adams & Hutton, 1985; Adams & Roughley, 2006; Bogduk, 2005). The initial damage to these aspects of the disc usually occurs as a result of excessive or repeated structural loading (Adams & Roughley, 2006; Beattie, 2008; Bogduk, 2005; Hadjipavlou et al., 2008). Damage to the endplate or annulus impairs the overall function of the disc such that the nucleus is no longer able to withstand the higher forces imposed upon it, leading to degradation of the nucleus (Adams & Roughley, 2006; Beattie, 2008; Bogduk, 2005; Hadjipavlou et al., 2008). The reduced ability of the nucleus to evenly disperse forces results in higher loads being transferred to the annulus and a common result of this is annular tearing (Adams & Roughley, 2006; Hadjipavlou et al., 2008). Although there are different types and locations of annular tears, the most relevant to DHR are radial fissures that progress outwardly from the nucleus, usually in a posterior or posterolateral direction where the posterior longitudinal ligament is weakest (Adams & Roughley, 2006; Beattie, 2008; Bogduk, 2005; Herzog, 1996; Moore, 1992).

As radial fissures progress peripherally through the annulus, they can become symptomatic when they reach the innervated outer third of the annulus (Bogduk, 2005; Schafer, Hall, & Briffa, 2009). Experimental studies have shown that stimulation of the outer annulus typically produces back pain and/or somatic referred pain into the legs (Adams & Roughley, 2006; Bogduk, 2005; O'Neill, Kurgansky, Derby, & Ryan, 2002; Raj, 2008; Schafer et al., 2009). If nuclear material migrates along a radial fissure to the outer annulus, it can result in a disc herniation (see Figure 2.4) (Adams & Roughley, 2006; Beattie, 2008; Martin, Boxell, & Malone, 2002). These are considered to be “contained” if the nuclear material remains enclosed by the outer annulus, or “uncontained” if the nuclear material escapes the annulus through a breach in its outer surface (Fardon & Milette, 2001).



Radial fissure **Disc herniation with nerve root impingement**

Figure 2.4: Typical pathogenesis of a disc herniation, commencing with a radial fissure and culminating with herniation of nuclear material through the breached outer annulus (adapted from Bogduk, 2005)

Once a disc herniation develops it can affect other structures in close proximity to the disc (Bogduk, 2005). As most disc herniations occur in a posterolateral direction, the structure most commonly affected is the descending spinal nerve root coursing posterolaterally across the disc towards its intervertebral foramen (Bogduk, 2005; Martin et al., 2002). More lateral disc herniations can affect the traversing nerve root (including its dorsal root ganglion) as it exits the intervertebral foramen at the same level as the herniated disc (Bogduk, 2005; Martin et al., 2002). Nerve roots can be affected by herniated disc material in various ways. The herniated disc material can directly compress the nerve root, impairing circulation to the nerve root and leading to demyelination and degeneration of its nerve fibres (Bogduk, 2005; Jancalek & Dubovy, 2007; Kobayashi, Yoshizawa, & Yamada, 2004; Lipetz, 2002; Takamori, Arimizu, Izaki, Naito, & Kobayashi, 2011; Valat et al., 2010; Yoshizawa, Kobayashi, & Hachiya, 1991). Such damage to the nerve root may result in clinical signs that are indicative of radiculopathy including paraesthesia, motor weakness and depression of deep tendon reflexes (Awad & Moskovich, 2006; Bigos et al., 1994; Bogduk, 2005, 2009; Koes, van Tulder, & Peul, 2007). Mechanical compression of a spinal nerve root may also lead to referred leg pain; either somatic referred pain from stimulation of the dural sleeve surrounding the nerve root, or radicular pain from direct stimulation of the nerve fibres themselves (Bogduk, 2005, 2009; Lipetz, 2002). However, mechanical compression of a nerve root alone is not usually sufficient to produce pain, as experimental studies have shown. While these experiments have shown that any

contact with a dorsal root ganglion consistently evokes pain (Bogduk, 2005; Howe, Loeser, & Calvin, 1977; Lipetz, 2002), they have also shown that the application of compressive or traction forces to normal nerve roots is not typically painful (Bogduk, 2005; Howe et al., 1977; Lipetz, 2002; Rhee et al., 2006; Smyth & Wright, 1958). Only when similar forces have been applied during surgery to nerve roots that were already damaged or inflamed have participants reported typical radicular pain (Bogduk, 2005; Kuslich, Ulstrom, & Michael, 1991; Norlen, 1944; Rhee et al., 2006; Smyth & Wright, 1958). In addition to these experimental studies showing that mechanical compression does not necessarily lead to pain, it is also known that radiological depictions of nerve root compression do not always correlate with symptoms (Boden, Davis, Dina, Patronas, & Wiesel, 1990; Bogduk, 2005; Delauche-Cavallier et al., 1992; Jensen et al., 1994; Wiesel, Tsourmas, Feffer, Citrin, & Patronas, 1984). These findings suggest that symptomatic DHR is more complex than a purely mechanical disorder, so other pathological processes are likely to be involved (Bogduk, 2005; Lipetz, 2002; Rhee et al., 2006).

Much research has been performed investigating the role of inflammation in the pathophysiology of symptomatic DHR (Bogduk, 2005; Goupille, Jayson, Valat, & Freemont, 1998; Lipetz, 2002; Saal, 1995; Valat et al., 2010). It is thought that inflammation of the nerve root resulting from mechanical compression or contact with disc material plays a critical role in the development of symptoms associated with DHR (Bogduk, 2005; Kobayashi et al., 2004; Lipetz, 2002; Rhee et al., 2006; Saal, 1995; Valat et al., 2010). Studies have shown that cells and chemicals involved in the inflammatory process are prevalent both within degraded discs (Freemont, 2009; Le Maitre, Freemont, & Hoyland, 2005; Martin et al., 2002; Podichetty, 2007; Weiler, Nerlich, Bachmeier, & Boos, 2005) and in herniated disc material (Bogduk, 2005; Goupille et al., 1998; Habtemariam, Gronblad, Virri, Seitsalo, & Karaharju, 1998; Martin et al., 2002; Saal, 1995; Virri et al., 2001). It has also been established through experimental studies that herniated disc material can induce an inflammatory response in surrounding spinal tissues including nerve roots (Bogduk, 2005; Marshall, Trethewie, & Curtain, 1977; McCarron, Wimpee, Hudkins, & Laros, 1987; Olmarker et al., 1995), while surgeons have commonly observed inflamed nerve roots during surgery on lumbar discs (Bogduk, 2005; Greenbarg, Brown, Pallares, Tompkins, & Mann, 1988; Murphy, 1977). Inflammation may therefore be implicated in rendering a herniated disc and its related structures as symptomatic.

The previous section discussed the mechanism of nuclear migration within normal intervertebral discs during movements of the lumbar spine. Studies involving normal subjects have consistently shown that the nucleus moves or distorts posteriorly during lumbar flexion movements and anteriorly during extension (Alexander et al., 2007; Bogduk, 2005; Kolber & Hanney, 2009; Wetzel & Donelson, 2003). It is worth considering nuclear migration within abnormal discs as part of the current discussion on the pathophysiological effects of DHR. Studies have shown that nuclear migration is less predictable in damaged discs (Kolber & Hanney, 2009) but it has been hypothesised that a proportion of symptomatic discs retain similar patterns of nuclear responses to movements as those seen in normal discs (Donelson, 2011; Petersen et al., 2003; Wetzel & Donelson, 2003). This hypothesis has been extended further to propose that in damaged discs with nuclear material that has migrated posteriorly or posterolaterally through an annular tear, lumbar extension movements may have potential to temporarily relocate the displaced nuclear material into a more normal physiological location towards the centre of the disc (Donelson, 2011; Donelson, Aprill, Medcalf, & Grant, 1997; McKenzie & May, 2003; Wetzel & Donelson, 2003). Flexion movements of the lumbar spine may therefore have potential to promote the peripheral migration of nuclear material through a posterior or posterolateral annular tear (Donelson, 2011; Donelson et al., 1997; McKenzie & May, 2003; Wetzel & Donelson, 2003). The extensive pathological changes in a disc that has herniated would theoretically limit the potential for nuclear migration to occur, especially in cases of non-contained disc herniation where nuclear material has breached the outer annulus (Donelson, 2011; Donelson et al., 1997; Wetzel & Donelson, 2003). However, one experimental study showed that lumbar extension movements in cadavers with simulated DHR resulted in reduced pressure on compressed nerve roots, while flexion produced increased pressure (Schnebel, Watkins, & Dillin, 1989). Another experimental study conducted on porcine cervical spine discs found that 45% of disc protrusions that had been induced by repeated flexion movements were later relocated by repeated extension movements (Scannell & McGill, 2009). These studies indicate that even in DHR there may be potential for nuclear migration and relocation of displaced nuclear material to occur in a proportion of cases.

To summarise, the pathogenesis of DHR is a complex process that typically commences with an injury to a vertebral endplate or the annulus fibrosus that leads to

progressive disc degradation. The development of an annular fissure allows nuclear material to penetrate the annulus culminating in the herniation of disc material beyond the normal disc margin. Once a disc has herniated, mechanical and/or chemical irritation of an adjacent nerve root can result, leading to radicular pain and impaired nerve conduction. A disc herniation also has potential to impair the normal mechanism of nuclear migration in response to lumbar spine movements, although in a proportion of cases extension movements may still be associated with relocation of displaced nuclear material and a reduction in pressure exerted on an adjacent spinal nerve root.

2.4 Healing of disc herniation with associated radiculopathy

The degree to which the pathophysiological processes involved in DHR are reversible is a critical consideration when evaluating the role of treatments for this condition. Understanding the mechanisms involved in the healing of DHR allows an appreciation of how treatments for this condition may have a therapeutic effect. While the discussion of the pathogenesis of DHR commenced with the nucleus migrating through an annular fissure until a herniation occurred, recovery typically occurs in the opposite direction beginning with relocation or resorption of the herniated disc material and concluding with attempted healing of the disc itself (Adams, Stefanakis, & Dolan, 2010).

Cohort studies that have utilised serial radiological imaging have shown that disc herniations commonly reduce in size over a 3 to 24 month period, with some disappearing completely (Autio et al., 2006; Benoist, 2002; Bush, Cowan, Katz, & Gishen, 1992; Delauche-Cavallier et al., 1992; Jensen, Albert, Soerensen, Manniche, & Leboeuf-Yde, 2006; Komori et al., 1996; Maigne, Rime, & Deligne, 1992; Takada, Takahashi, & Shimada, 2001). While the previous section indicated that some potential exists for displaced nuclear material to be relocated towards the centre of the disc in response to extension movements, other mechanisms have been proposed that can also explain reductions in the size of disc herniations that have been depicted on radiological imaging. One hypothesised mechanism is based on knowledge that the nucleus is comprised primarily of water, hence dehydration of herniated nuclear material might be sufficient to lead to a substantial reduction in herniation size (Benoist, 2002; Henmi et al., 2002). Another mechanism that has been well researched is the resorption of disc material through a series of chemical and metabolic processes (Benoist, 2002; Doita, Kanatani, Harada, & Mizuno, 1996; Ito et al., 1996; Postacchini,

1999). It has been hypothesised that the formation of highly vascularised granulation tissue at the site of disc herniation plays a central role in initiating the process of disc resorption (Benoist, 2002; Doita et al., 1996; Ito et al., 1996; Postacchini, 1999). The newly established vascularised tissue is thought to promote an inflammatory and auto-immune response, bringing an influx of macrophages, fibroblasts, chondrocytes, monocytes and lymphocytes which have been shown to be present in herniated nuclear material (Benoist, 2002; Ito et al., 1996; Postacchini, 1999). These cells in turn are thought to produce chemical mediators and enzymes that break down the intracellular matrix of the disc by digesting its collagen fibres and proteoglycans, allowing the tissue to then be phagocytized (Benoist, 2002; Postacchini, 1999).

Once a herniated disc decreases in size sufficiently to reduce pressure on a nerve root, improvements in nerve function have been shown to follow in many cases. Reversal of the signs and symptoms of nerve root dysfunction have been reported following discectomy surgery (Ghahreman, Ferch, Rao, Chandran, & Shadbolt, 2009; Postacchini, Giannicola, & Cinotti, 2002) and following conservative treatment (Balague et al., 2001; Ronen et al., 2004). This includes evidence of improved nerve conduction measured via electro-diagnostic testing performed before and after treatment for DHR (Naguszewski, Naguszewski, & Gose, 2001; Osawa, Ogura, Hayashida, Mori, & Hase, 2003; Toyokura, Ishida, & Murakami, 1996). In addition to these clinical observations, animal studies have shown that impaired nerve conduction due to artificial nerve compression is reversible within hours of the compression being removed (Pedowitz et al., 1992; Rydevik et al., 1991; Sato et al., 1995). Another animal study showed that experimentally induced DHR improved to the point where nerve conduction normalised after two months (Otani et al., 1997). The recovery rate of nerve function does however seem to depend on the severity and duration of nerve compression (Pedowitz et al., 1992; Rydevik et al., 1991; Sato et al., 1995) and clinical studies confirm that the degree of functional recovery following discectomy surgery is typically more limited in people with long-standing leg symptoms (Ng & Sell, 2004; Nygaard, Kloster, & Solberg, 2000; Quigley, Bost, Maroon, Elrifai, & Panahandeh, 1998). Although the precise mechanisms involved in the recovery of nerve function are not fully understood, reduction in mechanical compression, reversal of nerve root ischaemia, remyelination of axons and reduced inflammation are all thought to play a role (Hida, Naito, & Kubo, 2003; Jancalek & Dubovy, 2007; Olmarker, 1991; Urban & Somjen, 1990; Wong & Tan, 2002).

In addition to resorption of the herniated disc material, limited healing can also occur inside the disc (Adams et al., 2010). Any breach in the outer annulus needs to be sealed to prevent further leakage of inflammatory cells or a recurrent disc herniation (Adams et al., 2010). This occurs via formation of granulation tissue along the radial fissure in the outer annulus, a process that allows ingrowth of blood vessels and nerves (Adams et al., 2010; Bron, Helder, Meisel, Van Royen, & Smit, 2009; Melrose et al., 2008; Moore, Latham, Vernon-Roberts, & Fraser, 1994; Osti, Vernon-Roberts, & Fraser, 1990). Animal studies have shown that a small degree of remodeling of the granulation tissue can occur in the outer few millimeters of the annulus until it approximates a collagen network (Adams et al., 2010; Ahlgren, Lui, Herkowitz, Panjabi, & Guiboux, 2000; Melrose et al., 2008; Moore et al., 1994; Osti et al., 1990). Although this tissue appears capable of withstanding mechanical forces as early as six weeks post injury (Adams et al., 2010; Ahlgren et al., 2000), more advanced healing continues to occur for 12 months or more (Bron et al., 2009; Melrose et al., 2008; Osti et al., 1990). However, full healing or the achievement of pre-injury disc strength is unlikely to be achieved (especially in the nucleus and inner annulus) due to the limited blood supply, low cell density and limited collagenous remodeling capabilities within the disc (Adams & Roughley, 2006; Adams et al., 2010; Beattie, 2008; Bron et al., 2009; Melrose et al., 2008; Osti et al., 1990). This could explain why clinical studies report that recurrent disc herniation occurs at a rate of 5% to 15% following discectomy surgery (Davis, 1994; Gaston & Marshall, 2003; Hakkinen, Kiviranta, Neva, Kautiainen, & Ylinen, 2007; Kim et al., 2009; Swartz & Trost, 2003) and why persistent or recurrent symptoms are common after conservative or surgical treatment for DHR (Atlas, Keller, Wu, Deyo, & Singer, 2005; Bron et al., 2009; Weber, 1983).

In summary, the healing of DHR is a complex process that requires multiple structures to recover from significant damage. Herniated disc material exhibits a good potential for resorption, and once mechanical deformation and chemical irritation of a nerve root reduces there is potential for recovery of nerve function. The damaged disc itself exhibits much less potential for healing but the outer layers of the annulus can undergo limited healing to seal a radial fissure, albeit without the achievement of normal pre-injury structure and function of the disc. Understanding the mechanisms involved in the healing of DHR could assist in developing suitable treatments that add to the natural healing process to expedite the rate of improvement.

2.5 Disc herniation with associated radiculopathy as a valid subgroup of low back disorders

Chapter 1 of this thesis discussed the classification of LBDs and it was suggested that DHR was a widely recognised pathoanatomical subgroup. In order to justify targeting this specific subgroup in the studies that appear later in this thesis, further discussion regarding the validity of DHR as a subgroup of LBDs is required. The previous sections of the current chapter have presented information relating to the terminology, anatomy, pathophysiology and healing relating to DHR. This background information informs the current section that discusses the development and validation of DHR as a subgroup of LBDs in accordance with the principles of classification validation outlined in Chapter 1.

2.5.1 Development of disc herniation with associated radiculopathy as a pathoanatomical subgroup of low back disorders

Like many pathoanatomical subgroups, DHR was initially postulated as a cause of back pain and referred leg pain by pathologists and medical practitioners during the course of their clinical practice (Stafford et al., 2007). Pathologists have reported posterior disc protrusions in cadavers since 1929 (Stafford et al., 2007) and the first description of surgical discectomy in a patient was published the same year (Dandy, 1929). A few years later Mixter and Barr made the connection between disc herniation and referred leg pain when they reported a case series where participants noted significant improvement in leg symptoms following discectomy surgery (Mixter & Barr, 1934). Today, discectomy is still considered to be an effective treatment targeting the specific pathoanatomical condition of DHR (Gibson & Waddell, 2007). The recognition of DHR as a pathoanatomical subgroup has also led to the development of other specific treatments including epidural and selective nerve root injections, and these too have demonstrated some evidence of effectiveness for the management of this condition (Armon et al., 2007; DePalma et al., 2005).

Since the initial reports of DHR approximately 80 years ago, research has provided further evidence of the link between disc herniation and clinical symptoms of radicular pain and radiculopathy (Section 2.3). The findings of this research provide evidence that DHR satisfies Bogduk's postulates for the biological plausibility of a pathoanatomical subgroup (see Section 1.2.1.2) (Bogduk, 2005). The first of Bogduk's postulates was that the hypothesised causal structure must have a nerve supply. As

described earlier in this chapter (Section 2.2), the outer 1/3 of the annulus fibrosus is innervated while the spinal nerve roots contain sensory nerve fibres with their cell bodies located in the dorsal root ganglion (Adams & Roughley, 2006; Bogduk, 2005; Rhee et al., 2006). The key structures implicated in DHR therefore have a nerve supply. The second postulate was that the involved structures must be capable of causing pain that is seen clinically. Experimental studies have shown that stimulation of intervertebral discs results in the perception of back pain and somatic referred leg pain (Adams & Roughley, 2006; Bogduk, 2005; O'Neill et al., 2002; Raj, 2008; Schafer et al., 2009), while the stimulation of a damaged or inflamed nerve root leads to characteristic radicular pain and paraesthesia (Bogduk, 2005; Kuslich et al., 1991; Norlen, 1944; Rhee et al., 2006; Smyth & Wright, 1958). Other studies have shown that compression or damage to a nerve root leads to demyelination and disrupted conduction along the nerve fibres (Bogduk, 2005; Kobayashi et al., 2004; Lipetz, 2002; Takamori et al., 2011; Valat et al., 2010), which explains the deficits in sensation, motor power and reflexes seen clinically in radiculopathy (Bigos et al., 1994; Bogduk, 2005, 2009). Furthermore, an intra-operative study performed on people undergoing discectomy showed that higher nerve root pressures exerted by disc herniations were associated with an increased chance of pre-operative neurological dysfunction, suggesting a direct cause and effect association (Takahashi, Shima, & Porter, 1999). Bogduk's second postulate is therefore satisfied for DHR. The third postulate is that the structure must be prone to injury that is known to be painful. This postulate is satisfied based on evidence that the disc is susceptible to injury, with imaging studies frequently depicting disc protrusions with associated nerve root compression (Fardon & Milette, 2001; Herzog, 1996). In addition, experimental studies have reproduced annular tears and disc herniations through excessive flexion or compression loading (Adams & Hutton, 1982, 1985; Adams & Roughley, 2006; Hadjipavlou et al., 2008). While these injuries are not always symptomatic (Deyo, Loeser, & Bigos, 1990), they are commonly associated with classic signs and symptoms that are consistently reported in many people with DHR, and this is discussed further in the next section. The final criterion required to satisfy Bogduk's postulates relates to the reliability and validity of tests used to classify people as having DHR and this is considered in the next section.

While the experimental research presented above has aided in the development of DHR as a subgroup of LBDs, additional judgmental approaches have assisted in DHR becoming a widely accepted subgroup. A study of pattern recognition amongst

musculoskeletal physiotherapists in Australia revealed that DHR was consistently recognised as a clinical pattern based on information from the history, subjective examination and physical examination of people with LBDs (Bartram, 2005). In addition, almost all clinical practice guidelines (which are developed by experts collating the best available research) recognise radicular disorders such as DHR to be a unique subgroup of LBDs (Koes et al., 2010).

2.5.2 Validation of disc herniation with associated radiculopathy as a subgroup of low back disorders

While there is good biological plausibility surrounding DHR, along with widespread recognition of this condition by experts, evidence concerning the validity and reliability of DHR as a subgroup of LBDs is required to justify research that focuses on this condition (Bogduk, 2005; Buchbinder et al., 1996; Feinstein, 1972; Ford et al., 2007). Even though the findings of experimental studies discussed in the previous section suggest that DHR is a valid pathoanatomical subgroup of LBDs, it is important to determine which clinical features have the best established validity and reliability for diagnosing this condition. A recent study has shown that there is considerable variation in the selection criteria used in clinical trials involving people purported to have DHR (Genevay et al., 2010), hence the features for diagnosing this condition are not well standardised. This discussion begins with concurrent validity of the clinical features commonly used to diagnose DHR, followed by predictive validity, discriminant validity and the reliability of assessing these features (see Section 1.2.1.3 for definitions). The clinical features of DHR that have demonstrated the highest degree of validity and reliability are summarised in a table at the end of this section.

2.5.2.1 Criterion validity: concurrent validity

In chapter 1, concurrent validity was defined as the comparison of subgroup selection criteria to reference standards with established validity (Anastasi & Urbina, 1997; Buchbinder et al., 1996; Ford et al., 2007; Portney & Watkins, 2009). When considering concurrent validity for the features used to classify (or diagnose) a person with DHR, it should first be acknowledged that no ideal reference standards exist for this condition (Deyo et al., 1994; van der Windt et al., 2010). Concurrent validity studies in this field have typically used a variety of reference standards, including electro-diagnostic testing, radiological imaging and surgical exploration (Deyo et al., 1994; van der Windt et al., 2010). While acknowledging the limitations of each of these reference standards, such studies provide one method of establishing preliminary

validity for the features that increase or decrease the likelihood that a person has DHR. The discussion requires an understanding of the terms “sensitivity” and “specificity” in relation to diagnostic testing, so these are defined in the glossary of terms (Pages xv-xvi) (Andersson & Deyo, 1996; Deyo et al., 1994; Pewsner et al., 2004).

The location of pain is generally the first clinical feature detected that suggests a person may have DHR (Andersson & Deyo, 1996). Systematic reviews have shown that the presence and location of referred leg pain is the only self-reported feature that correlates with DHR confirmed via surgical, imaging, or electro-diagnostic findings (Andersson & Deyo, 1996; Lauder, 2002; Vroomen, de Krom, & Knottnerus, 1999). The presence of referred leg pain was shown to be sensitive (0.85) but not specific (0.12) for detecting radiculopathy in a study that used electro-diagnostic testing as the reference standard (Lauder et al., 2000). Pain referring below the knee has been shown to be a sensitive feature (0.90) for identifying lower lumbar DHR but it lacks specificity (0.15) (Knutsson, 1961; Vroomen, de Krom, & Knottnerus, 1999). This indicates that lower lumbar DHR *may* be present in people with referred leg pain but it is highly unlikely to be present when leg pain is either absent or fails to extend below the knee (Andersson & Deyo, 1996; Pewsner et al., 2004). In relation to upper and mid lumbar DHR, anterior thigh pain has been shown to be the self-reported feature with the highest degree of concurrent validity (Aronson & Dunsmore, 1963; Sanderson et al., 2004; Suri et al., 2011). These findings from concurrent validity studies are also consistent with experimental studies showing typical referral patterns from stimulation of damaged nerve roots at various spinal levels (Falconer, McGeorge, & Begg, 1948; Howe et al., 1977; Kuslich et al., 1991; Norlen, 1944; Smyth & Wright, 1958).

Systematic reviews evaluating the concurrent validity of physical examination findings have reported mixed results (van der Windt et al., 2010; Vroomen, de Krom, & Knottnerus, 1999). The most sensitive physical examination finding indicative of lower lumbar DHR is a positive straight-leg-raise (SLR) test (sensitivity = 0.74 to 0.97), although its specificity has been found to be low in several studies (specificity = 0.10 to 0.82) (De Luigi & Fitzpatrick, 2011; Deville, van der Windt, Dzaferagic, Bezemer, & Bouter, 2000; Lauder, 2002; Rubinstein & van Tulder, 2008; van der Windt et al., 2010; Vroomen, de Krom, & Knottnerus, 1999). Concurrent validity studies have also shown that lower SLR angles predict a higher chance of a disc herniation being present at surgery (Hakelius & Hindmarsh, 1972; Jonsson & Stromqvist, 1993; Kosteljanetz,

Espersen, Halaburt, & Miletic, 1984). Aside from the SLR test, other physical examination findings have been shown to be more specific than they are sensitive (Andersson & Deyo, 1996; Lauder, 2002; van der Windt et al., 2010; Vroomen, de Krom, & Knottnerus, 1999), indicating they are better at ruling in DHR than they are at ruling it out (Lauder, 2002; Pewsner et al., 2004). The presence of segmental loss of motor strength has been shown to increase the likelihood of DHR being present (specificity = 0.47 to 1.0; sensitivity = 0.13 to 0.62) (Lauder, 2002; Suri et al., 2011; van der Windt et al., 2010; Vroomen, de Krom, & Knottnerus, 1999; Vroomen, de Krom, Wilmink, Kester, & Knottnerus, 2002). Depression of knee jerk or ankle jerk reflexes have shown moderate-to-high specificity (0.60 to 0.93) with lower sensitivity (0.04 to 0.61) (Hancock, Koes, Ostelo, & Peul, 2011; Lauder, 2002; Suri et al., 2011; van der Windt et al., 2010; Vroomen, de Krom, & Knottnerus, 1999; Vroomen et al., 2002), as have sensory deficits (specificity 0.57 to 0.93; sensitivity 0.28 to 0.60) (Hancock et al., 2011; Lauder, 2002; Suri et al., 2011; van der Windt et al., 2010; Vroomen, de Krom, & Knottnerus, 1999). Compromise of the upper and mid lumbar nerve roots is highly likely when there is a positive finding on the prone-knee-flexion test (specificity = 1.0; sensitivity = 0.50), a reduced patellar tendon reflex (specificity = 1.0; sensitivity = 0.28), or reduced sensation in the regions supplied by the upper and mid lumbar nerve roots (specificity = 0.96; sensitivity = 0.08 to 0.17) (De Luigi & Fitzpatrick, 2011; Suri et al., 2011).

In addition to demonstrating some degree of concurrent validity for the overall diagnosis of DHR, other studies have shown that pain location, as well as sensory, motor and reflex deficits, give an accurate indication to the side and level of the likely nerve root compromise (Bogduk, 2009; Hancock et al., 2011; Nitta, Tajima, Sugiyama, & Moriyama, 1993; Suri et al., 2011). For example, in one study where all participants had a disc herniation, sensory loss over the S1 dermatome (lateral aspect of the foot) was found to correlate with MRI demonstrating an L5/S1 disc herniation with S1 nerve root compromise (sensitivity = 0.59, 95% CI: 0.51 to 0.66; specificity = 0.60, 95% CI: 0.50 to 0.69). To standardise the spinal cord levels that comprise dermatomes and myotomes, this thesis uses the definitions outlined by the American Spinal Injury Association that appear in Table 2.1 (American Spinal Injury Association, 2002; Maynard et al., 1997). Based on the myotomes, the ankle jerk reflex was considered to be supplied primarily by the S1 nerve root, while the knee jerk reflex was considered to be supplied primarily by the L3 nerve root.

Table 2.1: Definitions of the spinal cord levels that comprise dermatomes and myotomes according to the American Spinal Injury Association (2002)

Spinal cord level	Dermatome	Myotome
L1/L2	Anterior thigh	Hip flexors
L3	Medial aspect of knee	Knee extensors
L4	Medial aspect of ankle/foot	Ankle dorsiflexors
L5	Dorsum of foot	Great toe extensor
S1	Lateral foot	Ankle plantarflexors

Studies investigating the ability of radiological imaging to detect disc herniations and nerve root impingement indicate that MRI and CT findings correlate well with surgical findings (sensitivity= 0.6 to 1.0; specificity= 0.43 to 0.97) (Fries, Abodeely, Vijungco, Yeager, & Gaffey, 1982; Herzog, 1996; Jarvik & Deyo, 2002; Kim, Kim, Lee, Kang, & Kim, 1993; Pfirrmann et al., 2004). There do not appear to be significant differences between the accuracy of MRI and CT for detecting disc herniations, with head to head comparisons showing a high degree of concurrence (Jarvik & Deyo, 2002; Mena & Sherman, 2011; Modic, Masaryk, Boumphrey, Goormastic, & Bell, 1986; Thornbury et al., 1993; van Rijn et al., 2006). However, CT and MRI have been shown to be superior to myelography due to their higher concurrent validity in relation to surgical findings (Fagerlund & Thelander, 1989; Gillstrom, Ericsson, & Hindmarsh, 1986; Jackson et al., 1989). This may be due to the fact that myelography does not allow direct visualisation of herniated discs (Fagerlund & Thelander, 1989). There are limitations to CT and MRI as well, namely that morphological depictions of disc herniations on imaging do not definitively determine whether these abnormalities are the cause of symptoms (Deyo, Loeser et al., 1990). Several studies have found that disc herniations tend to be present on CT or MRI in 20-35% of people with no history of back pain (Boden et al., 1990; Herzog, 1996; Jackson et al., 1989; Jensen et al., 1994; Wiesel et al., 1984). In addition, disc herniations can remain radiologically unchanged following symptomatic recovery from DHR (Delauche-Cavallier et al., 1992; Maigne et al., 1992). These findings may be due to the fact that the pathophysiology of symptomatic DHR is more complex than a purely mechanical disorder, as discussed in Section 2.3. Nonetheless, it has been shown that disc herniations depicted on radiological imaging are considerably less likely to be asymptomatic than disc bulges or degeneration (which have been detected

in up to 50% of asymptomatic adults), while disc extrusions are almost always symptomatic (being found in only 1% of people with no symptoms) (Boden et al., 1990; Jensen et al., 1994; Weishaupt, Zanetti, Hodler, & Boos, 1998). In addition, nerve root compromise has been shown to be rare in MRI scans performed on asymptomatic populations, with one study reporting a 1.6% rate of nerve root compression and a 4% rate of nerve root deviation in people without back or leg symptoms (Weishaupt et al., 1998).

While no individual feature of DHR discussed above appears to have demonstrated optimal values of both specificity and sensitivity, several studies have shown that these values can be altered by combining the results of multiple tests that assess features indicative of DHR (Lauder, 2002; Lauder et al., 2000; Morris, Di Paola, Vallance, & Waddell, 1986; Suri et al., 2011; van der Windt et al., 2010; Vroomen, de Krom, & Knottnerus, 1999; Vroomen et al., 2002). Studies that have evaluated the concurrent validity of combining two or more positive tests have shown that this practice increases specificity but reduces sensitivity (Hancock et al., 2011; Lauder et al., 2000). For example, in one study that compared a range of symptoms and physical examination findings to electro-diagnostic confirmation of radiculopathy showed that an absent reflex had a specificity of 0.87 and a sensitivity of 0.25 (see Figure 2.5) (Lauder et al., 2000). By requiring four features of DHR to be present (absent reflex, reduced sensation, motor weakness and a positive SLR), the specificity increased to 0.99 while the sensitivity reduced to 0.06 (Figure 2.5) (Lauder et al., 2000). Studies that have allowed a diagnosis of DHR to be made when any one out of several features were present have demonstrated higher sensitivity values but lower specificity (Hancock et al., 2011; Lauder et al., 2000; Suri et al., 2011). To continue the previous example, when any one feature of DHR was present (out of absent reflex, reduced sensation, motor weakness, or a positive SLR), the specificity reduced to 0.35 while the sensitivity increased to 0.87 (Figure 2.5) (Lauder et al., 2000). Relatively high values of both sensitivity and specificity have been reported in two studies that allowed a neurologist to make an overall diagnosis of DHR following an interview and physical examination with the participants (Hancock et al., 2011; Vroomen et al., 2002). For example, in one of the studies the sensitivity of the neurologist's opinion for diagnosing an L5/S1 disc herniation was 0.77 (95% CI: 0.70 to 0.84) while the specificity was 0.83 (95% CI: 0.75 to 0.90) (Hancock et al., 2011). The above studies have not however

established a standardised and reproducible set of features for the diagnosis of DHR that are both highly sensitive and highly specific.

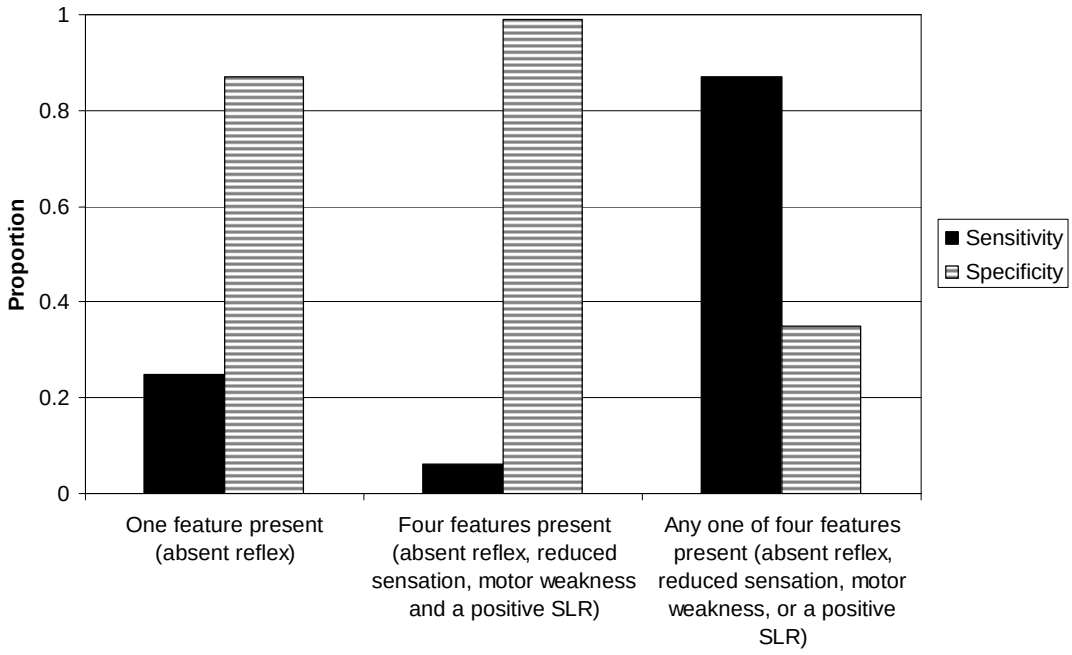


Figure 2.5: Graph showing the influence of combining multiple features on the sensitivity and specificity for diagnosing disc herniation with associated radiculopathy

To summarise this section relating to the concurrent validity of features that indicate a diagnosis of DHR, it appears that there are limitations with relying on any individual test. Referred leg symptoms are an indicator that DHR may be present but many people with these symptoms have other pathologies aside from DHR. The straight-leg-raise test is usually positive in people with lower lumbar DHR but again this test lacks diagnostic specificity. Lower limb neurological examination findings are a sign that radiculopathy is likely to be present but they do not indicate the precise cause of the nerve root dysfunction. Radiological imaging findings are able to accurately depict morphological features such as disc herniations and nerve root compromise but some of these features are also seen in asymptomatic people. Specificity can be improved by requiring several features of DHR to be present before a diagnosis is made, while sensitivity can be increased by allowing any one of a number of features to be present. A neurologist's overall decision following assessment of the participant seems to result in high sensitivity and specificity values for the diagnosis of DHR. There are not, however, any standardised and accepted combinations of features that are known to be ideal for diagnosing this condition. This finding appears to be reflected in research

studies that target people with DHR, as the inclusion criteria in such studies vary widely but commonly require a combination of features from different aspects of the condition including symptoms, physical examination findings and radiological imaging results (Genevay et al., 2010).

2.5.2.2 Criterion validity: predictive validity

Another method of validating a subgroup and determining its key diagnostic features is to demonstrate the ability of those features to predict future outcomes (see Section 1.2.1.3) (Anastasi & Urbina, 1997; Buchbinder et al., 1996; Ford et al., 2007; Portney & Watkins, 2009). There is evidence to suggest that people with DHR achieve different outcomes to people with other LBDs. The presence of the most basic feature of potential DHR, referred leg pain, predicts poorer future outcomes compared to low back pain without referral (O'Hearn, 1997; Selim et al., 1998; van der Weide et al., 1999; Waddell et al., 2003). Furthermore, people with referred pain extending below the knee have been shown to achieve inferior outcomes to those with back pain alone or referred pain localised above the knee (Cherkin et al., 1996; Loisel et al., 2002). For example, calculations made from the raw data of one study showed that people with pain referring below the knee had a significantly higher chance of unsatisfactory outcome at 12 month follow-up compared to those without this symptom (odds ratio for unsatisfactory outcome= 2.4, 95% CI: 1.2 to 5.0) (Cherkin et al., 1996). When additional features of DHR are also present such as physical examination findings and imaging studies, people diagnosed with DHR based on these multiple features have been shown to have a lower chance of returning to work compared to those with other LBDs (odds ratio for returning to work at 6 month follow-up = 0.14, 95% CI: 0.02 to 0.78) (Heymans et al., 2007).

While in the above predictive validity studies people with features of DHR were found to achieve inferior outcomes to those with non specific LBDs, other studies have shown that DHR is associated with *better* outcomes than other causes of radiculopathy such as spinal canal stenosis or spondylolisthesis (Atlas, Deyo, Patrick et al., 1996; Bejia et al., 2004; Deyo, 2007). One study involving 1092 people with sciatica showed that people with DHR had a higher chance of achieving a good outcome (defined as adequate pain relief, returing to all functional activities, and not requiring further treatment) compared to those with spinal stenosis or spondylolisthesis (odds ratio for obtaining a good outcome, calculated from raw data = 1.5, 95% CI: 1.1 to 2.1) (Bejia et al., 2004). While

this finding provides further evidence supporting the predictive validity of DHR, it also demonstrates the importance of distinguishing between DHR and other causes of radiculopathy in clinical trials (Deyo, 2007). This distinction between different pathoanatomical causes of radiculopathy can only be achieved accurately via radiological imaging (Bogduk, 2009; Herzog, 1996).

2.5.2.3 Construct validity: discriminant validity

Discriminant validity was defined in Chapter 1 as the degree to which a subgroup can be discriminated from others based on variables that measure constructs relevant to LBDs (Anastasi & Urbina, 1997; Buchbinder et al., 1996; Ford et al., 2007; Portney & Watkins, 2009). There appears to be considerable evidence that people with DHR typically present with distinctive indicators of higher injury severity compared to people with other LBDs (Atlas, Deyo, Patrick et al., 1996; Loisel et al., 2002; Ren et al., 1999; Selim et al., 1998). On this basis, a person presenting with a low severity of pain and activity limitation would be less likely to have DHR as opposed to another LBD.

People with pain radiating below the knee were shown in one study to have a significantly higher chance of scoring more than 20 at baseline on the McGill Pan Questionnaire than those with localised back pain (odds ratio for scoring > 20 = 7.8, 95% CI: 2.2 to 32.0) (Loisel et al., 2002). The same study showed a trend towards a greater chance of scoring more than 20 at baseline on the McGill Pain Questionnaire in people with referred pain above the knee compared to people with localised back pain but this underpowered comparison was not statistically significant (odds ratio for scoring > 20 = 2.3, 95% CI: 0.6 to 9.3). Another study has shown that people with pain referring below the knee plus signs of nerve root compression (based on physical examination or radiological imaging) had greater activity limitation at baseline compared to those with proximal referred leg pain and no nerve compression signs (mean between group difference for activity limitation on the Roland Morris = 2.2, $p<.05$) (Atlas, Deyo, Patrick et al., 1996). Two other cross-sectional studies have shown that people with referred leg pain (above or below the knee) and a positive straight leg raise had significantly higher pain intensity scores, lower quality of life, higher medication use, higher use of radiological imaging, more work absences and higher rates of surgery compared to those with localised back pain (Ren et al., 1999; Selim et al., 1998). Figure 2.6, created using data from Selim et al. (1998), shows the

increasingly higher chances of a person utilising medication, MRI scans and surgery when additional diagnostic features of DHR are present relative to people with low back pain alone.

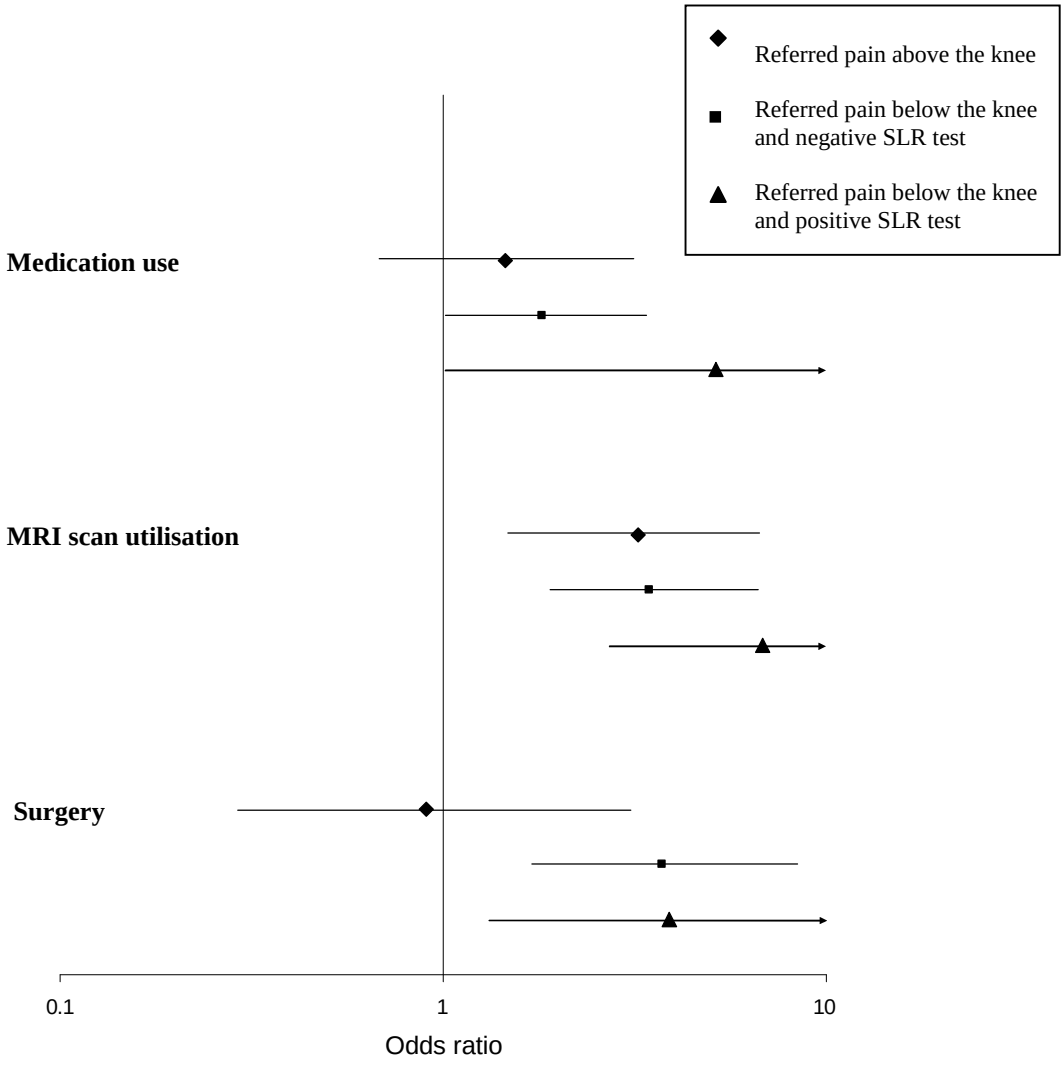


Figure 2.6: Forest plots showing increased chances of utilisation of medication, MRI scans and surgery in people with different diagnostic indicators of disc herniation with associated radiculopathy compared to people with low back pain (odds ratio for back pain alone = 1.0, error bars represent 95% CI's)

In addition to the distinction between DHR and other non-specific LBDs, there is evidence that DHR can be distinguished from radiculopathy caused by other pathologies based on symptom severity. One study showed that people with referred leg pain plus nerve root compression had greater activity limitation and more frequent leg symptoms at baseline than those with a confirmed diagnosis of spinal canal stenosis (mean between group difference in activity limitation measured on the Roland Morris =

3.6, $p<.005$, mean between group difference on the sciatica frequency scale = 6.1, $p<.005$) (Atlas, Deyo, Patrick et al., 1996).

The above evidence indicates that people with DHR differ from people with other LBDs or other causes of radiculopathy across a range of constructs. This provides additional support for the validity of DHR and its associated features.

2.5.2.4 Reliability

The above sections have presented evidence relating to the validity of features commonly used to classify (or diagnose) a person as having DHR. The identification of these features in people with LBDs is dependent on the reliability of tests that determine whether these features are present. The primary purpose of this section is to examine the reliability of tests that aim to determine the presence or absence of the features that were found in the previous sections to have established validity for the classification of DHR. The reliability papers in this section either reported intraobserver and interobserver agreement using the kappa statistic (K), or their raw data allowed these calculations to be performed. The terminology used to describe the degree of agreement in this section is consistent with the qualitative terms proposed by Landis and Koch in relation to K values: 0.0 to 0.2 (slight agreement), 0.2 to 0.4 (fair), 0.4 to 0.6 (moderate), 0.6 to 0.8 (substantial) and 0.8 to 1.0 (almost perfect) (Landis & Koch, 1977). The discussion of reliability is divided into the three main categories of features that were found to be indicative of DHR in Section 2.5.2.1; reliability of symptom reporting, physical examination tests and radiological imaging findings. Finally, the reliability of making an overall diagnosis of DHR based on multiple tests is explored.

As the presence and location of referred leg symptoms were found to have some evidence of concurrent, predictive and discriminant validity, the reliability of patient reporting of symptom location was of particular interest. Reliability studies on patient self-reports of symptom location have utilised the pain drawing, which allows a person to draw their area of perceived symptoms onto a body chart (Uden, Astrom, & Bergenudd, 1988). These studies have shown that the determination of pain location (including pain radiation into the leg) can be reliably assessed using this instrument (K = 0.55, 95% CI: 0.20 to 0.90 for rating the presence versus absence of referred leg pain) (Ford, Story, & McMeeken, 2009; Margolis, Chibnall, & Tait, 1988). No studies were

located that assessed the reliability of judging whether a person's pain extends below the knee or not, although the reliability of determining the presence of distal paraesthesia has been found to be moderate (K = 0.57, 95% CI: 0.22 to 0.92) (Ford et al., 2009).

The interobserver reliability of physical examination tests relevant to DHR has been assessed in a study involving participants with suspected nerve root compression (Vroomen, de Krom, & Knottnerus, 2000). Based on K values ranging from 0.42 (95% CI: 0.38 to 0.46) to 0.82 (95% CI: 0.80 to 0.84) which represent moderate to almost perfect agreement, there was evidence that the assessment of segmental motor strength, dermatomal sensation, reflexes, SLR and prone knee flexion were all reliable. In the case of the SLR, different methods were compared for defining a positive test, with the determination of whether the participant's typical clinical leg symptoms had been reproduced at any angle during raising of the leg (K = 0.68, 95% CI: 0.67 to 0.69) found to be more reliable than the determination of whether any pain had been reproduced at an angle of less than 45° (K = 0.43, 95% CI: 0.41 to 0.45).

Reliability studies investigating radiological imaging have shown that the interobserver and intraobserver agreement for classifying disc morphology (eg. normal, bulge, protrusion, extrusion or sequestration) using CT or MRI ranges from moderate to almost perfect (between K = 0.57, 95% CI: 0.51 to 0.64 and K = 0.81, 95% CI: 0.78 to 0.85) (Brant-Zawadzki, Jensen, Obuchowski, Ross, & Modic, 1995; Herzog, 1996; Lurie et al., 2008). More specifically, the ability of radiologists to distinguish between a herniated versus a non-herniated disc using MRI or CT is associated with substantial to almost perfect levels of agreement, with K values ranging between 0.61 (95% CI: 0.50 to 0.72) and 0.80 (95% CI: 0.71 to 0.88) (Brant-Zawadzki et al., 1995; Herzog, 1996; van Rijn et al., 2006; van Rijn et al., 2005). Categorisation of the degree of nerve root impingement (no contact, contact, deviation, or compression) using MRI has shown moderate to substantial intraobserver and interobserver agreement (between K = 0.47, 95% CI: 0.36 to 0.56 and K = 0.75, 95% CI: 0.67 to 0.83) (Lurie et al., 2008; Pfirrmann et al., 2004; van Rijn et al., 2005). While CT scans are also able to detect nerve root impingement, they have been shown to be less reliable than MRI for this purpose based on a head-to-head comparison (K= 0.59 for CT vs K = 0.78 for MRI; p=.01) (van Rijn et al., 2006).

The previous sections relating to the validity of features indicative of DHR concluded that a combination of tests might lead to a more accurate diagnosis, although no standardised battery of tests has been established for this purpose. The reliability of individual tests that are used to identify the key features of DHR was discussed above. However, another reliability issue relates to the overall judgement as to whether a person has DHR or not. While two observers may agree that an ankle jerk reflex is absent in a particular person, they may disagree as to whether that person has DHR or not. One study was identified that assessed the overall reliability of judging whether people with back and leg symptoms have nerve root compression presumed to be caused by a disc herniation (Vroomen, de Krom, & Knottnerus, 2000). In that study, two neurologists independently examined 91 people with back and leg symptoms using a standardised battery of tests relating to history, subjective assessment and physical examination. The interobserver agreement was found to be substantial, as indicated by a K value of 0.66 (95% CI: 0.64 to 0.68). This indicates that an overall diagnosis of DHR can be reliably made based on a battery of tests, although it is not clear from that study which tests were the most influential upon the final diagnostic decision made by the two neurologists.

In summary, the reliability of assessing the key diagnostic features of DHR appears to be mixed, however several tests have demonstrated levels of intraobserver and interobserver agreement ranging from moderate to almost perfect. A reliable diagnosis of DHR can be made by considering the results of a battery of tests that assess the key features that are indicative of this condition, although it is not clear which tests have the greatest influence on the overall diagnostic decision.

2.5.2.5 Section summary

To conclude this major section relating to the validation of DHR as a subgroup of LBDs, Table 2.2 presents a summary of the key features of DHR that have acceptable levels of reliability and validity. The information in this table is utilised in the remainder of this thesis when establishing the selection criteria to be employed in each of the research studies. Given that no individual feature has very high levels of reliability and validity, it has been recommended that more than one feature should be present to increase the specificity of diagnosing DHR (Lauder, 2002; Morris et al., 1986; Suri et al., 2011; van der Windt et al., 2010; Vroomen, de Krom, & Knottnerus, 1999; Vroomen et al., 2002). This recommendation is commonly followed in research

trials, with a review article showing that most RCTs targeting people with DHR require participants to have several features indicative of this condition in order to be included (Genevay et al., 2010). In addition to the acceptable reliability and validity of the key features for diagnosing DHR in Table 2.2, this condition has well established biological plausibility, widespread recognition and significant convergence of validity as a distinct subgroup of LBDs.

Table 2.2: Summary of diagnostic features for disc herniation with associated radiculopathy that have acceptable levels of reliability and validity

Feature	Reliability kappa (95%CI)	Concurrent validity Sensitivity	Concurrent validity Specificity	Predictive validity (Y / N)	Discriminant validity (Y / N)
Presence of any referred leg pain	0.55 (0.20 to 0.90)	0.85	0.12	Y	Y
Referred symptoms below the knee	0.57 (0.22 to 0.92) (paraesthesia)	0.90	0.15	Y	Y
Presence of disc herniation on MRI or CT	0.61 (0.50 to 0.72) to 0.80 (0.71 to 0.88)	0.6 to 1.0	0.43 to 0.97	Y	Y
Straight-leg-raise	0.68 (0.67 to 0.69)	0.74 to 0.97	0.10 to 0.82	Y	Y
Prone knee flexion test (for upper to mid lumbar DHR)	0.47 (0.45 to 0.49)	0.28	1.0	N	N
Segmental sensory reduction	0.71 (0.69 to 0.73)	0.28 to 0.60	0.57 to 0.93	Y	Y
Segmental motor weakness	0.59 (0.56 to 0.62) to 0.82 (0.80 to 0.84)	0.13 to 0.62	0.47 to 1.0	Y	Y
Reflex impairment	0.42 (0.38 to 0.46) to 0.53 (0.51 to 0.55)	0.04 to 0.61	0.60 to 0.93	Y	Y

2.6 Prevalence of disc herniation with associated radiculopathy

The varying terminology and range of features that have been used for diagnosing DHR in the past presents a challenge when it comes to estimating the prevalence of this condition (Bogduk, 2009; Genevay et al., 2010; Tarulli & Raynor, 2007; Van Boxem et al., 2010). Consequently, many prevalence studies have focused on conditions that are

less specific than DHR such as sciatica or radiculopathy. For example, systematic reviews of prevalence studies have concluded that the lifetime prevalence of "sciatica" ranges between 1.2% and 43.0% (Konstantinou & Dunn, 2008; Stafford et al., 2007). Many of the original studies in those systematic reviews relating to sciatica do not provide a valid estimate of the prevalence of DHR, as the previous section showed that the area of leg symptoms is not sufficient on its own to accurately diagnose DHR due to its low specificity.

An estimate of the prevalence of disc herniation has been made from a large population survey conducted between 1976 and 1980 in the United States of America (Deyo & Tsui-Wu, 1987). In that survey, 2.1% of respondents had previously been told by a medical specialist that they had a "ruptured disc" (Deyo & Tsui-Wu, 1987). A more recent survey of an Australian population in 2004-05 estimated that the point prevalence of "slipped disc" was 5.4% (a total of 1.059 million people) (Australian Institute of Health and Welfare, 2009). The accuracy of these estimates would be affected by limitations with patient recall and comprehension, as well as by the diagnostic ability of thousands of different medical practitioners across those countries who may use different features to diagnose the condition.

A Finish epidemiological study went beyond patient self-reporting by physically examining a representative sample (7217 people) of the population aged above 30 years (Heliovaara et al., 1987). That study reported a point prevalence of "lumbar disc syndrome" (diagnosed via medical history, symptom distribution, standardised physical examination and imaging in some cases) of 5.1% for men and 3.7% for women. In another population survey in Tunisia, the annual self-reported incidence of "disc-related sciatica" was 2.2%, with 45% of respondents possessing a CT scan that confirmed this diagnosis (Younes et al., 2006). These two studies appear to provide the most plausible prevalence estimates for DHR since the diagnosis was made by combining multiple features with established reliability and validity (Section 2.5.2).

In relative terms, it has been estimated that DHR accounts for 5-12% of all LBDs (Bogduk, 2005; Deyo & Tsui-Wu, 1987; Friberg, 1954; Mooney, 1987). These figures are supported by data from the United States of America estimating that DHR accounts for 11% of all back-related physician visits (Hart, Deyo, & Cherkin, 1995). Within the diagnosis of DHR, it has been estimated that upper and mid lumbar DHR accounts for

10% of all DHR cases, with the majority occurring at L4/5 and L5/S1 (Suri et al., 2011).

In summary, although it is difficult to precisely determine the incidence and prevalence of DHR, it appears that it may account for 5-12% of all LBDs, with an estimated population prevalence of 2-5%. While these rates indicate that recruiting participants for research relating to DHR may be more challenging than for other LBDs that are more prevalent, the importance of establishing effective conservative treatments for DHR makes this a challenge worth pursuing.

2.7 Chapter summary

In a thesis focusing on a pathoanatomical LBD subgroup, this chapter has provided important background information relating to DHR. As terminology relevant to DHR has not always been well defined in the literature, the meaning of key terms was established in this chapter so they could be used consistently throughout the remainder of the thesis. The anatomy and pathophysiology relevant to DHR was discussed, revealing that mechanical and inflammatory processes both play a role in the development of symptoms and signs that characterise this condition. The healing potential of DHR was considered, along with a description of the known or hypothesised mechanisms involved in the healing process. The pathophysiology and healing information is utilised later in the thesis to develop and justify a treatment protocol to be evaluated in the RCT. To justify targeting people with DHR in the RCT, a case was presented that this condition is a well established and widely recognised LBD subgroup, while evidence was summarised regarding the most valid and reliable tests for diagnosing this condition. The reliability and validity associated with the key diagnostic features for DHR are used to guide the establishment of selection criteria for the studies that comprise the remainder of this thesis. The key diagnostic features also allowed the prevalence of DHR to be estimated at between 2% and 5%, which accounts for approximately 5-12% of all LBDs. The next chapter of the thesis considers the effectiveness and safety of conservative treatments for DHR.

CHAPTER 3: A SYSTEMATIC REVIEW OF THE EFFECTIVENESS AND SAFETY OF CONSERVATIVE MANAGEMENT FOR LUMBAR DISC HERNIATION WITH ASSOCIATED RADICULOPATHY

The use of classification to identify subgroups within the domain of LBDs has been identified as an important research priority. A primary purpose of classification is to aid with the identification, development and evaluation of suitable treatments for specific subgroups (Billis et al., 2007; Ford et al., 2007; Hancock et al., 2007; Miller Spoto & Collins, 2008). Having justified the existence of DHR as a pathoanatomical subgroup in the previous chapter, the remainder of this thesis considers the conservative management of this condition. The aim of the current chapter is to evaluate the effectiveness and safety of existing conservative treatments for DHR. To place this discussion into context, the natural history of DHR is briefly considered, while evidence relating to the effectiveness and safety of invasive treatments (surgery and injections) is presented from existing literature reviews. The absence of existing systematic reviews relating specifically to conservative treatments for DHR is then noted. The remainder of this chapter fills this gap in the literature by presenting an original systematic review evaluating the effectiveness and safety of conservative treatments for people with a clinical and radiological diagnosis of DHR.

3.1 Introduction

3.1.1 Natural history of disc herniation with associated radiculopathy

The natural history of a disorder refers to the degree and duration of recovery without treatment (Hestbaek et al., 2003). If the natural history of a disorder is very positive, such as with the common cold (Arruda, Pitkaranta, Witek, Doyle, & Hayden, 1997), then no specific medical treatment may be necessary. Understanding the natural history of a disorder is therefore important before the effectiveness of treatment for that disorder can be considered (Hestbaek et al., 2003; Weber, 1994).

It is difficult to estimate the natural history of DHR, since in most cases some form of treatment is sought. Narrative reviews on the natural history of DHR have discussed studies involving people without confirmed DHR, or studies where conservative treatments were received by participants making it difficult to distinguish natural history from therapeutic effects (Benoist, 2002; Casey, 2011; Weber, Holme, & Amlie, 1993). Even with individual cohort studies that claim to evaluate the natural history of

DHR, conservative interventions (including injections) were received by participants (Bush et al., 1992; Cowan, Bush, Katz, & Gishen, 1992; Komori et al., 1996; Saal, Saal, & Herzog, 1990; Takada et al., 2001). While many participants in these studies have achieved improvement in symptoms, activities and nerve function, along with a reduction in the size of their disc herniations, it is not possible to determine whether these changes would occur without the treatment that they received.

The research outlined in Section 2.4 relating to the healing of DHR allows some presumptions to be made about the likely natural history of this condition. That section referred to animal studies showing that disc herniations can reduce in size over time without treatment, while the function of compressed or inflamed nerve roots can improve once a disc herniation abates. These findings suggest that there is a reasonable capacity for improvement in the symptoms and neurological signs associated with DHR without treatment. The slow and limited healing properties of the intervertebral disc however suggests that full recovery from DHR is unlikely to be achieved in most cases, with a distinct risk of persistent pain and recurrent disc herniation (Section 2.4).

In addition to the insights that animal research offers, inferences can be made about the likely natural history of DHR by reviewing clinical trials where participants (in either the intervention or the control group) received minimal intervention. Although this does not directly measure the natural history of DHR, it does provide an estimate of the outcomes that could be expected if no treatment were received. One study compared advice to remain active versus two weeks of bed rest in 183 people with “sciatica” (Vroomen, De Krom, Wilmink, Kester, & Knottnerus, 1999). Although MRI was performed on all participants without the prevalence of disc herniation being reported, the prevalence of nerve root compression (due to unreported cause) was 60%. This study showed that after 12 weeks, 87% of participants in both groups reported at least some improvement and 71-76% had returned to work, however 40% required additional treatment. Furthermore, 18% of the trial participants had undergone surgery within 6 months of entry to the trial (Vroomen, De Krom, Wilmink et al., 1999).

In the absence of highly relevant studies that would allow the natural history of DHR to be deduced over a longer timeframe, the results of the Maine Lumbar Spine Study were considered as an estimate. That was a cohort study involving 232 participants with “sciatica” who chose conservative over surgical treatment (Keller et al., 1996). All

participants had pain referring below the knee (Keller et al., 1996) but radiology was performed in only 80% of cases and the results were not disclosed (Atlas, Deyo et al., 1996a). Treatment methods were at the discretion of each participant and their treating medical practitioner but included a range of conventional treatments such as exercises and physical therapy that were mainly administered in the first three months of the ten year observation period (Atlas, Deyo et al., 1996a). One year outcomes revealed that only 55% of participants reported any improvement in back or leg pain, while 8.2% had undergone discectomy surgery (Atlas, Deyo et al., 1996a). By five years, the proportion of participants noting improvement in back or leg pain remained unchanged but the rate of surgery had increased to 16.2% (Atlas, Keller, Chang, Deyo, & Singer, 2001). Ten year symptomatic outcomes were slightly better, with 59% and 64% of participants reporting some improvement in back and leg pain respectively, however the rate of surgery had increased further to 25% (Atlas et al., 2005). The number of participants who reported that their primary symptom had completely resolved compared to baseline was only 11.4%, 11.6% and 16.6% at the one, five and ten year follow-ups respectively, indicating that full symptomatic recovery was rare (Atlas, Deyo et al., 1996a; Atlas et al., 2001; Atlas et al., 2005).

With regards to recurrence of symptoms, only one relevant study was located that reported on this outcome. A 24% rate of recurrence within four years was reported among conservatively treated participants with DHR (Weber, 1983).

To summarise, there appear to be no current studies that have definitively determined the natural history of DHR without treatment. Some inferences have been drawn from clinical studies but these should be interpreted cautiously due to the use of selection criteria that are not optimal for diagnosing DHR (see Section 2.5.2) and also due to the fact that some treatment was received by participants in all studies. It does, however, appear likely that the majority of people with DHR achieve some improvement over time with treatment, particularly in the first year, although full recovery is uncommon even after 10 years. Future recurrence and transfer to surgical management both appear relatively common outcomes in conservatively treated participants. These findings appear consistent with the studies discussed in Section 2.4 relating to the healing mechanisms associated with DHR. There appears to be ample scope for treatments to improve upon the likely natural history of this condition.

3.1.2 Surgical treatment of disc herniation with associated radiculopathy

Discectomy surgery is a treatment that directly addresses the pathophysiology of DHR (see Section 2.3). Surgical removal of the herniated portion of a disc immediately eliminates mechanical compression on a nerve root which is a pathological process known to be involved in the production of leg pain and radiculopathy. A systematic review concluded that discectomy provides faster relief of leg symptoms than conservative treatment in people with DHR but there are no long term differences in outcomes between these approaches (Gibson & Waddell, 2007). The authors of that review acknowledged that their conclusions were suggestive rather than definitive due to methodological limitations in the four relevant trials, including a large proportion of participants changing treatment groups (Gibson & Waddell, 2007). Although back pain can also be relieved following discectomy, a 30-40% rate of significant ongoing back pain has been reported (Atlas et al., 2005; Parker et al., 2010). The cost of managing post-surgical back pain has been estimated at US$15,418 per patient (Parker et al., 2010). Studies have also reported a 5-15% rate of recurrent disc herniation following discectomy (Ambrossi et al., 2009; Davis, 1994; Gaston & Marshall, 2003; Hakkinen, Kiviranta et al., 2007; Kim et al., 2009; Swartz & Trost, 2003), with the average cost of managing these recurrences estimated at US$26,593 per case (Ambrossi et al., 2009). These findings are consistent with the healing potential of DHR outlined in Section 2.4, which suggested that full healing of the disc itself is unlikely to occur even after the herniated portion of the disc recedes or is removed via surgery.

There appear to be some risks associated with discectomy surgery, with studies estimating a less than 1% chance of catastrophic adverse events such as death or major neurological damage (Hoffman, Wheeler, & Deyo, 1993; Ramirez & Thisted, 1989). Less severe adverse events include haemorrhage, infection, nerve root injury, dural tear, epidural scar formation, discitis, arachnoiditis, pseudomeningocele, facet joint fracture and epidural haematoma (Awad & Moskovich, 2006; Swartz & Trost, 2003). The incidence of at least one such adverse event occurring in a person undergoing discectomy has been estimated at 15-30% (Swartz & Trost, 2003).

3.1.3 Injection therapy for disc herniation with associated radiculopathy

While the surgical removal of a herniated portion of disc material relieves mechanical compression on a nerve root, Section 2.3 noted that inflammation also plays a key role in the pathophysiology of DHR. For this reason, injection of corticosteroid to reduce

inflammation of a nerve root is another treatment that directly targets the pathophysiology of DHR (Abdi et al., 2007). Epidural corticosteroid injections can be delivered via a caudal, interlaminar or transforaminal approach (with the later also know as selective nerve root injections) (Abdi et al., 2007). Systematic reviews have concluded that all three types of epidural corticosteriod injections are effective for providing short term (less than 6 weeks) relief of leg symptoms in people with DHR but longer term effects are typically absent (Abdi et al., 2007; Armon et al., 2007; DePalma et al., 2005).

Several risks are known to be associated with epidural corticosteroid injections, with the reported incidence of any complication ranging from 10% to 34% per injection (Abdi et al., 2007). The most common adverse effects include dural puncture and associated headache, vasovagal reactions, increased back or leg pain, intravascular injection, as well as some systemic effects of corticosteroid administration (such as weight gain, insomnia, suppression of the pituitary-adrenal axis, Cushing's syndrome and facial flushing) (Abdi et al., 2007; Armon et al., 2007; DePalma et al., 2005). Other less common adverse events include infection, meningitis, epidural abscess, spinal cord or nerve damage, hypertension, hyperglycemia, dizziness, vomiting and urinary retention (Abdi et al., 2007; Armon et al., 2007; DePalma et al., 2005; Stafford et al., 2007).

3.1.4 Conservative treatment for disc herniation with associated radiculopathy

The collation of evidence regarding the effectiveness of discectomy surgery and epidural injections in the previous sections was aided by existing systematic reviews that have focussed specifically on people with a clinical and radiological diagnosis of DHR (Abdi et al., 2007; Armon et al., 2007; DePalma et al., 2005; Gibson & Waddell, 2007). All papers included in those reviews required participants to have clinical signs and symptoms consistent with DHR, as well as radiological evidence of the likely cause of the symptoms. No such reviews were located for the collation of evidence relating to the conservative and non-injection management of people with a specific diagnosis of DHR.

Although no existing systematic reviews have utilised strict selection criteria for the evaluation of the effectiveness of conservative treatments for DHR, two reviews have evaluated the evidence relating to conditions approximating DHR. One of these

reviews included RCTs involving participants with sciatica of unconfirmed cause (Vroomen, de Krom, Slofstra, & Knottnerus, 2000). The other review on "lumbo-sacral radicular syndrome" included trials involving anyone with referred leg symptoms, again of unconfirmed cause (Luijsterburg et al., 2007). As discussed in Section 2.5.2.1, the presence of self-reported leg symptoms alone is an indicator that DHR *may* be present but it is not sufficient for diagnosing this condition with a high degree of specificity. As a result of the broad selection criteria utilised in these previous systematic reviews, participants with a wide variety of conditions aside from DHR were included in the individual trials. As discussed in Section 1.2.1, sample heterogeneity is considered to be a major reason why RCTs and systematic reviews find low effect sizes or no difference between interventions (Atlas, Deyo, Patrick et al., 1996; Ford et al., 2007; Foster, Hill et al., 2010; Fritz et al., 2007; Kent & Keating, 2004). This may be one explanation as to why both of the reviews cited above concluded that no conservative treatments are more effective than either no treatment or other interventions for people with lumbosacral radicular syndrome (Luijsterburg et al., 2007) or sciatica (Vroomen, de Krom, Slofstra et al., 2000). By focussing on participants with a more precise diagnosis of DHR based on both clinical symptoms and radiological imaging, the issue of sample heterogeneity could be reduced leading to stronger conclusions about the effectiveness of conservative treatments for this specific condition.

The remainder of this chapter presents a systematic review evaluating the effectiveness of conservative treatments for people with symptomatic and radiological evidence of DHR. This systematic review also describes adverse effects that were reported in the included RCTs. The published version of this systematic review appears in Appendix A (Hahne, Ford, & McMeeken, 2010).

3.2 Methods

The methodology in this review was guided via published guidelines produced by the Cochrane Collaboration (Higgins & Green, 2006; van Tulder, Furlan, Bombardier, & Bouter, 2003), as well as the QUORUM statement (Moher et al., 1999).

3.2.1 Criteria for selecting trials in this review

3.2.1.1 Types of trials

All full reports of RCTs were eligible to be included if they were published in English between 1st January 1971 and 31st August 2008. Trials published earlier than 1971 could not have been eligible as CT and MRI were not in use (Beckmann, 2006). As this systematic review was undertaken as the first in a series of studies that comprised this thesis, it was completed well before the thesis was submitted. The search was not updated for the thesis because any new findings could not have been applied to the subsequent studies that commenced immediately following the systematic review based on the evidence base at that time.

3.2.1.2 Types of participants

Trials were included if they involved participants aged over 18 years who had referred leg symptoms either with or without low back pain, where at least 75% of the participants had confirmation of a disc herniation via CT or MRI. Trials verifying disc herniation with myelography alone were excluded, as disc herniations are not directly visualised or accurately diagnosed with this technique as described in Section 2.5.2.1 (Fagerlund & Thelander, 1989; Gillstrom et al., 1986; Jackson et al., 1989). Trials including > 25% of participants who had previously undergone surgery, or who had symptoms likely attributable to bony or ligamentous spinal stenosis, were excluded. Participants with symptoms of any duration were included but for the purposes of additional subgrouping, trials were categorised according to the duration of symptoms of their participants, with acute symptoms defined as less than 6 weeks, subacute 6 weeks to 26 weeks and chronic more than 26 weeks (Pengel, Maher, & Refshauge, 2002; van Tulder et al., 2003; Woods, Kishino, Haider, & Kay, 2000).

3.2.1.3 Types of interventions

Trials were included if at least one group of participants received a conservative intervention. For the purposes of this review, a conservative intervention was defined as one that did not involve penetration through the deep skin layers. Trials where all groups received injection therapy or any type of surgical intervention were therefore excluded, however acupuncture was considered a conservative treatment. This definition was chosen as previous reviews discussed earlier (Section 3.1.4) have already evaluated the literature relating to surgical (Gibson & Waddell, 2007) and

injection therapies (Abdi et al., 2007; Armon et al., 2007; DePalma et al., 2005) for people with clinical and radiological evidence of DHR.

3.2.1.4 Types of outcome measures

Trials were included if they reported data relating to treatment outcomes and/or adverse events. The outcomes of interest in this review were i) activity limitation (eg. Oswestry Disability Index, Roland-Morris); ii) pain intensity (eg. visual analogue scale, numerical rating scale); iii) global measures of improvement (eg. percentage of participants recovering, overall improvement ratings); and iv) adverse events or complications potentially attributable to the interventions. The timing of follow-up for outcomes was categorised as short term (less than 3 months after randomisation), intermediate (between 3 months and 1 year), or long term (1 year or more) (van Tulder et al., 2003).

3.2.2 Search methods

The following methods were utilised for identifying trials that were potentially relevant:

- Computer database searching was undertaken for the period between 1971 and 31st August 2008 using MEDLINE (Ovid), CINAHL (Ovid), EMBASE (Elsevier 1971-1987, Ovid 1988-2008), PEDro, Current Contents (Ovid), Cochrane central register of controlled trials, Cochrane database of systematic reviews, AMED, ISI Web of Science and Australasian Medical Index (Informit). The database search strategy utilised key words for the condition of interest, combined with terms for locating RCTs as recommended by the Cochrane Collaboration (van Tulder et al., 2003) and empirical studies investigating sensitive search strategies (Wong, Wilczynski, & Haynes, 2006a, 2006b; Zhang, Ajiferuke, & Sampson, 2006). Intervention-specific terms were not used to avoid biasing the search results towards particular treatments. The search terms utilised in these databases are shown in Appendix C.
- Citation tracking was performed via the ISI Web of Science (Thomson Reuters). This involved obtaining and checking a list of all articles that had referenced any of the trials included in the review.
- The reference lists of all included trials were checked.
- Past relevant systematic reviews were searched (Luijsterburg et al., 2007; Vroomen, de Krom, Slofstra et al., 2000).

3.2.3 Trial selection

Two reviewers independently evaluated the eligibility of trials. Elimination of trials first occurred if *both* reviewers independently excluded them following initial review of the title and abstract (Stage 1). Full text copies of remaining articles were then obtained and evaluated independently by the two reviewers (Stage 2). Subsequently, disagreement was resolved via discussion until consensus was achieved. A third reviewer was to be consulted for unresolved disagreements but was not required for this purpose. The level of agreement between the two independent reviewers (prior to discussion) was estimated using the kappa statistic (Landis & Koch, 1977).

3.2.4 Methodological quality assessment

The two reviewers independently assessed the methodological quality of included trials using the PEDro scale (Maher, Sherrington, Herbert, Moseley, & Elkins, 2003). This scale rates RCTs on ten key methodological criteria that were identified by research experts involved in a consensus study using the Delphi method (Verhagen et al., 1998). The PEDro scale has demonstrated adequate reliability (Maher et al., 2003) and has been shown to be a valid indicator of trial methodological quality (de Morton, 2009). In addition, several items on the PEDro scale have been shown to be capable of influencing the outcomes of trials: randomisation (Colditz, Miller, & Mosteller, 1989; Juni, Altman, & Egger, 2001; van Tulder et al., 2003), concealed allocation (Moher et al., 1998; Schulz, Chalmers, Hayes, & Altman, 1995; Wood et al., 2008) and blinding of participants, treaters and outcome assessors (Colditz et al., 1989; Juni et al., 2001; Schulz et al., 1995; van Tulder et al., 2003; Wood et al., 2008). The items included on the PEDro scale are shown in Table 3.1.

Table 3.1: Methodological criteria rated on the PEDro scale

Item	Description
1	Were eligibility criteria specified?
2	Were participants randomly allocated to groups?
3	Was allocation concealed?
4	Were the groups similar at baseline regarding the most important prognostic indicators?
5	Were all participants blinded?
6	Was there blinding of all therapists who administered the therapy?
7	Was there blinding of all assessors who measured at least one key outcome?
8	Were measures of at least one key outcome obtained from more than 85% of the participants initially allocated to groups?
9	Did all subjects for whom outcome measures were available receive the treatment or control condition as allocated or, where this was not the case, was data for at least one key outcome analysed by "intention to treat"?
10	Were the results of between group statistical comparisons reported for at least one key outcome?
11	Did the study provide both point measures and measures of variability for at least one key outcome?

Note: only items 2-11 are included in the calculation of the PEDro score as these items relate to trial internal validity.

A variation in the scoring of Item 7 of the PEDro scale (blinding of outcome assessors) was adopted for the current review. When subjective self-adminstered outcomes (such as questionnaires) are measured in trials, the PEDro scale considers that blinding of outcome assessors is only achieved if the participant completing the questionnaire was blinded to their treatment allocation (The Centre for Evidence-Based Physiotherapy, 2009). Since the outcomes of interest in this review were all subjective in nature (global rating of change, pain and activity limitation), Item 7 of the PEDro scale (blinding of outcome assessors) would have been scored identically to Item 5 (blinding of participants). To avoid this duplication in the current review, Item 7 was judged based on whether the person who scored and entered data from questionnaires in each trial was blinded to the group allocation of participants. This allowed Item 7 to be used to evaluate this additional potential source of bias (Moher et al., 2010) rather than scoring two items based on the same criterion (blinding of participants).

3.2.5 Assessment of clinical relevance

The two reviewers independently evaluated the clinical relevance of included trials using the five criteria recommended by the Cochrane Back Review Group (van Tulder et al., 2003):

1. Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?

2. Are the interventions and treatment settings described well enough so that you can provide the same for your patients?
3. Were all clinically relevant outcomes measured and reported?
4. Is the size of the effect clinically important?
5. Are the likely treatment benefits worth the potential harms?

The third criterion was extended to require papers to comment on the reliability and validity of the outcome measures used, as reporting on such properties is recommended in the CONSORT statement (Altman et al., 2001; Moher et al., 2010).

3.2.6 Data extraction and analysis

Information from each trial regarding the number of participants, their presenting characteristics and the interventions used, were independently extracted by the two reviewers and entered into standardised computer spreadsheets. For continuous data, treatment effects and 95% confidence intervals were calculated using the Hedges adjusted-g standardised mean difference (SMD) (Deeks & Higgins, 2007; Hedges & Olkin, 1985). The SMD was chosen as it allows comparison of effect sizes from different outcome measures both between and within trials (Higgins & Green, 2006; White & Thomas, 2005). The SMD was calculated using group mean scores and pooled standard deviations (SDs) at the follow-up time of interest. When these values were not reported, they were estimated from mean change scores, baseline SDs, median values (Higgins & Green, 2006) or SDs derived from the standard error or range (Hozo, Djulbegovic, & Hozo, 2005). Positive SMD values were used to indicate treatment effects favouring the primary conservative intervention group. Standardised mean differences of 0.2, 0.5 and 0.8 were considered thresholds for small, moderate and large effect sizes, respectively (Cohen, 1988). For dichotomous data, the relative risk (RR) and 95% confidence intervals were calculated (Deeks & Higgins, 2007; Hildebrandt, Bender, Gehrmann, & Blettner, 2006). Relative risks were standardised so that RR > 1 indicated an increased risk of the event occurring in the primary conservative intervention group relative to the comparison group.

Data extraction, methodological quality ratings and clinical relevance ratings were piloted by the two reviewers on two ineligible trials (Carette et al., 1997; Cleland, Childs, Palmer, & Eberhart, 2006) prior to commencement of the review (van Tulder et al., 2003).

3.2.7 Data synthesis

Pooling of data via meta-analysis was planned in cases where at least two trials contained sufficiently similar participants (based on diagnostic features, duration of symptoms, baseline pain intensity and baseline activity limitation scores), treatment modalities, comparison interventions, outcome measures, methodological quality and length of follow-up. When clinically homogenous trials were identified, they were assessed for statistical heterogeneity, which was considered likely if p-values of < .1 were obtained on the chi-square test, or if the I^2 statistic was > 25% (Higgins, Thompson, Deeks, & Altman, 2003; Higgins & Green, 2006). Trials that were deemed to be both clinically and statistically homogenous were subjected to a fixed effects model meta-analysis (Higgins & Green, 2006) using RevMan 4.2 (REVMAN, 2003). A fixed effects model was chosen based on the high threshold for statistical and clinical homogeneity that needed to be reached in order for trials to qualify for meta-analysis, hence random variation between these studies was assumed to be minimal (Higgins & Green, 2006).

Where statistical pooling was deemed inappropriate due to clinical or statistical heterogeneity, effect sizes and 95% confidence intervals were reported for individual trials and collation of results was limited to a narrative analysis using the levels of evidence approach that was recommended by the Cochrane Collaboration at the time of this review (van Tulder et al., 2003). The levels of evidence approach is used to summarise literature by allocating the following ratings:

- Strong evidence —consistent findings among multiple high quality RCTs.
- Moderate evidence —consistent findings among multiple low quality RCTs and/or one high quality RCT.
- Limited evidence —one low quality RCT.
- Conflicting evidence —inconsistent findings among multiple RCTs.
- No evidence from trials—no RCTs.

The levels of evidence approach has been widely used to allow collation of results in reviews where meta-analysis is not possible (Luijsterburg et al., 2007; Maher, 2000; Roelofs, Deyo, Koes, Scholten, & van Tulder, 2008; Staal, de Bie, de Vet, Hildebrandt, & Nelemans, 2009; Trinh et al., 2007; van Tulder, Koes et al., 2006). Contradictory evidence was defined as <75% of trials agreeing (Maher, 2000; Staal et al., 2009). A PEDro methodological score of 6 or more out of 10 was considered to represent high

quality, in accordance with previous reviews (Bleakley, McDonough, & MacAuley, 2008; Slade & Keating, 2006). The GRADE approach is an alternative method for collating bodies of evidence in systematic reviews (Guyatt et al., 2008) and there is considerable similarity between the two approaches in the way summary statements are generated for a body of evidence. As this review commenced before the GRADE approach was recommended by the Cochrane Collaboration (Furlan, Pennick, Bombardier, & van Tulder, 2009), the levels of evidence approach had already been used for the analysis.

3.3 Results

3.3.1 Selection of trials

The number of trials considered at each stage of the review is outlined in Figure 3.1. The agreement between reviewers for selection of trials in Stage 1 (title and abstract review) was 98.2% with a K value of 0.62 (95% CI: 0.54-0.69) and 91.7% with a K value of 0.69 (95% CI: 0.53-0.84) in Stage 2 (review of full text). This indicated substantial agreement during both stages (Landis & Koch, 1977).

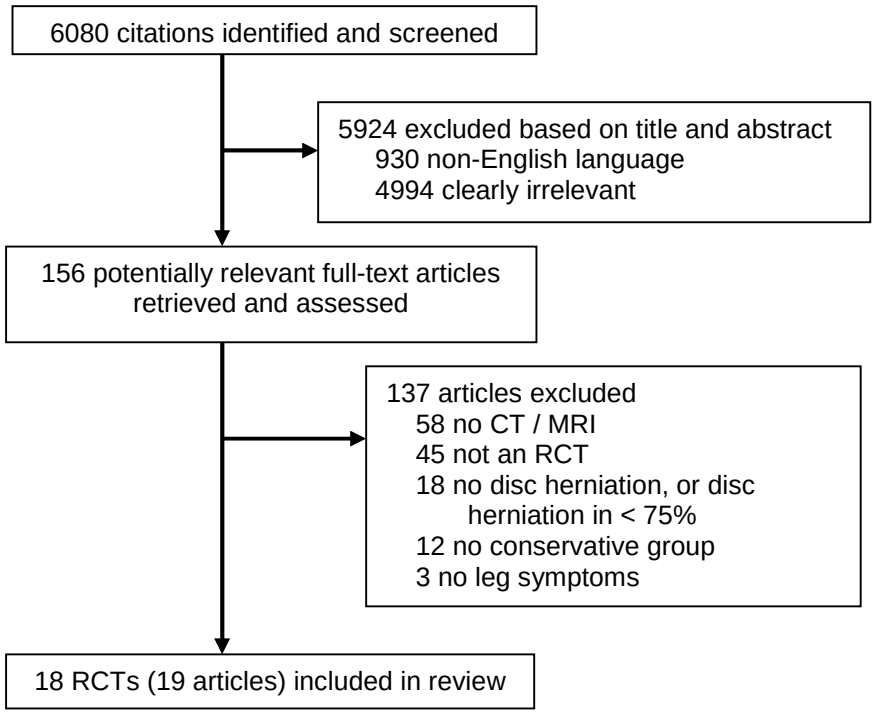


Figure 3.1: Flow chart showing progression of trials through the selection process

3.3.2 Description of trials

A total of 19 articles reporting on 18 RCTs randomising 1671 participants to groups were ultimately included in the review (Bakhtiary, Safavi-Farokhi, & Rezasoltani, 2005; Bonaiuti, Gatti, Raschi, Cantarelli, & Sirtori, 2004; Buchner, Zeifang, Brocai, & Schiltenwolf, 2000; Burton, Tillotson, & Cleary, 2000; Deli, 2007; Dincer, Kiralp, Cakar, Yasar, & Dursan, 2007; Guvenol, Tuzun, Peker, & Goktay, 2000; He et al., 2006; Kanayama, Hashimoto, Shigenobu, Oha, & Yamane, 2005; Liu & Zhang, 2000; Osterman, Seitsalo, Karppinen, & Malmivaara, 2006; Ozturk, Gunduz, Ozoran, & Bostanoglu, 2006; Peul, van den Hout, Brand, Thomeer, & Koes, 2008; Peul et al., 2007; Santilli, Beghi, & Finucci, 2006; Sherry, Kitchener, & Smart, 2001; Tesio & Merlo, 1993; Unlu, Tasci, Tarhan, Pabuscu, & Islak, 2008; Veihelmann et al., 2006). One trial focussed exclusively on participants with acute symptoms (Santilli et al., 2006), two trials included only participants with subacute symptoms (Osterman et al., 2006; Peul et al., 2007), one trial included only chronic participants (Veihelmann et al., 2006) and all other trials included participants with a mixed duration of symptoms (Bakhtiary et al., 2005; Bonaiuti et al., 2004; Buchner et al., 2000; Burton et al., 2000; Deli, 2007; Dincer et al., 2007; Guvenol et al., 2000; He et al., 2006; Kanayama et al., 2005; Liu & Zhang, 2000; Ozturk et al., 2006; Sherry et al., 2001; Tesio & Merlo, 1993; Unlu et al., 2008).

Seventeen trials presented short term follow-up data (Bakhtiary et al., 2005; Bonaiuti et al., 2004; Buchner et al., 2000; Burton et al., 2000; Deli, 2007; Dincer et al., 2007; Guvenol et al., 2000; He et al., 2006; Kanayama et al., 2005; Liu & Zhang, 2000; Osterman et al., 2006; Ozturk et al., 2006; Peul et al., 2007; Santilli et al., 2006; Sherry et al., 2001; Tesio & Merlo, 1993; Unlu et al., 2008), eight reported intermediate term follow-up data (Buchner et al., 2000; Dincer et al., 2007; Guvenol et al., 2000; Osterman et al., 2006; Peul et al., 2007; Santilli et al., 2006; Unlu et al., 2008; Veihelmann et al., 2006) and four trials contained long term follow-up data (Burton et al., 2000; Osterman et al., 2006; Peul et al., 2007; Veihelmann et al., 2006). A wide range of outcome measures were utilised but all trials included at least one measure of pain or global change, while 10 included measures of activity limitation or function (Bonaiuti et al., 2004; Buchner et al., 2000; Burton et al., 2000; Dincer et al., 2007; He et al., 2006; Osterman et al., 2006; Peul et al., 2007; Sherry et al., 2001; Unlu et al., 2008; Veihelmann et al., 2006). The most common measure of pain intensity was the visual analogue scale (13 trials) (Bakhtiary et al., 2005; Bonaiuti et al., 2004; Buchner

et al., 2000; Dincer et al., 2007; He et al., 2006; Kanayama et al., 2005; Osterman et al., 2006; Ozturk et al., 2006; Peul et al., 2007; Santilli et al., 2006; Sherry et al., 2001; Unlu et al., 2008; Veihelmann et al., 2006), while the most common measure of activity limitation was the Oswestry Disability Index (4 trials) (Dincer et al., 2007; Osterman et al., 2006; Unlu et al., 2008; Veihelmann et al., 2006).

In six trials a conservative intervention was compared to surgery or injections (Buchner et al., 2000; Burton et al., 2000; Dincer et al., 2007; Osterman et al., 2006; Peul et al., 2007; Veihelmann et al., 2006), hence the group receiving conservative treatment in these trials would have been considered a control rather than a primary intervention. One trial utilised a placebo control (Santilli et al., 2006), one used a no treatment control (Bakhtiary et al., 2005), while the remaining ten trials compared two or more conservative treatments (Bonaiuti et al., 2004; Deli, 2007; Guvenol et al., 2000; He et al., 2006; Kanayama et al., 2005; Liu & Zhang, 2000; Ozturk et al., 2006; Sherry et al., 2001; Tesio & Merlo, 1993; Unlu et al., 2008).

The characteristics of the included trials are outlined in Table 3.2.

Table 3.2: Characteristics of trails included in the systematic review

Trial	Participants	Primary conservative intervention	Comparison intervention
Bakhtiari PEDro=7 Clinical=4	Iran, n=60 (mean age 32.8, mean symptom duration 4 months) referred to a physical therapy department with > 2 months LBP, sciatic pain and reduced functional performance. MRI or CT showing L4/5 or L5/S1 disc herniation	Four-week lumbar stabilising exercise program (1x/week supervised by physical therapist, 2x/day at home)	Four-week no treatment period prior to cross-over to intervention
Bonaiuti PEDro=4 Clinical=1	Italy, n=64, (mean age 48.9, mean symptom duration 14 months), presenting to a hospital with > 4 months of LBP or "sciatalgia" (85% had referred leg pain), failed standard care, objective signs of benign LBP or "sciatalgia", normal neuro findings, CT or MRI showing disc herniation/protrusion	Manual autotraction for 45 minutes, 3x/week for 2 weeks	Natchev's autotraction for 45 minutes, 3x/week for 2 weeks
Buchner PEDro=7 Clinical=1	Germany, n=36, (mean age 34.4, median symptom duration 8 weeks), admitted to hospital with clinical symptoms of nerve root compression such as radicular pain below the knee, positive SLR < 60 degrees. MRI confirming a "lumbar nucleus pulposus prolapse" of at least 5mm	Inpatient multimodal treatment: bedrest, analgesics, NSAIDs, hydrotherapy, electrotherapy, postural exercise classes (back school), soft tissue massage, joint mobilisation, stabilisation program, dynamic and static strengthening exercises. Dosage not reported.	Primary conservative intervention PLUS 3x lumbar epidural injections over the first 14 days in hospital
Burton PEDro=4 Clinical=2	England, n=40 (mean age 41.9, mean symptom duration 31 weeks) from the orthopedic department of a hospital. Unilateral, unremitting sciatica (leg pain worse than back pain), positive SLR with positive tension signs, radiculopathy limited to a single nerve root, unequivocal evidence of a non-sequestered disc herniation on CT or MRI.	Osteopathic sessions including soft tissue techniques, mobilisation and high velocity thrust manipulations. Mean of 11 (range 6-18) sessions, x 15 minutes per session.	Chemonucleolysis
Deli PEDro=4 Clinical=1	China, n=147 (age range 17-53, duration of symptoms range 6 days to 17 years), with back and leg symptoms (pain, weakness or heaviness), disc herniation confirmed via CT or MRI	Oral herbal medications once per day for 30 days, PLUS the control group treatment	"Tuina massotherapy" : mobilisation, massage and mechanical traction, 1-2 x per week for total of 30 sessions
Dincer PEDro=5 Clinical=2	Turkey, n =64 (mean age 28.4, symptom duration 1-3 months) presenting to a military hospital with LBP and radicular pain below the knee, symptoms 1-3 months duration, at least one nerve root compression sign (radicular pain with SLR, distal paraesthesia, sensory deficit, motor deficit, reflex deficit), VAS pain score >4/10, MRI showing lumbar disc protrusion contained by the annulus and posterior longitudinal ligament	Diclofenac sodium 75mg, prescribed to be taken orally twice per day for 14 days, also advised to perform lumbopelvic mobilisation and lumbar stabilisation exercises daily	Single caudal epidural injection, also advised to perform lumbopelvic mobilisation and lumbar stabilisation exercises daily
Guvenol PEDro=4 Clinical=1	Turkey, n=30 (mean age 36.7, mean symptom duration 33.9 months), low back pain and lower extremity pain, >1 month duration, disc herniation diagnosed via CT.	Inverted traction daily for 10 days, 5-10 minutes traction, 15 minutes infrared, isometric abdominal and gluteal exercises, bed rest	Mechanical traction 5-10 minutes daily for 10 days, plus 15 minutes infrared, isometric abdominal and gluteal exercises, bed rest
He PEDro=5 Clinical=2	China, n=60 (mean age 42.6, symptom duration range 2 days to 12 years) outpatients and inpatients of a hospital, aged 18-70, first attack or acute stage of a recurrent attack, two of the following features: 1) LBP with radicular pain aggravated with increased abdominal pressure, 2) local tenderness on vertebral palpation, pain radiating to the leg or foot, or scoliosis, 3) limited lumbar flexion and positive SLR or femoral nerve stretch test, 4) 2 of 4 neurological signs: muscular atrophy, reduced myotome, abnormal reflex, sensory disturbance. Disc herniation on CT or MRI	Herbal magnetic corset (worn all day and lay on at night) PLUS the control group treatment, for 4 weeks	Traction, electrotherapy and massage daily for 4 weeks

Continued

Table 3.2 continued: Characteristics of trails included in the systematic review

Trial	Participants	Primary conservative intervention	Comparison intervention
Kanayama PEDro=5 Clinical=1	Japan, n=40 (mean age 32.7), presenting to a hospital, with low back and sciatic symptoms, MRI revealing herniated nucleus pulposus	Sarpogrelate hydroxychloride: orally 300mg / day for 2 weeks	Diclofenac sodium, orally 75mg / day for 2 weeks
Liu PEDro=4 Clinical=4	China, n=112 (“majority” aged 30-50, symptom duration range 2 hours to 20 years), age 18-75, lumbar and radiating buttock / leg pain increased by coughing or sneezing, history of trauma or chronic muscle strain prior to development of disc herniation, positive Lasegue's sign, location and degree of protrusion shown by CT scan	"Pulling and turning manipulations": massage, mobilisation and manipulation. Dosage not stated.	Mechanical traction daily for 40-50 minutes, for 4 weeks
Osterman PEDro=7 Clinical=2	Finland, n=56 (mean age 37.5, mean symptom duration 68.5 days), referred for orthopedic consultation at one of four hospitals, aged 20-50 with 6-12 weeks of radicular pain below the knee, plus ONE of the following findings: positive SLR < 70 degrees, muscle weakness, altered reflexes, or dermatomal sensory change. Disc extrusion or sequester on CT.	Physical therapy instructions to stretch, bend and perform isometric strengthening exercises (at baseline assessment), encouragement of activity at the three follow-up visits	Microdiscectomy within 2 weeks of randomisation. Isometric exercises prior to and post surgery. Post-op physical therapy included active instructions to stretch and bend, strength exercises.
Ozturk PEDro=6 Clinical=4	Turkey, n=46 (mean age 46.2) hospitalised due to < 6 months of low back pain or sciatica (91% had sciatica), L3-S1 radiculopathy, consistency between pain patterns, neurological examination and radiological findings, no history of previous physical therapy, disc herniation verified by CT.	Continuous mechanical lumbar traction for 15 minutes (15 sessions, one session per weekday for 3 weeks), PLUS the electrotherapy and medication that the control group received	Electrotherapy modalities: 15 minutes hot pack, 5 minutes ultrasound, 10 minutes, diadynamic currents (15 sessions over 3 weeks). Medication: ibuprofen 400mg 3x/day, mephenoxalone 200mg 3x/day, paracetamol 450mg 3x/day.
Peul PEDro=7 Clinical=1	Netherlands, n=283 (mean age 42.6, mean duration of symptoms 9.5 months) referred from GP’s to one of nine hospitals, aged 18-85 years with incapacitating lumbosacral radicular syndrome for 6-12 weeks. All had MRI confirming a disc herniation.	General practitioner care: advice regarding good prognosis, encouragement to return to daily activities and remain active, medication if required, physical therapy if fearful of moving.	Microdiscectomy within 2 weeks of randomisation, followed by postoperative home-based rehabilitation supervised by a physical therapist.
Santilli PEDro=8 Clinical=4	Italy, n=102 consecutive patients presenting to 2 medical rehabilitation centres with acute LBP (< 10 days), > 5/10 on a VAS (as evoked by palpation), radiating pain > 5/10 (during SLR or femoral stretch). MRI showing disc protrusion with intact annulus.	Active manipulation: soft tissue manipulations and brisk rotational thrust. Up to 20 sessions over 30 days, 5 minutes per session.	Simulated manipulation: soft tissue muscle pressing with no thrusting. Up to 20 sessions over 30 days, 5 minutes per session.
Sherry PEDro=5 Clinical=4	Australia, n=44 (mean age 42.0, mean duration of symptoms 7.3 years), responding to newspaper advertising, aged 18-65, chronic LBP (> 3 months) and leg pain with minimum VAS of 2/10, living within 45 minutes of a treatment clinic, able to follow protocol, disc herniation on CT or MRI.	Vertebral axial decompression (VAX-D) therapy: 5x / week for 4 weeks, then weekly for 4 weeks, 30 minutes / session	TENS: 30 minutes daily for 20 days, then weekly for 4 weeks
Tesio PEDro=4 Clinical=4	Italy, n=44 (mean age 44.6, median symptom duration 1 year), selected from outpatient department of a hospital rehabilitation unit with unremitting LBP +/- radiating pain (75%) along a lumbosacral root distribution, duration > 1 month, failure of conservative approaches, consistency between pain pattern, neurological findings and radiological findings, disc herniation on CT or MRI.	Auto-traction: 3 sessions of traction with patient generating own traction force, 30-60 minutes sessions every 2-3 days.	Passive mechanical traction: 5 sessions on a daily basis, lasting 45 minutes per session.

Continued

Table 3.2 continued: Characteristics of trails included in the systematic review

Trial	Participants	Primary conservative intervention	Comparison intervention
Unlu PEDro=6 Clinical=2	Turkey, n=60 (mean age=44.5, mean symptom duration=44.6 days) consecutive patients presenting to a medical facility aged 20-60, with acute low back and leg pain (sciatica or femoral neuralgia) of < 3 months duration. MRI showing herniation of one or more discs consistent with the pain complaints and neurological examination findings.	Traction (mechanical): 5 days per week for 3 weeks, 15 minute sessions.	1) Ultrasound: 5 days per week for 3 weeks, 8 minutes at 1.5W/cm^2 2) Low powered laser: 5 sessions per week for 3 weeks, 50mV, wavelength 830nm, 4 minutes per point
Veihelmann PEDro=5 Clinical=0	Germany, n=99 (mean age=43.6), with chronic LBP and radicular leg pain. MRI confirmed nerve root compression by either a LDH (87%) or scar tissue from previous surgery (13%).	"Conservative treatment with physical therapy" not described further.	Epidural neuroplasty: local anaesthetic, steroid and saline injected into the LDH or scar tissue adjacent to the nerve

Abbreviations: VAS=visual analogue scale; NSAIDs= non steroidal anti-inflammatory drugs; mg=milligramsl; mV=millivolts; nm=nanometer; SLR=straight leg raise; GP=general medical practitioner; W/cm^2 = watts per square centimetre

3.3.3 Methodological quality and clinical relevance of trials

Ratings for all trials on each item of the PEDro scale and clinical relevance scale are presented in Table 3.3. The agreement between reviewers on PEDro scale items was 85.4%, with a K value of 0.70 (95% CI: 0.60-0.80) indicating substantial agreement. For items on the clinical significance scale, the interrater agreement was 60.0%, with a K value of 0.43 (95% CI: 0.27-0.59) indicating moderate agreement.

Table 3.3: Methodological and clinical quality ratings for included trials

	PEDro scale												Clinical relevance scale					
Study	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**Total**	**1**	**2**	**3**	**4**	**5**	**Total**
Bakhtiari	✓	✓	✓	–	–	–	✓	✓	✓	✓	✓	7	✓	✓	–	✓	✓	4
Bonaiuti	✓	✓	–	✓	–	–	–	–	–	✓	✓	4	✓	–	–	–	–	1
Buchner	✓	✓	✓	✓	–	–	–	✓	✓	✓	✓	7	✓	–	–	–	–	1
Burton	✓	–	–	–	–	–	✓	✓	–	✓	✓	4	✓	✓	–	–	–	2
Deli	–	✓	–	–	–	–	–	✓	–	✓	✓	4	–	–	–	✓	–	1
Dincer	✓	✓	–	–	–	–	✓	✓	–	✓	✓	5	–	–	–	✓	✓	2
Guvenol	✓	✓	–	–	–	–	–	✓	–	✓	✓	4	✓	–	–	–	–	1
He	✓	✓	–	✓	–	–	–	✓	–	✓	✓	5	✓	✓	–	–	–	2
Kanayama	✓	✓	–	–	–	–	–	✓	✓	✓	✓	5	✓		–	–	–	1
Liu	✓	✓	–	–	–	–	–	✓	–	✓	✓	4	✓	✓	–	✓	✓	4
Osterman	✓	✓	✓	✓	–	–	✓	✓	–	✓	✓	7	✓	–	–	–	–	1
Ozturk	✓	✓		✓	–	–	✓	✓	–	✓	✓	6	✓	✓	–	✓	✓	4
Peul	✓	✓	✓	✓	–	–	–	✓	✓	✓	✓	7	✓	–	–	–	–	1
Santilli	✓	✓	✓	–	✓	–	✓	✓	✓	✓	✓	8	✓	✓	–	✓	✓	4
Sherry	✓	✓	–	✓	–	–	–	✓	–	✓	✓	5	✓	✓	–	✓	✓	4
Tesio	✓	✓	–	–	–	–	–	✓	–	✓	✓	4	✓	✓	–	✓	✓	4
Unlu	✓	✓	–	✓	–	–	✓	✓	–	✓	✓	6	✓	✓	–	–	–	2
Veihelmann	✓	✓	–	–	–	–	✓	✓	–	✓	✓	5	–	–	–	–	–	0
Total	17	17	5	8	1	0	8	17	5	18	18		15	9	0	8	8	

The mean methodological quality score on the PEDro scale was 5.4 out of 10, with a range of 4 to 8. Seven trials (39%) were considered high quality based on achieving a PEDro score of six or more (Bakhtiary et al., 2005; Buchner et al., 2000; Osterman et al., 2006; Ozturk et al., 2006; Peul et al., 2007; Santilli et al., 2006; Unlu et al., 2008). Common methodological limitations were failure to blind treating therapists (all 18 trials), failure to blind participants (17 trials) (Bakhtiary et al., 2005; Bonaiuti et al., 2004; Buchner et al., 2000; Burton et al., 2000; Deli, 2007; Dincer et al., 2007; Guvenol et al., 2000; He et al., 2006; Kanayama et al., 2005; Liu & Zhang, 2000; Osterman et al., 2006; Ozturk et al., 2006; Peul et al., 2007; Sherry et al., 2001; Tesio & Merlo, 1993; Unlu et al., 2008; Veihelmann et al., 2006), failure to report an intention to treat analyses (13 trials) (Bonaiuti et al., 2004; Burton et al., 2000; Deli, 2007; Dincer et al., 2007; Guvenol et al., 2000; He et al., 2006; Liu & Zhang, 2000; Osterman et al., 2006; Ozturk et al., 2006; Sherry et al., 2001; Tesio & Merlo, 1993; Unlu et al., 2008; Veihelmann et al., 2006) and inadequate concealment of treatment allocation (13 trials) (Bonaiuti et al., 2004; Burton et al., 2000; Deli, 2007; Dincer et al., 2007; Guvenol et al., 2000; He et al., 2006; Kanayama et al., 2005; Liu & Zhang, 2000; Ozturk et al., 2006; Sherry et al., 2001; Tesio & Merlo, 1993; Unlu et al., 2008; Veihelmann et al., 2006). The mean clinical relevance score was 2.2, with all trials failing to comment on the validity or reliability of their chosen outcome measures.

3.3.4 Data extraction variations

As with most systematic reviews, there was variation in the reporting of data among the included trials. As such, in order to calculate SMDs the following methods were employed:

- One article presented only standard errors as a measure of variability in outcomes (Peul et al., 2007). These were converted to standard deviations using the formula ($SD=SE \times \sqrt{n}$), where n was the actual group sample size at that outcome time point.
- Two trials did not present mean scores of outcome measures, hence they were extrapolated from graphs (Saggini et al., 2004; Santilli et al., 2006).
- Three studies reported ranges as the only measure of variability in outcomes (Bonaiuti et al., 2004; Buchner et al., 2000; Sherry et al., 2001). As those studies all had sample sizes between 15 and 70, the standard deviation was estimated to be one-quarter of the range (Hozo et al., 2005).

- One study reported that they had presented “SEM” values as the measure of variability (Veihelmann et al., 2006). This abbreviation, when used as a measure of variability for an outcome measure, typically represents the standard error of the mean. However, the reported values exceeded the largest possible standard error of the mean for the outcomes being measured and the values were of a similar magnitude to standard deviations reported in other studies. The authors did not respond to emails requesting clarification. It was therefore assumed that an error had occurred in the reporting of the study, so the values were treated as standard deviations.
- One study reported baseline means and SDs for each group, as well as mean change scores for each group at each follow-up (Bakhtiary et al., 2005). The SMD was therefore calculated using the difference between the mean change scores of the two groups divided by the baseline SD. There may therefore be some inaccuracies in the SMD scores for this study, although these would be expected to be minor.
- For one study, SDs were estimated as one quarter of the range, while change scores from baseline were used because actual mean scores were not provided at follow-up (Bonaiuti et al., 2004).

3.3.5 Evidence for effectiveness of interventions

The interrater agreement for extraction of means and SDs from articles was 98.2%. The treatment effect sizes and associated 95% confidence intervals are presented in Table 3.4 and Figure 3.2.

Table 3.4: Between group differences calculated from included trials

Comparison	Back pain / overall pain: SMD (95%CI)	Leg pain: SMD (95%CI)	Activity limitation: SMD (95%CI)	Global effect: RR (95%CI)
Stabilisation V waiting list (Bakhtiari et al., 2005))				
	VAS			
4 weeks	**SMD= 2.7 (2.0 to 3.3)**			
Manual auto-traction V Natchev's auto-traction (Bonaiuti et al., 2004)				
	VAS		Backill scale	
2 weeks	SMD= 0.5 (-0.1 to 1.0)		SMD= 0.0 (-0.6 to 0.5)	
Inpatient multimodal program V epidural plus multimodal program (Buchner et al., 2004)				
	VAS		Hannover	Rating "good" or "very good"
2 weeks	SMD= -0.4 (-1.1 to 0.2)		SMD= -0.4 (-1.0 to 0.3)	
6 weeks	SMD= -0.2 (-0.9 to 0.4)		SMD= -0.2 (-0.8 to 0.5)	
6 months	SMD= -0.3 (-0.9 to 0.4)		SMD= -0.3 (-1.0 to 0.4)	RR= 0.8 (0.6 to 1.2)
Manipulation (Osteopathic) V Chemonucleolysis (Burton et al., 2000)				
	7-point thermometer	7-point thermometer	Roland Morris	
2 weeks	**SMD= 0.7 (0.0 to 1.3)**	SMD= 0.0 (-0.6 to 0.7)	**SMD= 0.7 (0.1 to 1.3)**	
6 weeks	**SMD= 0.7 (0.0 to 1.3)**	SMD= 0.0 (-0.6 to 0.7)	SMD= 0.5 (-0.2 to 1.2)	
12 months	SMD= 0.4 (-0.3 to 1.1)	SMD= 0.1 (-0.6 to 0.8)	SMD= 0.2 (-0.5 to 0.9)	
Oral herbal medication added to mobilisation, massage & mechanical traction (Deli, 2007)				
				Rating "any improvement" V's "failed treatment"
? 30 days				**RR= 1.1 (1.0 to 1.3)**
Diclofenac sodium orally V's epidural injection (Dincer et al., 2007)				
	VAS		Oswestry	
2 weeks	**SMD= -2.2 (-2.8 to -1.6)**		**SMD= -1.5 (-2.0 to -1.0)**	
1 month	**SMD= -1.0 (-1.5 to -0.5)**		**SMD= -0.6 (-1.2 to -0.2)**	
3 months	**SMD= -0.6 (-1.1 to -0.1)**		SMD= -0.4 (-1.9 to 0.1)	
Inverted traction V's mechanical traction (Guvenol et al., 2000)				
	0-10 scale			
10 days	Data not reported			
3 months	Data not reported			
Herbal magnetic corset added to traction, electrotherapy and massage (He et al., 2006)				
	VAS		Lumbar Disease Grade	
1 week	**SMD= 0.5 (0.0 to 1.0)**		SMD= 0.3 (-0.2 to 0.8)	
2 weeks	**SMD= 0.7 (0.1 to 1.2)**		**SMD= 0.8 (0.2 to 1.8)**	
4 weeks	**SMD= 0.8 (0.2 to 1.3)**		**SMD= 1.0 (0.4 to 1.5)**	
Sarpogrelate hydroxychloride V's diclofenac sodium (Kanayama et al., 2005)				
	VAS	VAS		
2 weeks	SMD= 0.0 (-0.6 to 0.7)	SMD= 0.5 (-0.1 to 1.1)		
Manipulation V's mechanical traction (Liu & Zhang, 2000)				
				Rating "cured or improved" V's "ineffective"
? 5 weeks				**RR= 1.3 (1.1 to 1.6)**
Advice V's microdiscectomy (Osterman et al., 2006)				
	VAS	VAS	Oswestry	Rating "full recovery" V's "not full recovery"
6 weeks	SMD= -0.3 (-0.8 to 0.2)	**SMD= -0.5 (-1.1 to 0.0)**	SMD= -0.4 (-0.9 to 0.2)	RR= 0.1 (0.0-1.6)
3 months	SMD= -0.3 (-0.9 to 0.2)	SMD= -0.3 (-0.9 to 0.2)	SMD= -0.5 (-1.0 to 0.1)	RR= 0.8 (0.2-2.7)
6 months	SMD= -0.3 (-0.8 to 0.3)	SMD= -0.4 (-0.9 to 0.2)	SMD= -0.3 (-0.8 to 0.2)	
12 months	SMD= 0.1 (-0.4 to 0.6)	SMD= -0.2 (-0.7 to 0.3)	SMD= -0.1 (-0.6 to 0.5)	
24 months	SMD= -0.4 (-1.0 to 0.1)	SMD= -0.5 (-1.0 to 0.0)	SMD= -0.4 (-0.9 to 0.2)	RR= 0.7 (0.3 to 2.0)

Continued

Table 3.4 continued: Between group differences calculated from included trials

Comparison	Back pain / overall pain: SMD (95%CI)	Leg pain: SMD (95%CI)	Activity limitation: SMD (95%CI)	Global effect: RR (95%CI)
Mechanical traction added to electrotherapy modalities and medication (Ozturk et al., 2006)				
				Back pain "present" V's "absent"
	VAS			
? 3 weeks	SMD= 0.5 (-0.1 to 1.1)			RR= 0.8 (0.3 to 1.8)
				Sciatica "present" V's "absent"
				RR= 0.5 (0.2 to 0.9)
Advice V's microdiscectomy (Peul et al., 2008)				
	VAS	VAS	Roland	7-point global rating
2 weeks	SMD= -0.1 (-0.3 to 0.2)	**SMD= -0.7 (-0.9 to -0.5)**	**SMD= 0.2 (0.0 to 0.5)**	**SMD= -0.3 (-0.6 to -0.1)**
8 weeks	**SMD= -0.5 (-0.7 to -0.2)**	**SMD= -0.8 (-1.0 to -0.6)**	**SMD= -0.5 (-0.8 to -0.3)**	
6 months	SMD= -0.1 (-0.3 to 0.1)	**SMD= -0.3 (-0.5 to 0.0)**	SMD= -0.1 (-0.4 to 0.1)	**SMD= -0.8 (-1.0 to -0.5)**
12 months	SMD= -0.1 (-0.3 to 0.1)	SMD= 0.0 (-0.2 to 0.2)	SMD= -0.1 (-0.3 to 0.2)	SMD= -0.2 (-0.4 to 0.1)
24 months	SMD= -0.1 (-0.3 to 0.2)	SMD= 0.1 (-0.2 to 0.3)	SMD= -0.1 (-0.2 to 0.3)	SMD= -0.2 (-0.4 to 0.1)
				Rating "full or near-full recovery" V "not full recovery"
2 weeks				**RR= 0.5 (0.4 to 0.6)**
6 months				RR= 0.9 (0.8 to 1.1)
12 months				RR= 1.0 (0.9 to 1.1)
24 months				RR= 1.0 (0.9 to 1.1)
Manipulation V's sham manipulation (Santilli et al., 2006)				
	VAS	VAS		Free of back pain
2 weeks	**SMD= 0.5 (0.1 to 0.9)**	SMD= 0.4 (0.0 to 0.8)		RR= N / A
4 weeks	**SMD= 0.5 (0.1 to 0.9)**	**SMD= 0.7 (0.3 to 1.1)**		RR= 6.5 (0.3 to 122.4)
6 weeks	**SMD= 0.8 (0.4 to 1.2)**	**SMD= 0.7 (0.3 to 1.1)**		RR= 3.0 (0.9 to 10.4)
3 months	**SMD= 0.9 (0.5 to 1.3)**	**SMD= 0.9 (0.5 to 1.3)**		**RR= 4.3 (1.3 to 14.2)**
6 months	**SMD= 0.7 (0.3 to 1.2)**	**SMD= 0.7 (0.3 to 1.1)**		**RR= 5.0 (1.5 to 16.2)**
				Free of leg pain
2 weeks				RR= 3.4 (0.7 to 15.4)
4 weeks				RR= 2.0 (0.8 to 4.9)
6 weeks				**RR= 2.6 (1.3 to 5.2)**
3 months				**RR= 4.8 (2.2 to 10.6)**
6 months				**RR= 2.9 (1.6 to 5.3)**
Vertebral axial decompression V's transcutaneous electrical nerve stimulation (Sherry et al., 2001)				
			4 self-selected items on	
	VAS		4-point scale)	Rating "successful case"
? 8 weeks	**SMD= 2.6 (0.4 to 1.8)**		**SMD= 1.5 (0.8 to 2.2)**	**RR= 29.7 (1.9 to 467.9)**
Auto-traction V's mechanical traction (Tesio & Merlo, 1993)				
				Rating "improved" V's "not improved"
1-2 weeks				**RR= 4.3 (1.7 to 10.6)**
Traction V Ultrasound (Unlu et al., 2008)				
	Back pain (VAS)	VAS	Roland Morris	
3 weeks	SMD= 0.0 (-0.6 to 0.6)	SMD= 0.1 (-0.5 to 0.7)	SMD= -0.1 (-0.7 to 0.5)	
2 months	SMD= 0.1 (-0.5 to 0.7)	SMD= 0.3 (-0.3 to 0.9)	SMD= -0.1 (-0.7 to 0.6)	
4 months	SMD= -0.3 (-0.9 to 0.4)	SMD= -0.3 (-0.9 to 0.4)	SMD= -0.1 (-0.7 to 0.6)	
			Oswestry	
3 weeks			SMD= 0.0 (-0.7 to 0.6)	
2 months			SMD= 0.1 (-0.5 to 0.8)	
4 months			SMD= -0.1 (-0.7 to 0.5)	

Continued

Table 3.4 continued: Between group differences calculated from included trials

Comparison	Back pain / overall pain: SMD (95%CI)	Leg pain: SMD (95%CI)	Activity limitation: SMD (95%CI)	Global effect: RR (95%CI)
Physical therapy V's epidural neuroplasty (Veihelmann et al., 2006)				
	VAS	VAS	Oswestry	
3 months	**SMD= -1.4 (-1.9 to -1.0)**	**SMD= -1.4 (-1.8 to -0.9)**	**SMD= -1.0 (-1.5 to -0.6)**	
6 months	**SMD= -1.5 (-2.0 to -1.0)**	**SMD= -1.6 (-2.1 to -1.1)**	**SMD= -1.5 (-2.0 to -1.0)**	
12 months	**SMD= -1.1 (-1.6 to -0.7)**	**SMD= -1.2 (-1.7 to -0.7)**	**SMD= -1.0 (-1.5 to -0.6)**	

Note: results in bold represent statistically significant comparisons based on the 95% confidence interval of the SMD or relative risk.
*Comparisons for traction V laser and ultrasound V laser not presented, as SMDs and confidence intervals were similar for all comparisons.
Abbreviations: SMD=hedges-g standardised mean difference; RR=relative risk; CI=confidence interval.

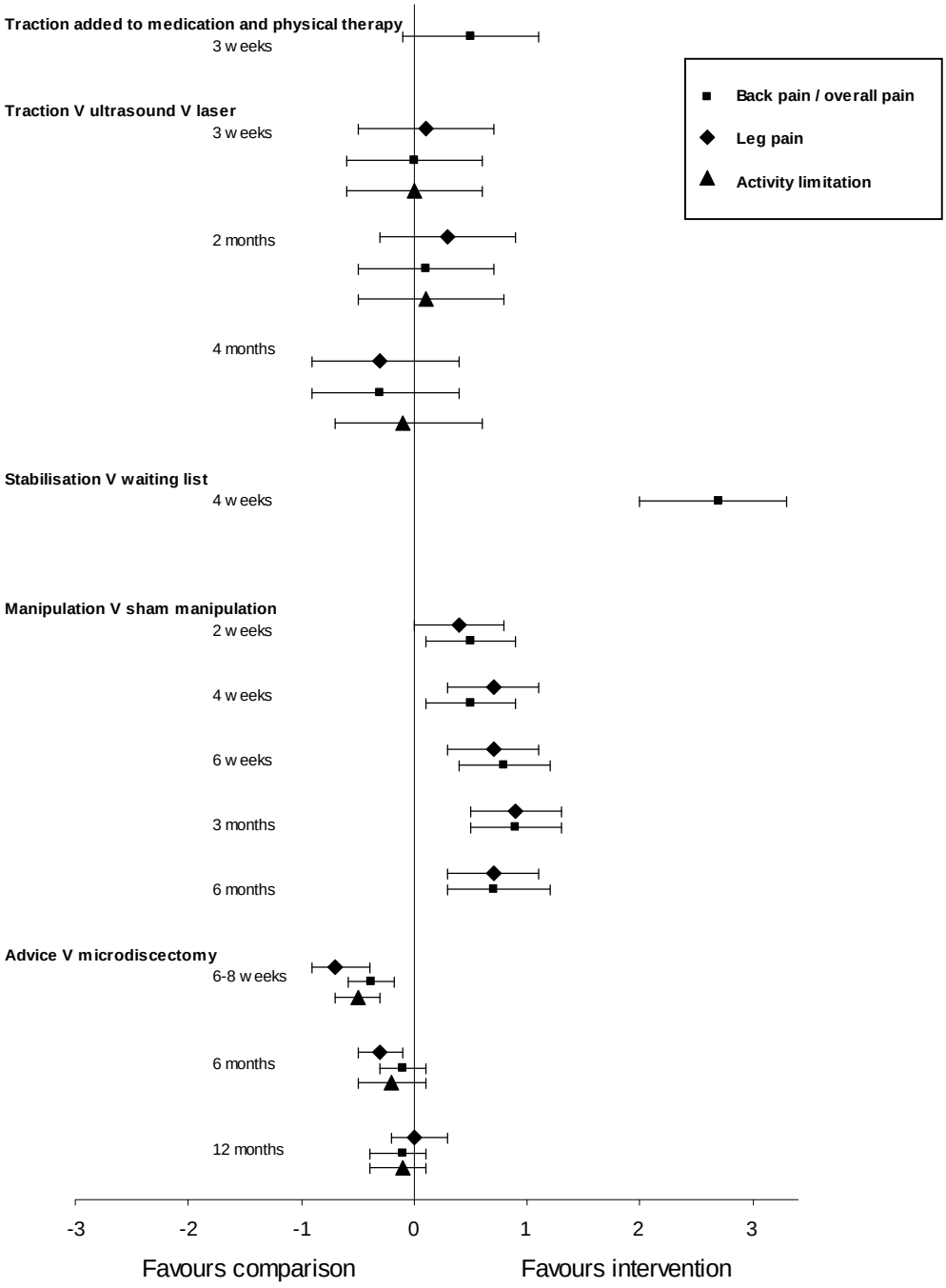


Figure 3.2: Forest plot of standardised mean differences with 95% confidence intervals for all high quality trials

3.3.5.1 Advice

Two high quality trials compared advice with microdiscectomy surgery in participants with subacute DHR (Osterman et al., 2006; Peul et al., 2007). These trials were deemed clinically homogenous and tests for statistical heterogeneity were negative for all outcomes measured at 6-8 weeks, 6 months and 12 months. Meta-analysis was

therefore performed for these follow-up periods using a fixed effects model. The pooled SMD for back pain intensity from these two trials that allocated a total of 337 participants to the two groups was -0.4 (95% CI: -0.6 to -0.2; $I^2 = 0\%$) at short term follow-up, indicating a statistically significant effect favouring surgery over advice. However, the pooled SMD values for intermediate and long term back pain intensity were -0.1 (95% CI: -0.3 to 0.1; $I^2 = 0\%$) and -0.1 (95% CI: -0.3 to 0.2; $I^2 = 0\%$) respectively, indicating no statistically significant difference between groups at these later follow-ups.

For leg pain intensity, a total of 337 participants from the two trials resulted in pooled SMDs of -0.7 (95% CI: -1.0 to -0.5; $I^2 = 0\%$) and -0.3 (95% CI: -0.5 to -0.1; $I^2 = 0\%$) for short term and intermediate term follow-ups respectively, indicating significant effects in favour of surgery over advice. The long term outcomes revealed no statistically significant difference between groups, with a pooled SMD of 0.0 (95% CI: -0.3 to 0.2; $I^2 = 0\%$). The actual mean leg pain scores at 12 month follow-up were 9/100 for the advice group and 6/100 for the surgery group in the Ostermann et al study (Osterman et al., 2006) and 11/100 for both groups in the Peul et al. (2007) study.

For activity limitation, a fixed effects meta-analysis conducted on 337 participants from the two trials showed a statistically significant effect favouring surgery compared to advice at short term follow-up, with a pooled SMD of -0.5 (95% CI: -0.7 to -0.3; $I^2 = 0\%$). Intermediate and long term outcomes revealed no statistically significant differences between surgery and advice, with pooled SMD values of -0.2 (95% CI: -0.4 to 0.1; $I^2 = 0\%$) and -0.1 (95% CI: -0.3 to 0.2; $I^2 = 0\%$) respectively.

For global recovery, 337 participants from the two trials produced a statistically significant pooled RR of 0.4 (95% CI: 0.4 to 0.6; $I^2 = 21\%$) at short term follow-up, indicating that participants receiving advice were significantly less likely than the surgical group to achieve a full or almost-full recovery at short term follow-up. The difference between groups on global recovery was not maintained at intermediate or long term follow-ups, with pooled RR values of 0.9 (95% CI: 0.8 to 1.1; $I^2 = 0\%$) and 1.0 (95% CI: 0.9 to 1.1; $I^2 = 0\%$), respectively. In terms of overall global outcomes at 12 months, the Peul et al. (2007) study reported that 83% of the advice group and 86% of the surgery group described a “full or almost-full recovery” at the 12 month follow-

up, while in the Ostermann et al. (2006) study a “full recovery” was reported by 18% of the advice group and 25% of the surgery group at 12 months.

Follow-up data at 24 months failed at least one statistical test of heterogeneity for each outcome, hence results were pooled via a narrative analysis. This provided strong evidence (2 high quality trials, n=316) (Osterman et al., 2006; Peul, van den Hout et al., 2008) that no difference existed between advice and microdiscectomy surgery for the long term (24 month) outcomes of back pain intensity, leg pain intensity, or activity limitation, in people with subacute DHR.

3.3.5.2 Medication

Two trials contained a group of participants who received oral diclofenac (Dincer et al., 2007; Kanayama et al., 2005). The results of one of these trials provided limited evidence (1 low quality trial, n=64) (Dincer et al., 2007) that diclofenac was less effective than caudal epidural injection for reducing pain intensity at short and intermediate term follow-up, as well as for reducing activity limitation at short term follow-up. The same trial provided limited evidence that there was no difference between diclofenac and caudal epidural injection for the outcome of activity limitation at short term follow-up (Dincer et al., 2007). The other trial provided limited evidence (1 low quality trial, n=40) (Kanayama et al., 2005) that there was no difference between diclofenac and sarpogrelate hydroxychloride for short term outcomes of back pain intensity or leg pain intensity.

There was limited evidence (1 low quality trial, n=147) (Deli, 2007) that the addition of oral herbal medication to “tunia massotherapy” (massage, mobilisation and mechanical traction) provided greater global improvement at short term follow-up.

3.3.5.3 Traction

Nine trials included traction in at least one treatment group (Bonaiuti et al., 2004; Deli, 2007; Guvenol et al., 2000; He et al., 2006; Liu & Zhang, 2000; Ozturk et al., 2006; Sherry et al., 2001; Tesio & Merlo, 1993; Unlu et al., 2008).

Three trials compared two types of traction (Bonaiuti et al., 2004; Guvenol et al., 2000; Tesio & Merlo, 1993). One low quality trial (n=44) (Tesio & Merlo, 1993) provided limited evidence that manual auto-traction was more effective than passive mechanical traction for providing global improvement at short term follow-up. One low quality

trial (n=64) (Bonaiuti et al., 2004) provided limited evidence that there was no difference between manual auto-traction and Nachev's auto-traction for short term pain intensity and activity limitation. Another trial that compared inverted traction to mechanical traction did not report sufficient primary outcome data to allow SMDs and their associated confidence intervals to be calculated (Guvenol et al., 2000).

Three trials compared traction to other treatments (Liu & Zhang, 2000; Sherry et al., 2001; Unlu et al., 2008). One high quality trial (n=60) (Unlu et al., 2008) provided moderate evidence that there was no difference between mechanical traction and either ultrasound or laser for back pain intensity, leg pain intensity, or activity limitation at short term or intermediate term follow-ups. One low quality trial (n=44) (Sherry et al., 2001) provided limited evidence that vertebral axial decompression (VAX-D) traction therapy was more effective than transcutaneous electrical nerve stimulation (TENS) for intermediate term outcomes of pain intensity, activity limitation and risk of global treatment success. One low quality trial (n=112) (Liu & Zhang, 2000) provided limited evidence that mechanical traction was less effective than "pulling and turning manipulations" for global ratings of improvement at short term follow-up.

One high quality trial (n=46) (Ozturk et al., 2006) provided moderate evidence that the addition of mechanical traction to electrotherapy modalities (hot pack, ultrasound, diadynamic currents) and medication (ibuprofen, mephenoxalone, paracetamol) reduced the risk of participants having sciatica at short term follow-up, but it provided no additional short term benefit for pain intensity or risk of having low back pain.

3.3.5.4 Stabilisation exercises

One high quality trial (n=60) (Bakhtiary et al., 2005) provided moderate evidence that a stabilisation exercise program was more effective than no treatment for reducing pain intensity at short term follow-up.

3.3.5.5 Physiotherapy

There was limited evidence from one low quality trial (n=99) (Veihelmann et al., 2006) that physiotherapy (not described further) was less effective than epidural neuroplasty for the intermediate and long term outcomes of leg pain intensity, back pain intensity and activity limitation, for people with chronic DHR.

3.3.5.6 Manipulation

Three trials investigated the effect of manipulation but all utilised different comparison interventions precluding meta-analysis (Burton et al., 2000; Liu & Zhang, 2000; Santilli et al., 2006). In all of these trials manipulation consisted of soft tissue manipulation or massage along with high velocity rotational thrusts. One high quality trial (n=102) (Santilli et al., 2006) provided moderate evidence that, in people with acute DHR and an intact annulus, manipulation was more effective than simulated manipulation for the outcomes of back pain intensity (short and intermediate follow-up), leg pain intensity (4 week, 6 week and intermediate follow-up), risk of becoming free of back pain (intermediate term follow-up) and risk of becoming free of leg pain (6 week and intermediate follow-ups). The same trial provided moderate evidence that there was no difference between active and simulated manipulation for leg pain intensity (2 week follow-up), risk of becoming free of back pain (short term follow-up) and risk of becoming free of leg pain (2 week and 4 week follow-ups).

One low quality trial (n=40) (Burton et al., 2000) provided limited evidence that manipulation was more effective than chemonucleolysis for the outcomes of back pain intensity (short term follow-up) and activity limitation (2 week follow-up), while no difference existed between these treatments for the outcomes of leg pain intensity (short and long term follow-ups), back pain intensity (long term follow-up) and activity limitation (6 week and long term follow-ups).

Another low quality trial (n=112) (Liu & Zhang, 2000) provided limited evidence that manipulation was more effective than mechanical traction for short term global improvement ratings.

3.3.5.7 Laser or ultrasound

One high quality trial (n=60) (Unlu et al., 2008) provided moderate evidence that there was no difference between laser and mechanical traction, no difference between ultrasound and mechanical traction, and no difference between laser and ultrasound, for back pain intensity, leg pain intensity, or activity limitation at short and intermediate term follow-ups.

3.3.5.8 Corsets

One low quality trial (n=60) (He et al., 2006) provided limited evidence that the addition of a herbal magnetic corset to a program of traction, electrotherapy and massage provided additional benefits in short term pain intensity and activity limitation compared to traction, electrotherapy and massage alone.

3.3.5.9 Multimodal inpatient program

One high quality trial (n=36) (Buchner et al., 2000) investigated the effect of adding three epidural injections to a multimodal inpatient treatment program consisting of bed rest, hydrotherapy, electrotherapy, back school, massage, mobilisation and exercises. There were no significant differences between groups on short or intermediate term outcomes of pain intensity, activity limitation and subjective rating of outcome (see Table 3.4). Since both groups received the same multimodal treatment program, it was not possible to determine the relative effectiveness of the conservative component of the treatment.

Having presented the levels of evidence statements for each comparison, these are summarised in Table 3.5 to provide an overview of the findings of this review.

Table 3.5: Summary of results according to the levels of evidence criteria

Comparison	Symptom duration	Level of evidence	Global rating	Pain (back or overall)	Pain (leg)	Activity limitation
Advice						
V microdiscectomy[1,2]	Subacute	High	- (S), = (I, L)	-(S),=(I, L)	-(S, I),=(L)	- (S), = (I, L)
Medication						
Diclofenac V Epidural[3]	Mixed	Low		- (S, I)		- (S), = (I)
Diclofenac V sarpogrelate Hydroxychloride[4]	Mixed	Low		= (S)	= (S)	
Herbal added to massage, mobilisation & traction[5]	Mixed	Low	+ (S)			
Traction						
Auto V mechanical[6]	Mixed	Low	+ (S)			
Auto V Natchev's[7]	Mixed	Low		= (S)		= (S)
Inverted V mechanical[8]	Mixed	Low				
Mechanical V ultrasound V Laser[9]	Mixed	Moderate		= (S, I)	= (S, I)	= (S, I)
VAX-D V TENS[10]	Chronic	Low	+ (I)	+ (I)		+ (I)
Mechanical V Manipulation[11]	Mixed	Low	- (S)			
Mechanical added to medication and electrotherapy[12]	Mixed	Moderate		= (S)	+ (S)	
Stabilisation exercises						
V waiting list control[13]	Mixed	Moderate		+ (S)		
Physical therapy						
V epidural neuroplasty[14]	Mixed	Low		- (I, L)	- (I, L)	- (I, L)
Manipulation						
V sham manipulation[15]	Acute	Moderate		+ (S, I)	=/+ (S)* + (I)	
V chemonucleolysis[16]	Mixed	Low		+ (S), = (L)	= (S, L)	+/= (S)† = (L)
V mechanical traction[11]	Mixed	Low	+ (S)			
Laser and ultrasound						
Laser V Ultrasound V Traction[9]	Mixed	Moderate		= (S, I)	= (S, I)	= (S, I)
Corset						
Added to traction, electrotherapy & massage[17]	Mixed	Low		+ (S)		+ (S)

+ indicates an effect in favour of the intervention over the comparison
- indicates an effect in favour of the comparison intervention
= indicates no significant difference between interventions
Abbreviations: S= short term follow-up; I=intermediate term follow-up; L= long term follow-up; VAX-D=vertebral axial decompression; TENS= transcutaneous electrical nerve stimulation.
* there was no significant difference at the 2 week follow-up but significant differences in favour of manipulation at the 4 week and 6 week follow-ups.
† there was a significant difference in favour of manipulation at the 2 week follow-up but no significant difference at 6 week follow-up.

1=Peul et al. (2007), 2=Ostermann et al. (2006), 3=Dincer et al. (2007), 4=Kanayama et al. (2005), 5=Dincer et al. (2007), 6=Tesio & Merlo (1993), 7=Bonaiuti et al (2004), 8=Guvenol et al. (2000), 9=Unlu et al. (2008), 10=Sherry et al. (2001), 11=Liu & Zhang (2000), 12=Ozturk et al. (2006), 13=Bakhtiary et al. (2005), 14=Veihelmann et al. (2006), 15=Santilli et al. (2006), 16=Burton et al. (2000), 17=He et al. (2006)

3.3.6 Adverse events

Three trials reported at least one adverse event in conservative treatment groups (Guvenol et al., 2000; Liu & Zhang, 2000; Ozturk et al., 2006). Several adverse events were associated with traction treatment. In one trial comparing inverted traction with mechanical traction (Guvenol et al., 2000), 11 of the 16 participants in the inverted traction group reported pain associated with treatment compared to 2 of the 15 participants in the mechanical traction group, which was a statistically significant difference: RR=5.2 (95% CI: 1.4-19.5). The same trial reported that "almost all" of the participants in the inverted traction group reported anxiety during treatment, while one developed lower limb muscle weakness following treatment, compared to no such events in the mechanical traction group. In one trial, 2 of the 50 participants receiving mechanical traction fainted (Liu & Zhang, 2000). In another trial, 2 out of 46 participants needed to cease ibuprofen medication due to gastrointestinal effects (Ozturk et al., 2006).

A further four trials reported that there were no adverse events associated with conservative treatment (Burton et al., 2000; Dincer et al., 2007; He et al., 2006; Kanayama et al., 2005). Four trials reported adverse events associated with surgery or injections (Dincer et al., 2007; Osterman et al., 2006; Peul et al., 2007; Veihelmann et al., 2006). Six trials made no mention of adverse events (Bakhtiary et al., 2005; Bonaiuti et al., 2004; Deli, 2007; Santilli et al., 2006; Sherry et al., 2001; Tesio & Merlo, 1993; Unlu et al., 2008).

3.4 Discussion

3.4.1 Effectiveness of conservative treatments for lumbar disc herniation with associated radiculopathy

This review of conservative management for DHR revealed that a wide variety of treatments have been evaluated in RCTs focusing on people with a combined clinical and radiological diagnosis of this condition. Conservative interventions included advice, medication, traction, manipulation, stabilisation exercises, physiotherapy, laser, ultrasound and corsets. A wide range of comparison interventions were utilised in these trials, including sham manipulation, waiting lists, other conservative treatments, surgery and injections. Most trials included participants with mixed symptom durations. Several outcome measurement tools were employed and the length of

follow-up varied from one week to 24 months. The differences in all of these variables made it difficult to collate the findings of multiple trials via meta-analysis or even by using the levels of evidence approach. Most of the evidence summaries were therefore derived from individual trials.

The only strong evidence to emerge from this review was obtained by collating the results of two clinically and statistically homogenous trials that compared advice to microdiscectomy in people with subacute DHR (Osterman et al., 2006; Peul et al., 2007). Meta-analysis indicated that advice was less effective than surgery for producing short term improvements in back pain intensity, leg pain intensity, activity limitation and global improvement. These differences were maintained at intermediate term follow-up for leg pain intensity, but not for back pain intensity, activity limitation, or global change. There was strong evidence that no difference existed on any of these outcome measures at long term follow-up. Both trials reported that mean leg pain scores at the 12 month follow-up were quite low in both the surgically and conservatively treated groups (ranging from 6-11/100), indicating that the long term prognosis on this outcome was good regardless of the intervention received. In both trials, the advice group was a control intervention that was compared to the primary intervention of microdiscectomy. The relative effectiveness of advice in relation to other conservative interventions remains unclear as no trials investigated this. Other reviews of advice for the management of non-specific LBDs suggest that advice may be more effective than several other conservative treatments (Liddle, Gracey, & Baxter, 2007; Pengel et al., 2002). Further research comparing advice to other conservative interventions for people with DHR therefore seems warranted.

Moderate strength evidence relating to several interventions was derived from individual high quality trials. There was moderate evidence that stabilisation exercises were more effective than no treatment for short term improvement in pain intensity (Bakhtiary et al., 2005). The evidence relating to stabilisation exercises for DHR is consistent with another review of the effectiveness of motor control exercises for non-specific LBDs (Macedo, Maher, Latimer, & McAuley, 2009). It remains unclear whether stabilisation exercises are more effective than other treatments for people with DHR, as no trials have investigated this. There was also moderate evidence that manipulation was more effective than sham manipulation for back and leg pain intensity outcomes in people with an intact annulus in the acute stage of injury (Santilli

et al., 2006), although the results may not be generalisable to people who have a ruptured annulus where nuclear material has escaped. Other systematic reviews on LBDs have also shown that manipulation is more effective than placebo (Assendelft, Morton, Yu Emily, Suttorp, & Shekelle, 2004; Ferreira, Ferreira, Latimer, Herbert, & Maher, 2003). The other moderate strength evidence that emerged from this review was the finding of no difference in outcomes between laser, mechanical traction and ultrasound (Unlu et al., 2008), and that the addition of mechanical traction to a treatment program involving electrotherapy modalities and medication added some benefits in terms of reducing the likelihood of sciatica being present at short term follow-up (Ozturk et al., 2006). The evidence relating to all other trials in this review was rated as limited due to their low methodological quality scores.

A number of trials in this review showed no difference between groups on several outcomes. This could indicate that many of the intervention and comparison treatments were truly equivalent, or it may be that low statistical power limited the detection of true differences between groups, resulting in Type II errors (Altman & Bland, 1995). The latter explanation may be plausible in some cases, as sample sizes were small in many trials included in this review. Caution should therefore be used when interpreting evidence summaries in this review that conclude that there was no difference between two interventions, as an alternative explanation may be that significant effects were missed due to low statistical power in the original trials (Altman & Bland, 1995).

3.4.2 Methodological limitations of included trials

The PEDro scale was used in this review to evaluate the methodological quality of trials due to its documented reliability and validity for measuring trial quality (de Morton, 2009; Maher et al., 2003; Verhagen et al., 1998). Some concerns have been expressed about the validity of assigning equal weights to individual items on scales such as PEDro and then summing the scores to achieve an overall methodological quality rating for each trial (Higgins & Green, 2011). However, a study has validated this practice for the PEDro scale (de Morton, 2009). When assessing the quality of trials in this review however, it is worthwhile considering the individual methodological criteria for each trial (Table 3.3) in addition to the total PEDro score. Some specific areas of methodological quality are discussed below in order to discourage sole reliance on the PEDro score when assessing the quality of trials in this review.

The most common methodological limitation of trials included in this review was failure to blind participants and therapists. Only one trial in this review attempted to blind participants by comparing manipulation to sham manipulation (Santilli et al., 2006), while no trials attempted to blind therapists. Achieving adequate blinding of participants and therapists in trials of physical treatments is very difficult, although it is more easily achieved in drug trials (Deyo, Walsh, Schoenfeld, & Ramamurthy, 1990). However, the one trial in this review that compared two drugs (Kanayama et al., 2005) also failed to blind participants or therapists. While it was more common for outcome assessments to be undertaken in a blinded manner, 10 of the 18 trials still failed to achieve this. Future trials of conservative treatments for DHR should aim to blind outcome assessors at a minimum, even when blinding of therapists or participants is not possible.

While the PEDro scale includes random allocation as a methodological quality criterion, it only requires trials to mention random allocation to satisfy this criterion. Only nine trials described robust randomisation methods (Bakhtiary et al., 2005; Bonaiuti et al., 2004; Buchner et al., 2000; He et al., 2006; Kanayama et al., 2005; Osterman et al., 2006; Peul et al., 2007; Santilli et al., 2006; Sherry et al., 2001; Veihelmann et al., 2006), seven failed to describe the method used (Deli, 2007; Dincer et al., 2007; Guvenol et al., 2000; Liu & Zhang, 2000; Ozturk et al., 2006; Tesio & Merlo, 1993; Unlu et al., 2008) and in one trial the planned randomisation process was compromised for 15 of the 40 subjects due to an administrative error (Burton et al., 2000). Failing to report the precise method of randomisation raises questions as to whether a truly random method was applied in these trials and this may have implications for the validity of their results (Altman & Bland, 1999; Altman et al., 2001).

Several trials that were considered high quality based on achieving a PEDro score of six or more still contained key methodological flaws. Two trials in the review (Buchner et al., 2000; Peul et al., 2007) that both scored 7/10 on the PEDro scale failed to utilise blinded outcome assessment which introduces significant potential for bias (Colditz et al., 1989). Another high quality trial failed to utilise concealed allocation (Ozturk et al., 2006) which has been shown to lead to inflated estimates of treatment effects (Juni et al., 2001; Moher et al., 1998; Schulz et al., 1995; Wood et al., 2008).

3.4.3 Clinical significance of included trials

While each of the items on the clinical significance rating scale appear to have merit, the reviewers found the scale to be lacking in standardised decision criteria. This may explain the lower levels of interrater agreement obtained for ratings on this scale. Features of trials that may influence clinical relevance have been suggested elsewhere (Altman et al., 2001; Malmivaara, Koes, Bouter, & van Tulder, 2006) and these may serve as a useful starting point to provide further standardisation to the clinical significance scale. Despite the limitations of the existing scale, no trials in this review mentioned the validity or reliability of their outcome measurement tools. While some authors using common low back pain measurement tools such as visual analogue scales may have assumed that these properties were widely accepted, several of the scales were not in common use which warranted clarification of their psychometric properties.

3.3.4 Adverse events

No trials in the review described an intention or a methodology for detecting adverse events. This raises the possibility that other adverse events may have been overlooked or dismissed by the authors of the trials, particularly if some authors defined an adverse event differently to others. Authors of future RCTs should take note of the CONSORT statement which recommends that adverse events be operationally defined and reported in all RCTs (Moher et al., 2010).

Adverse events reported by trials in this review were rare but they were most commonly attributed to traction. Pain, anxiety, lower limb weakness and fainting were all reported in trials utilising traction, although only pain associated with inverted traction produced a statistically significant relative risk (Guvenol et al., 2000). Gastrointestinal side effects are commonly associated with the use of non steroidal anti-inflammatory drugs (NSAIDs) (Roelofs et al., 2008). While one trial in this review reported gastrointestinal side effects associated with the use of ibuprofen (Ozturk et al., 2006), the two trials that utilised diclofenac as a sole treatment reported no “serious” side effects without defining these (Dincer et al., 2007; Kanayama et al., 2005).

While this review of RCTs provides some indication of the frequency and nature of adverse effects, the limited sample sizes of the included studies reduces the precision of these estimates. When adverse events are rare, data from other sources such as case series and case reports can add to the body of evidence regarding adverse effects that

may be associated with treatments (Higgins & Green, 2006). Other reviews have collated data from case series and case reports relating to adverse events associated with manipulation (Jordon, Tamara, Weinstein, & Konstantinou, 2007; Oliphant, 2004; Oppenheim, Spitzer, & Segal, 2005). These reviews suggest that some concerns remain over the potential for manipulation to cause or exacerbate a disc herniation (Jordon et al., 2007; Oppenheim et al., 2005), although no adverse events related to manipulation were reported by the trials in the current review.

3.3.5 Comparison to other reviews

This review differed from previous reviews that have been conducted on the effectiveness of interventions for people with sciatica (Vroomen, de Krom, Slofstra et al., 2000) and lumbosacral radicular syndrome (Luijsterburg et al., 2007). The current review focussed on a specific diagnostic subgroup with symptomatic and radiological evidence of DHR. None of the previous reviews had specific inclusion criteria for clarifying the presence of DHR in participants. It is therefore likely that these other reviews included trials that contained participants with a more heterogeneous array of pathologies. One example of this is seen from a trial that compared four different physiotherapy treatments for people with symptoms of sciatica (Coxhead, Inskip, Meade, North, & Troup, 1981). That trial was included in all previous reviews, but was excluded from the current one. To be included in that trial, participants needed only to have "sciatic symptoms" as far as the gluteal fold and no imaging was undertaken to confirm the potential source of the symptoms. Those broad inclusion criteria would likely have resulted in a heterogeneous group of participants, as it was discussed in Chapter 2 that pain extending only to the buttock is unlikely to be due to DHR (Knutsson, 1961; Vroomen, de Krom, & Knottnerus, 1999). The conclusions of the current review are therefore more specifically applicable to people with DHR due to the use of stricter diagnostic inclusion criteria.

The different inclusion criteria and search strategies between this and previous reviews appeared to result in a considerably different collection of trials. For example, only two (Buchner et al., 2000; Burton et al., 2000) of the 18 trials in the current review were included by Luijsterburg et al. (2007). This appeared to be partially attributable to 12 of the trials in the current review being published after the Luijsterburg et al. (2007) review. Four other trials that were included in the current review (Guvenol et al., 2000; Liu & Zhang, 2000; Sherry et al., 2001; Tesio & Merlo, 1993) were not present in the

Luijsterburg et al. (2007) review, possibly due to the different search strategies used. Conversely, of the 30 trials included in the Luijsterburg et al. (2007) review, 28 did not meet the inclusion criteria of the current review (in 13 trials all groups received injections, 11 did not utilise CT or MRI to confirm a disc herniation, two contained <75% of subjects with a confirmed disc herniation and two were not published in English).

The different collection of trials included in the current and previous reviews led to some differences in evidence summaries. While the current review found moderate evidence for the effectiveness of manipulation over sham manipulation for acute DHR, Vroomen et al. (2000) found limited evidence supporting manipulation while Luijsterburg et al. (2007) found no evidence in favour of manipulation for DHR. The current review found mixed results among trials utilising traction, with moderate evidence of effectiveness on one of the three outcome measures in one trial (Ozturk et al., 2006) limited evidence of effectiveness in two trials (Sherry et al., 2001; Tesio & Merlo, 1993) no difference in two trials (Bonaiuti et al., 2004; Unlu et al., 2008) and evidence of inferiority in one trial (Liu & Zhang, 2000). The previous reviews did not recommend traction for DHR (Luijsterburg et al., 2007; Vroomen, de Krom, Slofstra et al., 2000). The current review did not find any significant effects in trials utilising NSAIDs, a finding that was consistent with the previous reviews (Luijsterburg et al., 2007; Vroomen, de Krom, Slofstra et al., 2000). Only the current review included the trials investigating advice, stabilisation exercises, herbal magnetic corsets, herbal medication, laser and ultrasound, hence the previous reviews did not comment on the effectiveness of these treatments.

3.3.6 Strengths and limitations of this review

There was several strengths of this systematic review. A broad search of ten electronic databases was undertaken without treatment related search terms to avoiding biasing the search results to particular interventions. The use of two reviewers who independently selected trials for inclusion, rated their methodological quality and extracted data, with a high degree of agreement, provides confidence in the reliability of these processes. Consistent with recommendations that research on LBDs should focus on specific subgroups (Delitto, 2005; Ford et al., 2007; Foster et al., 2009), the current review targeted a specific pathoanatomical subgroup with established validity (DHR) (see Chapter 2).

While this review attempted to focus on participants with DHR, it was not possible to control all potential sources of variability among participants. The minimum required diagnostic features of referred leg pain combined with a disc herniation visualised on CT or MRI still leaves room for potential variation in diagnosis. In addition, while this review employed a standardised radiological definition of disc herniation (Fardon & Milette, 2001), authors of the included trials may have used terms such as herniation or protrusion differently to these guidelines. Variability in the severity and nature of symptoms was also apparent among the participants of the included trials. For example, two trials excluded people with motor or sensory neurological deficits (Bakhtiary et al., 2005; Bonaiuti et al., 2004), other trials contained a large proportion of participants with positive neurological findings (Buchner et al., 2000; Osterman et al., 2006; Ozturk et al., 2006; Peul, van den Hout et al., 2008) while others failed to report the proportion of participants with such features (Burton et al., 2000; Deli, 2007; Dincer et al., 2007; He et al., 2006; Liu & Zhang, 2000; Santilli et al., 2006; Sherry et al., 2001; Veihelmann et al., 2006). As discussed in Section 1.2.1, it has been proposed that clinical heterogeneity within RCTs and systematic reviews may account for some of the null and inconclusive results that are prevalent in back pain research (Ford et al., 2007; Kent & Keating, 2004). While reviews such as the current one that focus on specific LBD subgroups are therefore important, other sources of variability within the samples of different trials also contribute to heterogeneity. Authors of RCTs could aid systematic reviewers who may wish to evaluate the impact of these additional sources of participant variability by thoroughly reporting the baseline demographics, presenting features and measures of condition severity in their participants.

Another limitation of this review was the exclusion of trials published in languages other than English due to funding and resource limitations. However, there is some evidence to suggest that excluding non-English papers does not typically have a substantial effect on systematic review results (Moher, Pham, Lawson, & Klassen, 2003). Publication bias is also a possibility in this review. However, since most interventions showed only limited or moderate evidence of effectiveness, including more trials with null results is unlikely to have significantly changed the conclusions.

3.5 Chapter summary and conclusion

This chapter has provided an overview of the effectiveness and safety of existing treatments for people with DHR. Previous research has suggested that the natural history of DHR is likely to be positive for the achievement of some improvement, although failure to fully recover is common and the risk of recurrence is significant. Existing systematic reviews have found that discectomy surgery and epidural injections lead to more rapid short term improvement in symptoms, however long term benefits have not been demonstrated for these treatments and they are associated with some risk of adverse events. No previous systematic reviews have investigated the effectiveness and safety of conservative and non-injection treatments for people with a clinical and radiological diagnosis of DHR.

An original systematic review of RCTs involving people with symptomatic and radiological evidence of DHR was presented in this chapter. The review provided strong evidence that advice was less effective than microdiscectomy at short term follow-up, but equally effective at long term follow-up, for people with subacute DHR. There was moderate evidence that stabilisation exercises were better than no treatment at short term follow-up, that manipulation was better than sham manipulation at short and intermediate follow-ups for people with an intact annulus, and that no difference existed between traction, laser and ultrasound at short and intermediate follow-ups. Moderate evidence was found that the addition of mechanical traction to medication and electrotherapy modalities reduced the risk of sciatica being present at short term follow-up, but not the risk of back pain being present or mean pain intensity. There was either limited or no evidence to support the effectiveness of manipulation compared to other treatments, traction compared to other treatments, physiotherapy compared to neuroplasty, or for herbal medication, herbal magnetic corsets, or non-steroidal anti-inflammatory medication. Two trials reported adverse events associated with traction (pain, anxiety, lower limb weakness, fainting), while one trial reported gastrointestinal events associated with ibuprofen. Additional high quality trials are required to determine which conservative treatments are the safest and most effective for people with DHR.

CHAPTER 4: FUNCTIONAL RESTORATION AS A POTENTIAL CONSERVATIVE TREATMENT FOR DISC HERNIATION WITH ASSOCIATED RADICULOPATHY

The previous chapter presented an original systematic review that found few conservative treatments with evidence of effectiveness for people with DHR. The quality of many RCTs in this field was found to be low and most conservative treatments have been evaluated in only a single trial. An appraisal of the published version of that review concluded that it "highlights the need for well-designed, prospective, randomised, controlled trials evaluating the effectiveness of non-operative treatments for (lumbar) DHR" (Daffner, 2010, p.140). In pursuit of this goal, it is worthwhile considering the potential of conservative interventions for DHR that have not yet been evaluated in high quality RCTs. It is notable that in the systematic review (Chapter 3), the effectiveness of multimodal treatment packages were not evaluated in any of the included RCTs (Daffner, 2010). The only trial in the systematic review that utilised a multimodal treatment applied it in both groups to evaluate the effect of adding epidural injections (Buchner et al., 2000), so the benefit of the multimodal treatment could not be determined.

The current chapter proposes that functional restoration is one multimodal treatment worthy of evaluation for the management of DHR. Functional restoration is introduced and the mechanisms by which it could assist people with DHR are discussed. Existing evidence is reviewed outlining the effectiveness of functional restoration for LBDs, while the outcomes that have been achieved by a limited number of people with DHR who have undertaken functional restoration programs are also considered. This leads into an original research study that presents the outcomes and adverse events that were reported by a consecutive series of participants with DHR who undertook a physiotherapy functional restoration program. The exploration of the potential utility of functional restoration for DHR in this chapter represents important background work in the justification and planning of a RCT that follows later in the thesis.

4.1 Introduction

4.1.1 Definition of functional restoration

The term functional restoration (FR) was proposed by Mayer et al. (1985) to describe a supervised exercise rehabilitation approach for people with non-specific LBP. Mayer et al. (1985) defined FR as "a multimodal pain management program that employs a comprehensive cognitive behavioral treatment orientation to help patients better cope with, and manage, their pain . . . while undergoing the sports medicine physical approach to correct functional deficits" (Mayer et al., 1985, p.483). According to the original description by Mayer et al. (1985) and more recent reviews of the literature (Gatchel & Mayer, 2008; Poiraudeau, Rannou, & Revel, 2007; Rainville, Kim, & Katz, 2007; Schaafsma et al., 2010), the key components of FR are typically:

- The use of a multimodal biopsychosocial treatment approach aimed at improving the participant's physical, psychological and social function through their active participation in treatment. Passive treatment modalities (such as electrotherapy, massage and manual therapy) are discouraged in order to promote independent self-management and to avoid dependence on a therapist.
- Exercise sessions that are undertaken in a safe and supervised environment, involving exercises designed to simulate the specific work and/or activity limitations of the participant. The intensity of the exercises are progressively increased throughout the program to improve physical, psychological and emotional tolerance.
- The use of a cognitive-behavioural approach to address psychosocial factors. A cognitive-behavioural approach refers to the application of psychological treatment strategies based on theories of human cognition and behaviour (Grazebrook & Garland, 2005; Hansen, Daykin, & Lamb, 2010; Nicholas, 2008). This approach aims to change cognitions and behaviours that are interfering with a person's health or recovery (Grazebrook & Garland, 2005; Hansen et al., 2010; Nicholas, 2008). Examples of techniques that are commonly involved in the application of a cognitive-behavioural approach include cognitive restructuring (the identification of unhelpful beliefs and development of more accurate and productive beliefs), behavioural modification (the use of positive and negative reinforcement to increase desirable behaviour and reduce undesirable behaviour based on the principles of operant conditioning) and relaxation training (such as progressive muscle

relaxation or relaxed breathing aimed at reducing muscular tension and its negative influence upon pain) (Grazebrook & Garland, 2005; Hansen et al., 2010; Harding & Williams, 1995; Nicholas, 2008; Ostelo et al., 2005; Sowden, Hatch, Gray, & Coombs, 2006)

Although the term FR is often associated with multi-disciplinary full-time rehabilitation programs (Gatchel & Mayer, 2008; Poiraudeau et al., 2007), there are many examples of less time intensive programs delivered by a single physiotherapist that contain the key components of FR (Faas, van Eijk, Chavannes, & Gubbels, 1995; Kaapa, Frantsi, Sarna, & Malmivaara, 2006; Lindstrom, Ohlund, Eek, Wallin, Peterson, Fordyce et al., 1992; Roche et al., 2007; Schaafsma et al., 2010; Smeets et al., 2008; Storheim, Brox, Holm, Koller, & Bo, 2003; Wright, Lloyd-Davies, Williams, Ellis, & Strike, 2005).

4.1.2 Effectiveness of functional restoration for low back disorders

Functional restoration has been shown to be more effective than usual care at improving return to work outcomes in people with subacute or chronic LBP (Bendix et al., 1996; Kool et al., 2007; Lindstrom, Ohlund, Eek, Wallin, Peterson, Fordyce et al., 1992; Loisel et al., 1997; Schaafsma et al., 2010; Schonstein, Kenny, Keating, Koes, & Herbert, 2003; Staal et al., 2004). In addition to work outcomes, FR programs provide a range of other benefits compared to usual care including greater reduction in pain, greater improvement in activity limitation and decreased utilisation of other healthcare resources (Bendix et al., 1996; Guzman et al., 2001; Loisel et al., 1997; Macedo, Smeets, Maher, Latimer, & McAuley, 2010; Staal et al., 2004). There does not appear to be a significant difference between high intensity and low intensity FR programs based on direct comparisons in RCTs (Heymans et al., 2006; Schaafsma et al., 2010; Skouen, Grasdal, Haldorsen, & Ursin, 2002). Although no reviews have compared single and multi-disciplinary FR programs, individual trials comparing these two approaches have found minimal or no differences in outcomes (Bendix, Bendix, Labriola, Haestrup, & Ebbehoj, 2000; Dufour, Thamsborg, Oefeldt, Lundsgaard, & Stender, 2010; Kaapa et al., 2006; Roche-Leboucher et al., 2011; Roche et al., 2007).

4.1.3 Effectiveness of functional restoration for disc herniation with associated radiculopathy

The previous section outlined some existing evidence for the effectiveness of FR for people with non-specific LBP. However, RCTs investigating FR typically exclude people with specific pathoanatomical conditions including DHR (Hahne & Ford, 2006;

Schonstein et al., 2003). As a result, no RCTs have evaluated the effectiveness of FR for people with DHR (Chapter 3).

Some preliminary evidence supporting the application of FR for people with DHR has been provided by one observational study (Saal & Saal, 1989). In that case series, 62 participants with chronic DHR received FR, with a 90% success rate reported at a mean follow-up time of 31 months (Saal & Saal, 1989). While that study has provided some indication of the success rate that might be achieved when people with DHR undergo FR, limitations of the study raise additional questions. As the study did not utilise pre and post treatment standardised outcome measures, the magnitude of improvement in participants was not quantified. In addition, the study did not comment on adverse events that were associated with the treatment, so the safety of FR for people with DHR has not been established.

The author of this thesis has previously published a single case study describing the successful rehabilitation of a person with chronic DHR who undertook FR supervised by a physiotherapist (Hahne & Ford, 2006). That participant achieved a reduction in the Oswestry Disability Index from 48% to 22% after 9 weeks of supervised FR and a two year follow-up revealed that the score had reduced further to 14%. It is not known whether the outcome described in that case report is representative of the typical results that could be expected, hence evaluation of a larger series of participants is warranted.

4.1.4 Mechanisms of effect for functional restoration

Another consideration to make when evaluating the utility of FR as a potential treatment for people with DHR relates to the proposed mechanisms of effect. It has been suggested that treatments based on known or hypothesised mechanisms of effect are likely to have the greatest potential for pathoanatomical subgroups (Ford et al., 2007; Hancock et al., 2007; Miller Spoto & Collins, 2008). In their original description of FR, Mayer et al. (1985) proposed that a primary mechanism of effect was reversal of the “deconditioning syndrome”. They proposed that long term self-protection and disuse of spinal joints, perhaps mediated by a fear of re-injury (fear avoidance beliefs), leads to reduced physical function in people with subacute and chronic LBDs (Mayer et al., 1985). It was also proposed that healthcare providers often positively reinforce this behaviour with their precautionary advice to avoid certain activities (Mayer et al., 1985; Poiraudeau et al., 2007). Functional restoration was proposed as a means of

promoting a graded return to appropriate activities including work (Mayer et al., 1985). Although the validity of the fear avoidance model and the deconditioning syndrome have not been comprehensively proven (Bousema, Verbunt, Seelen, Vlaeyen, & Knottnerus, 2007; Duque, Parra, & Duvallet, 2009; Hasenbring & Verbunt, 2010; Smeets et al., 2006; Verbunt, Smeets, & Wittink, 2010), this remains one hypothesised mechanism of effect for FR (Hansen et al., 2010; Poiraudeau et al., 2007; Rainville et al., 2007; Schaafsma et al., 2010). It is conceivable that people with DHR might also develop deconditioning, hence re-establishing activity might equally benefit them. In fact, it could be argued that the higher severity of pain intensity and activity limitation typically seen in people with DHR (see Section 2.5.2.3) might increase the likelihood that deconditioning will result. In addition, surveys show that healthcare practitioners are more likely to recommend longer periods of bed rest for people with DHR compared to those with non-specific LBP (Legrand et al., 1998; Webster, Courtney, Huang, Matz, & Christiani, 2005), so deconditioning may be more likely to occur in this population.

Reversal of deconditioning is one of a number of potential mechanisms by which FR might have a beneficial effect. All LBDs can have a range of physical, psychological and social components (Bogduk, 2004b; Chou, Loeser et al., 2009; Ehrlich, 2003; Friedly et al., 2010) and DHR is no exception (Atlas et al., 2007; Edwards et al., 2007; Koes et al., 2007; Kose, Demir, Arikan, & Palaoglu, 2003; Zieger, Schwarz, Konig, Harter, & Riedel-Heller, 2010). The multimodal content of a FR program allows a range of physical, psychological and social factors to all be addressed through different components of treatment (Gatchel & Mayer, 2008; Mayer et al., 1985; Poiraudeau et al., 2007; Rainville et al., 2007; Schaafsma et al., 2010). For example, psychosocial factors such as depression, anxiety and fear avoidance beliefs are prevalent in people with DHR (Johansson, Linton, Rosenblad, Bergkvist, & Nilsson, 2010; Zieger et al., 2010) and the presence of these factors is known to predict inferior treatment outcomes in this population (Atlas et al., 2010; Atlas et al., 2007; Edwards et al., 2007; Johansson et al., 2010; Zieger et al., 2011; Zieger et al., 2010). The utilisation of cognitive-behavioural strategies in a FR program could therefore be another mechanism that contributes to the effectiveness of the intervention through means of reducing psychosocial dysfunction (Hansen et al., 2010). Uni-dimensional treatment approaches that focus purely on the physical aspects of DHR are likely to neglect these other avenues of potential treatment benefit (Chou, Loeser et al., 2009; Daffner, 2010; Mayer

et al., 1985; Poiraudeau et al., 2007). This may be one explanation for the limitations of existing treatments for DHR discussed in Chapter 3, including surgery, which in isolation do not address all potential sources of pain, activity limitation, social dysfunction and psychological distress (Chou, Loeser et al., 2009).

While the proposed mechanisms of FR for people with LBP appear equally applicable to those with DHR, modifications to the traditional FR approach may be necessary for DHR. Since FR has typically been applied to people with subacute and chronic non-specific LBP, an assumption has often been made that the original physical pathology has largely resolved and the remaining deficits are attributable to deconditioning and psychosocial distress (Gatchel & Mayer, 2008; Mayer et al., 1985). A consequence of this assumption is that progression of exercises in FR programs typically occurs on a time contingent basis, with pain and pathoanatomical factors given less consideration (Bogduk & McGuirk, 2002; Chou, Loeser et al., 2009; Mayer et al., 1985; Poiraudeau et al., 2007; Schonstein et al., 2003). However, discounting the physical elements of DHR would not be justified even in the chronic stage of injury, as Section 2.4 described how demonstrable physical pathology and healing is known to continue for over 12 months (Adams & Roughley, 2006; Adams et al., 2010; Bron et al., 2009; Melrose et al., 2008; Osti et al., 1990). This key difference between DHR and non-specific LBP suggests that FR programs applied to people with DHR may need to incorporate additional treatment components targeting long term pathophysiological processes, and pain associated with exercises may need to be respected to avoid exacerbation of the pathology. The case study (Hahne & Ford, 2006) and case series (Saal & Saal, 1989) discussed earlier both modified a traditional FR program to reflect the more serious pathology present in people with DHR.

4.1.5 Summary and aims of the study

Functional restoration was initially developed for people with non-specific LBP and has demonstrated effectiveness compared to usual care for people with subacute and chronic symptoms. People with DHR have typically been excluded from trials that evaluate FR, although a case has been made that they could benefit from this intervention based on its known or hypothesised mechanisms of effect. There is existing evidence from one case series and one case study showing that positive outcomes have been achieved when people with DHR have undergone a FR program modified for the presence of this specific pathology (Hahne & Ford, 2006; Saal & Saal,

1989). However, outcomes have not been quantified using validated measures for a large group of participants with DHR undergoing FR, and adverse events have not been investigated.

Based on the above findings, it is hypothesised that a FR program modified specifically for people with DHR may be a promising treatment for this condition. While a RCT is the ideal study design to answer questions relating to the effectiveness of interventions (Manchikanti, Hirsch, & Smith, 2008), collation of existing data relating to standardised outcomes and adverse events is considered an important step before a RCT can be justified (Bogduk, 2004a; Mann & Djulbegovic, 2003).

The aim of this study was therefore to describe the outcomes and adverse events reported by a consecutive series of people with DHR who were treated with a physiotherapy FR program. The published version of this study is presented in Appendix A (Hahne et al., 2011).

4.2 Methods

This study was approved by the Health Sciences Human Ethics Committee, The University of Melbourne (Approval #0718601, see Appendix D). An exemption was granted to allow de-identified data to be extracted from participants' records without requesting their consent.

4.2.1 Study Design

Retrospective case series.

4.2.2 Physiotherapists

The files of three physiotherapists with eight, nine and ten years of clinical experience in private physiotherapy practice were reviewed. These three physiotherapists were chosen due to their long-standing use of i) functional restoration for the management of LBDs; and ii) standardised assessment and follow-up protocols in their daily practice. The three physiotherapists worked for the same healthcare organisation at separate clinics in a metropolitan area and one regional centre. They had all undergone similar training, which included extensive mentoring by the same senior musculoskeletal physiotherapist, regular in-services and case conferences, as well as periodic auditing

of clinical outcomes. Their main source of referrals was from general medical practitioners, spinal surgeons and occupational rehabilitation providers.

The three physiotherapists subscribed to the biopsychosocial approach to managing LBDs (Weiner, 2008). They shared a common philosophy to use predominately active management strategies such as education, advice and exercise rehabilitation in the context of a FR program. When implementing FR on people with specific pathoanatomical conditions such as DHR, the physiotherapists had been trained to adapt the program to account for pathophysiological mechanisms associated with the condition. The severity of the presenting pathology was therefore respected and care was taken to avoid aggravation of participants' symptoms. However, this was coupled with the use of cognitive-behavioural strategies to address any unhelpful beliefs or behaviours that had potential to negatively impact upon recovery (Grazebrook & Garland, 2005; Harding & Williams, 1995; Sowden et al., 2006). The physiotherapists aimed to equip participants with the necessary skills to self-manage their condition in the long term, hence participants were often discharged prior to achieving full recovery if they had reached a stage of independent management.

4.2.3 Participant selection criteria

Consecutive participants were included if they i) had pain referring predominately into one leg; and ii) had a radiologist's report from a CT or MRI scan that described a lumbar disc herniation impinging on a spinal nerve root. Accepted terms for herniation followed the Fardon and Millette (2001) classification adopted in this thesis, hence herniated, protruded, extruded and sequestrated discs were included but bulges were excluded. Participants were excluded if they had leg symptoms that were bilateral in distribution and intensity. Participants who attended only an assessment without receiving treatment were also excluded.

4.2.4 Research procedures

All files from the period between 2001 and 2009 were reviewed, with those satisfying the selection criteria included in the study. All information to allow classification of people with DHR had been routinely recorded in all files using a standardised initial assessment form. The following descriptive data was available for participants and was extracted from the file: i) baseline demographics (age and gender); ii) subjective reports (area of symptoms, presenting complaints, duration of symptoms, previous treatment

and medication); and iii) physical examination findings (neurological examination, straight-leg-raise and response to mechanical loading strategies). Radiological diagnosis of DHR was confirmed by viewing the radiologist's report from each participant's CT or MRI scan.

Outcome measures were extracted from the standardised baseline assessment form and again from standardised follow-up forms. Primary Outcome measures were the Oswestry Disability Index Version 2.1 (Fairbank, Couper, Davies, & O'Brien, 1980) in participants with sufficient English, work status (number of hours working and the presence of any work restrictions) and the participant's global rating of change since program commencement at each formal reassessment (improved, unchanged, or worse) (Kamper, 2009). A baseline measure of psychosocial distress was also recorded, either the Fear Avoidance Beliefs Questionnaire (Waddell, Newton, Henderson, Somerville, & Main, 1993) (used between 2001 and 2004) or the Orebro Musculoskeletal Pain Questionnaire (Linton & Boersma, 2003) (used from 2004 onwards). None of the three physiotherapists routinely used visual analogue or numerical rating scales for pain assessment in their practice, hence these data were not available.

Other data of interest that had been recorded in a standardised manner were extracted from the files, including the treatment methods used for each participant, the participant's response to the treatment methods employed in each session, any co-interventions provided by other health practitioners and any adverse events related to the physiotherapy intervention. The reason for and time until discharge, was also recorded for all participants.

4.2.5 Data analysis

Statistical analyses were conducted using PASW Statistics 18.0[1]. Descriptive statistics (means and standard deviations for continuous data and totals with proportions for categorical data) were employed to describe the presenting characteristics of included participants and the specific treatment modalities used.

Outcomes were collated at two distinct phases of the treatment program; at the first formal reassessment and at discharge from the program. The proportion of participants

[1] SPSS Inc, 11th Floor, 233 Wacker Dr, Chicago IL 60606

reporting global improvement (as opposed to no change or worsening) on the global rating of change scale was tested for significance using the one-sample Chi square test. Changes in the proportion of participants at work, and the proportion of participants working full-time, were tested for statistical significance using McNemar's test. To determine whether a significant change in Oswestry scores had been achieved between baseline and the two follow-up assessments, a linear mixed model analysis was performed. This was chosen due to its strength in analysing longitudinal biological data, including its robust ability to handle missing data (Siddiqui, Hung, & O'Neill, 2009; West, 2009).

4.3 Results

4.3.1 Participants

A total of 1148 files were reviewed, with 95 files (8.3%) satisfying the selection criteria. One of the physiotherapists treated 56 participants, one treated 20, while the other treated 19. The flow of participants through the study is presented in Figure 4.1. The baseline characteristics of the included participants are presented in Table 4.1.

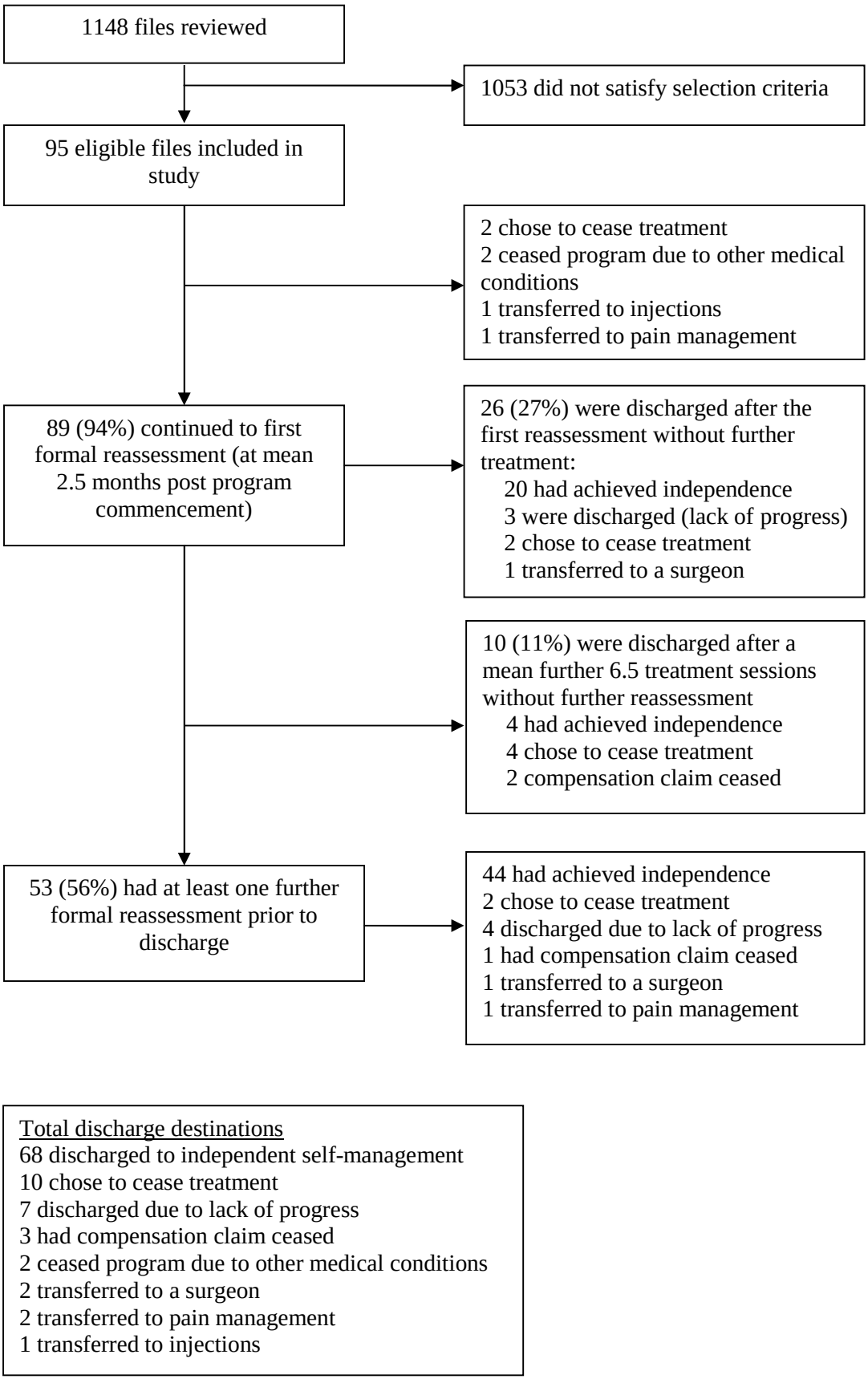


Figure 4.1: Flow of participants through the study

Table 4.1: Baseline characteristics of participants

Characteristic	n (%), or mean (+/- SD)
Workers compensation claim	67 (71%)
Male	66 (69%)
Age (years)	40.3 (+/- 11.7)
Fluent in English	82 (86%)
Leg pain extending below the knee	81 (85%)
Leg / foot paraesthesia	63 (66%)
Duration of leg symptoms (months)	14.0 (+/- 20.1)
Duration of back symptoms (months)	17.2 (+/- 24.8)
Participants reporting a previous episode of back pain	49 (52%)
Participants reporting a previous episode of leg pain	19 (20%)
Time off work current episode (months)	3.8 (+/- 6.7)
Previous treatment prior to assessment	
Physiotherapy	60 (63%)
Chiropractic / osteopathy	24 (25%)
Epidural injections	10 (11%)
Rehabilitation program / pain management	7 (7%)
Comorbidities	
Neck pain	11 (12%)
Diabetes	4 (4%)
Shoulder pain	3 (3%)
Smoker	37 (43%)
Only computerised tomography available	47 (49%)
Magnetic resonance imaging available	48 (51%)
Number with disc herniation at two or more levels	17 (18%)
Type of herniation	
Herniation / protrusion / prolapse	81 (85%)
Extrusion	13 (14%)
Sequestration	1 (1%)
Level of primary disc herniation	
L5/S1	54 (57%)
L4/5	33 (35%)
L3/4	4 (4%)
L2/3	4 (4%)
Nerve root involvement	
Compression	49 (52%)
Displacement	16 (17%)
Contact	30 (31%)
Examination findings	
Straight leg raise angle affected side (degrees)	48.6 (+/- 18.2)
Straight leg raise angle non-affected side (degrees)	62.8 (+/- 19.0)
Number with sensory deficit	37 (40%)
Number with motor weakness	35 (37%)
Number with reflex reduction / absence	24 (25%)
Number with at least one neurological sign	53 (56%)
Directional preference present	20 (39%)
Psychosocial risk factors questionnaire scores	
Fear avoidance beliefs questionnaire (n=29)	44.5 / 60 (+/- 12.4)
Orebro questionnaire (n=34)	121.7 / 210 (+/- 28.5)

Note: The treating physiotherapists used the fear avoidance beliefs questionnaire between 2001-2004 and the Orebro after 2004. These questionnaire data were not available for 32 participants (13 did not have sufficient English literacy and 19 did not complete or return the questionnaire).

4.3.2 Treatment methods

While all of the participants in this study had commenced treatment using a FR approach, the key components of the program varied (Figure 4.2). The most common components were specific motor control training (100%), functional exercise rehabilitation (98%) and education utilising a cognitive-behavioural approach (96%). The mean (SD) number of physiotherapy sessions attended throughout the treatment program was 30.3 (21.9) over a mean (SD) duration of 8.7 (9.4) months. Five participants were discharged before they had received all elements of a typical FR program (functional exercises and education with a cognitive-behavioural approach), although all of them received at least one of these key components.

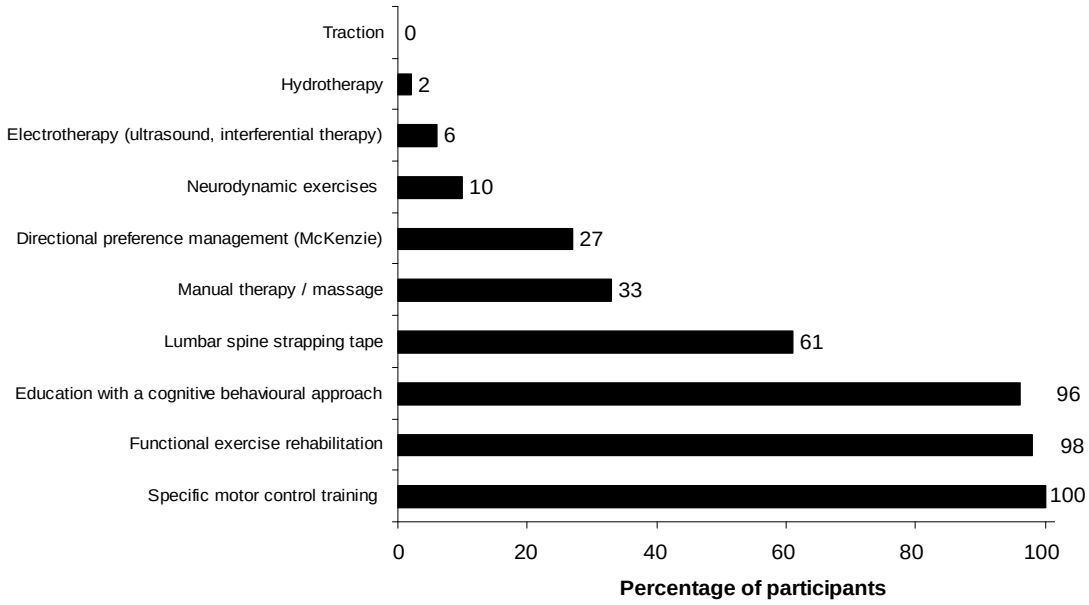


Figure 4.2: Treatment components used for participants

Treatment sessions were administered on a one-to-one basis, with the duration of each session lasting 20-40 minutes. Two main stages of treatment were evident for most participants. In the first stage, participants attended a mean (SD) of 16 (9) treatment sessions leading up to the first formal reassessment at a mean (SD) of 2.5 (1.1) months after commencing treatment. Thus, in this stage participants attended a mean of 1.6 sessions per week (6.4 sessions per month). Treatment in this stage typically involved education regarding DHR, lumbar spine taping and directional preference management (McKenzie method) in selected participants. Specific motor control training during this period commenced in static positions before integration into functional activities supervised in the physiotherapy clinic. In all cases, the functional exercises included

walking, step-ups and upper limb dumbbells (bicep curls, forward arm raises and side arm raises). Additional functional exercises that were tailored to each participant's work and daily functional demands included lunges, squats, lifting, abdominal crunches and erector spinae strengthening via active trunk extension. Participants who reported ongoing leg symptoms in specific positions that placed the sciatic nerve on stretch (eg. driving or sitting with the legs outstretched) were sometimes given 'neurodynamic exercises', consisting of nerve gliding exercises as described by Butler (Butler, 2000). Cognitive-behavioural strategies that were commonly used by the physiotherapists throughout the course of treatment included functional goal setting, promotion of appropriate beliefs surrounding recovery timeframes, challenging unhelpful beliefs, pacing, managing increases in pain, and positive reinforcement of increased exercise and activity levels (Hahne & Ford, 2006; Harding & Williams, 1995; Sowden et al., 2006). Following the first reassessment, 20 (21%) participants had improved sufficiently to allow them to be discharged to an independently self-managed exercise program at their home or local gymnasium without further review.

In the second stage of treatment, all participants who had not ceased treatment or been discharged continued with a home or gymnasium based exercise program. This consisted of continuing with the functional exercises that were established during the first stage of the program, with gradual progressions made in exercise intensity. Some additional exercises were also added during this stage of the program. Table 2 contains a representative example of the content, dosage and progression of a FR program for one participant at various stages of the program. For all participants during the second stage of the program, periodic review sessions with the physiotherapist continued at a mean rate of 1.6 sessions per month. The review sessions focused on goal setting, progression of exercise intensity and monitoring of compliance via an exercise diary. Since the exercise diary was kept by participants rather than the physiotherapists, a reliable record of exercise compliance could not be obtained from the files. Of the 63 participants who continued to be reviewed by their physiotherapist during this stage of management, a mean (SD) of 14 (16) sessions were attended over a mean (SD) of 14 (16) months until they achieved the ability to independently self-manage without further input from their physiotherapist.

Table 4.2: Representative example of the content and progressions of a functional restoration program for one participant

Exercise	Program dosage at commencement	Program dosage at first reassessment (mean 2.5 months)	Program dosage at discharge (mean 8.7 months)
Specific motor control training (transversus abdominis, multifidus, pelvic floor)	10 repetitions of 5-second contractions in side-lying, then standing, then walking	Formal practice twice per day in standing, integration to daily activities and to functional exercises	Formal practice once per day standing, automatic activation during daily activities
Treadmill	3 x 2 mins @ 3.0kph	3 x 4 mins @ 5.0 kph	1 x 20 mins @ 6.0kph 1 x 5 mins @ 10kph
Step-ups	3 x 10	3 x 20	3 x 30
Bicep curls	3 x 10 @ 1kg	3 x 10 @ 3kg	3 x 15 @ 5kg
Forward arm raises	3 x 10 @ 0.5kg	3 x 10 @ 2kg	3 x 15 @ 3kg
Side arm raises	3 x 10 @ 0.5kg	3 x 10 @ 2kg	3 x 15 @ 3kg
Lunges		3 x 10 @ 3kg	3 x 15 @ 5kg
Squats		3 x 10 @ 3kg	3 x 15 @ 5kg
Lifting from floor level		1 x 5 @ 5kg	1 x 5 @ 10kg
Lateral pull-down			3 x 15 @ 30kg
Triceps pushdown			3 x 15 @ 15kg
Abdominal crunches			3 x 15
Active trunk extensions (erector spinae)			3 x 15
Task specific training (eg. golf progressions as below)			
Resisted rotation		3 x 10 (resisted band)	3 x 20 (higher resistance)
Putting practice		1 x 20 putts	1 x 40 putts
Chipping practice			1 x 20 chips
Driving range			1 x 20 drives
9 holes			First 5 rounds
18 holes			After 5 rounds

Note: Program exercise frequency was 3-4 times per week, except for core stabilising in initial stages which was 4 times per day.
Abbreviations: mins=minutes; kph=kilometres per hour; kg=kilograms;

4.3.3 Outcomes

The primary outcome measures are presented in Table 4.3. A significant proportion of participants reported improvement on the global rating of change scale at both the first reassessment (87%, $\chi^2(1, n=89)=47.5$, $p<.001$) and at discharge from the program (80%, $\chi^2(1, n=89)=31.6$, $p<.001$). There was a significant increase in the number of participants working, from 52% at baseline to 68% at first reassessment ($\chi^2(1, n=76)=11.1$, $p<.001$) and to 78% at discharge ($\chi^2(1, n=76)=18.1$, $p<.001$). In addition, there was a significant increase in the number of participants working fulltime, from 37% at baseline to 51% by the first reassessment ($\chi^2(1, n=76)=8.1$, $p=.002$) and to 67% by discharge ($\chi^2(1, n=76)=21.0$, $p<.001$).

Table 4.3: Results for primary outcome measures

Outcome measure	Baseline	First formal reassessment (mean 2.5 months)	Discharge status (mean 8.7 months)
Global rating of change			
Improved		77/89 (87%)*	71/89 (80%)*
No change		11/89 (12%)	17/89 (19%)
Worse		1/89 (1%)	1/89 (1%)
Oswestry score mean (SD)	45.1 (15.5), n=77	34.4 (17.4), n=66†	29.8 (20.1), n=66†
Work status (excludes students, retirees and those unemployed pre-injury)			
Full hours	30/82 (37%)	39/76 (51%)‡	51/76 (67%)‡
Restricted hours	13/82 (15%)	13/76 (17%)	8/76 (11%)
Off work	39/82 (48%)	24/76 (32%)	17/76 (22%)

Note: 18 participants did not complete the Oswestry at baseline (13 due to insufficient English and five due to failure to return the questionnaire)
Abbreviations: SD=standard deviation; n=number of participants
* p <.001 for one-sample chi square test (improved V unchanged or worse relative to baseline)
† p <.001 for effect of change in Oswestry score compared to baseline using a linear mixed model
‡ p <.01 for change in proportion of participants at work and proportion of participants working full time (one sample chi-square test)

The mean Oswestry score reduced by 10.9 (95% CI: 7.5 to 14.4) points between baseline and first reassessment, and by 15.9 (95% CI: 11.8 to 20.1) points between baseline and discharge. By the time of discharge from the program, 39 of the 66 (59%) participants with follow-up Oswestry data had achieved a change in the Oswestry of more than the minimum clinically important difference (MCID) of 10 points (Lauridsen, Hartvigsen, Manniche, Korsholm, & Grunnet-Nilsson, 2006; Ostelo et al., 2008). In terms of actual activity limitation scores, 11 of the 66 (16%) participants with follow-up Oswestry data achieved a score of less than 10%, while 31 participants (46%) had achieved a score of 20% or less.

4.3.4 Co-interventions

Several participants sought co-interventions in addition to their FR program. Five participants (5.3%) underwent discectomy surgery, at a mean (SD) timeframe of 12.0 (8.7) months following commencement of their FR program. Four of these participants returned to continue with their program post-operatively. Eleven participants (11.6%) underwent a spinal injection during the study period, at a mean (SD) time of 3.8 (3.2) months following program commencement, with 10 of those returning to continue their

program following the injection. Other co-interventions included massage therapy (3 participants), hydrotherapy (1 participant), psychiatric care (1) and consultation with a pain management physician (1).

The proportion of participants taking any medication reduced throughout the treatment program from 68% at baseline to 37% at the first reassessment ($\chi^2(1, n=89)=21.8$, $p<.001$) and to 34% by discharge ($\chi^2(1, n=88)=22.4$, $p<.001$) (Table 4.4).

Table 4.4: Proportion of participants using various medications at each follow-up

Medication	Baseline n (%)	First reassessment (mean 2.5 months) n (%)	Discharge status (mean 8.7 months) n (%)
Simple analgesics	19/95 (20%)	7/89 (8%)	8/88 (9%)
Codeine-based analgesics	26/95 (27%)	11/89 (12%)	9/88 (10%)
Non steroidal anti-inflammatory drugs	44/95 (46%)	17/89 (19%)	16/88 (18%)
Opioid analgesics	10/95 (11%)	6/89 (7%)	6/88 (7%)
Muscle relaxants	10/95 (11%)	5/89 (6%)	4/88 (5%)
Anti-depressants	4/95 (4%)	3/89 (3%)	3/88 (3%)
Corticosteroids	1/95 (1%)	0/89 (0%)	0/88 (0%)
Neuropathic medication	1/95 (1%)	0/89 (0%)	0/88 (0%)
Any medication	65/95(68%)	33/89 (37%)*	30/88 (34%)*

* p <.001 for change in proportion of participants using any medication compared to baseline.

4.3.5 Adverse events

Six participants (6%) reported a temporary increase in their usual back or leg symptoms on at least one occasion following exercises. In five of these participants the increased symptoms lasted less than two hours, while in one participant they lasted for one day. Two participants (2%) noted shoulder pain during exercises that lasted for less than 30 minutes following the completion of the exercises. One other participant (1%) reported an onset of shoulder pain potentially attributable to upper limb exercises undertaken during the functional restoration program, and this participant later developed adhesive capsulitis in that shoulder.

4.4 Discussion

This case series of consecutive people presenting to three physiotherapists provides informative data regarding the management of DHR using FR. Significant improvements in all outcomes were achieved by participants both at the first

reassessment point and at discharge from the program. There was a significant improvement in activity limitation between baseline and both follow-up points, with the mean change in Oswestry scores exceeding the MCID of 10 points (Lauridsen et al., 2006; Ostelo et al., 2008) and the majority (59%) of participants improving beyond this value. By the time of discharge, 46% of participants with Oswestry data had achieved a score of 20% or less which is considered to indicate minimal disability (Fairbank et al., 1980). In addition to improvements in activity limitation, the majority of participants reported improvement on the global rating of change scale at the time of first reassessment relative to baseline (87%) and at discharge from the program relative to baseline (80%). Work status data also showed significant increases over time in the number of participants working and the number working full time.

The improvements achieved by most participants in this study occurred despite the presence of baseline factors that are typically predictive of a poorer prognosis. Many participants had chronic symptoms upon entry to the program, with a mean duration of leg symptoms of 14 months. Longer duration of leg symptoms has been associated with poorer outcomes in people with DHR (Vucetic, Astrand, Guntner, & Svensson, 1999). In this case series, 71% of participants also had a workers compensation claim which is also known to be a predictor of inferior outcomes in people with DHR (Atlas et al., 2006; Atlas et al., 2010). The high mean Orebro and Fear Avoidance Beliefs Questionnaire scores noted at baseline in participants are also indicators of poorer prognosis (Linton & Boersma, 2003; Waddell et al., 1993). In addition, 63% of the participants had already unsuccessfully tried physiotherapy treatment in the past, while 25% had no success with chiropractic or osteopathy prior to commencing the FR program.

The adverse events reported in this study were uncommon and most were minor. While the sample size may have been insufficient to detect rare adverse events, it was sufficient to provide some preliminary indication regarding the likely safety of FR for people with DHR. The only reported adverse event with prolonged consequences was the development of adhesive capsulitis in one participant. While it is not clear whether the FR program was responsible for this adverse event, the participant did attribute the initial onset of shoulder pain to upper limb exercises performed during the program. Two other participants reported shoulder pain during exercises, although in these cases the pain lasted for less than 30 minutes and was therefore of minimal consequence.

These events in relation to shoulder pain suggest that physiotherapists should be vigilant when prescribing upper limb weights for participants engaging in FR programs, although this recommendation need not be limited to people with DHR.

The results of this study add to the previous case series that has been published describing the use of FR principles for people with symptomatic and radiological evidence of DHR (Saal & Saal, 1989). The proportion of participants in the current study who reported global improvement by discharge (80%) was similar to the proportion of successful cases reported in the other study (90%) (Saal & Saal, 1989). The current study appears to be the first to have quantified the magnitude of improvement in activity limitation via a validated questionnaire (Oswestry Disability Index) among people with DHR undergoing FR. The current study also provides the first estimate of the likely safety of FR for this population.

A relatively small number of participants sought co-interventions throughout their physiotherapy FR program. The rate of discectomy surgery among participants was low (5.3%) within the period of treatment. This was lower than the 10% rate of surgery in the previous case series (Saal & Saal, 1989). Spinal injections such as epidural steroid injections were received by 11.6% of participants in the current study. This was presumably lower than the previous case series as epidural injections were part of the treatment protocol in cases where radicular pain did not resolve initially (Saal & Saal, 1989). Given the low rate of co-interventions in the current study, it was not possible to statistically assess the impact that these other interventions may have had on the final outcomes. However, participants who sought co-interventions tended to achieve poorer final outcomes even after they had received the additional treatments, indicating that the inclusion of these participants in the overall analysis did not artificially inflate the results of FR treatment.

The different components of treatment that were chosen by the physiotherapists in this case series gave an indication of how a traditional FR approach was tailored to treat the specific pathoanatomical condition of DHR. Functional exercises and education with a cognitive-behavioural approach are two key elements of traditional FR programs for people with non-specific LBP (Gatchel & Mayer, 2008; Mayer et al., 1985; Poiraudeau et al., 2007; Rainville et al., 2007; Schaafsma et al., 2010) and these were routinely applied by the physiotherapists in the current study. However, all participants in the

case series also received specific motor control training in the form of precise activation exercises for transversus abdominis and multifidus in static and then dynamic positions (Richardson, Hodges, & Hides, 2004). While specific motor control training is not traditionally a component of FR programs (Gatchel & Mayer, 2008; Mayer et al., 1985; Poiraudeau et al., 2007; Rainville et al., 2007; Schaafsma et al., 2010), the systematic review in this thesis (Chapter 3) found one study that demonstrated the effectiveness of stabilisation exercises for people with DHR (Bakhtiary et al., 2005). Other pathoanatomically based treatment components that were used by physiotherapists in the current study included application of strapping tape to the lumbar spine for postural feedback, neurodynamic exercises and directional preference management. Manual therapy or massage, which is typically discouraged in traditional FR programs, was limited mainly to participants with acute symptoms, or for a short period of time to assist with the management of an exacerbation in pain. While it is not possible to conclude that these treatment components were essential, it does reflect an increased focus on modalities with pathoanatomical mechanisms relating to DHR when compared to the content of traditional FR administered to people with non-specific LBP (Gatchel & Mayer, 2008; Mayer et al., 1985; Poiraudeau et al., 2007; Rainville et al., 2007; Schaafsma et al., 2010).

A strength of the current study was the selection of a group of participants with a specific diagnosis of DHR based on the presence of referred leg symptoms and radiological confirmation of a lumbar disc herniation with nerve root impingement. These minimum inclusion criteria resulted in a group of participants where 85% had leg pain referring below the knee, 66% had lower limb paraesthesia and 56% had neurological signs on examination. When coupled with the imaging findings to demonstrate that a disc herniation was the most likely cause of the radiculopathy, these clinical features are all valid and reliable diagnostic features indicative of DHR (see Chapter 2). The strict selection criteria resulted in the inclusion of only 8.3% of the reviewed files. This percentage is consistent with the discussion in Section 2.6, where it was estimated that DHR has a prevalence of 2-5% (Deyo & Tsui-Wu, 1987; Heliovaara et al., 1987; Younes et al., 2006) and accounts for 5-12% of all LBDs (Bogduk, 2005; Deyo & Tsui-Wu, 1987; Friberg, 1954; Hart et al., 1995; Mooney, 1987).

There were some limitations of the study due to its case series design (Kooistra, Dijkman, Einhorn, & Bhandari, 2009). Firstly, it is not possible to separate the benefits

of the intervention from natural recovery over time or placebo effects. However, the long duration of symptoms in most participants, combined with the presence of unfavourable prognostic indicators in a large proportion of the cohort, suggests that rapid improvements attributable to the passage of time alone were less likely to occur. Lack of standardisation of assessment, recording and treatment procedures is another common limitation of retrospective studies (Kooistra et al., 2009). However, by auditing outcomes of three physiotherapists working in the same organisation, employing the same treatment philosophies, using standardised assessment forms and standardised recording procedures, these variations were minimised. Finally, the retrospective design of this study did not allow the status of participants to be determined following discharge from the program, as the treating physiotherapists did not routinely follow-up participants after discharge. A prospective study with post-discharge follow-ups would be required to determine whether the improvements achieved by participants continue or are maintained over longer timeframes.

4.5 Chapter summary and conclusion

This chapter introduced functional restoration as a potential treatment for people with DHR. Based on existing evidence of effectiveness in RCTs involving people with LBP, combined with preliminary evidence of positive outcomes in one existing case series involving people with DHR, it was hypothesised that FR may be a suitable treatment for this condition. An original research study presented in this chapter showed that a consecutive series of people with symptomatic and radiological evidence of DHR who undertook a physiotherapy FR program achieved significant improvements over time in activity limitation scores and global rating of change. Participants also reduced their medication intake and the majority returned to work. Adverse events were uncommon but some cases of shoulder pain or injury were attributed to the upper limb weights involved in the program. These results provide support to the hypothesis that FR may be a useful treatment option for people with DHR and a RCT is warranted to determine its effectiveness in this population.

CHAPTER 5: THE DEVELOPMENT OF A FUNCTIONAL RESTORATION TREATMENT PROTOCOL FOR LUMBAR DISC HERNIATION WITH ASSOCIATED RADICULOPATHY

Chapter 4 provided a brief introduction to the definition, key features, potential mechanisms of action, and effectiveness of FR for people with LBDs. It was suggested that a physiotherapy FR program has potential to be a useful conservative treatment for people with DHR. The case series outlined in that chapter provided some initial indication of the outcomes that have been achieved when people with DHR have undertaken FR. In addition, it was apparent that adverse events in that case series occurred rarely and were minor in severity. Further research in the form of a RCT is the logical next step in evaluating the effectiveness and safety of FR for DHR. This chapter outlines and justifies the treatment protocol used in the RCT that follows in the next chapter.

5.1 Introduction

In order to conduct a RCT evaluating a complex multimodal intervention such as FR, a treatment protocol is required. In designing such a protocol there is a fine balance between standardisation of treatment among participants and provision of flexibility for treating therapists to tailor the intervention to suit individuals (Delitto, 2005). A highly standardised treatment protocol provides confidence that a similar intervention was received by all participants treated in the trial, while also allowing the treatment to be reproduced in other settings (Borrelli et al., 2005; Boutron, Moher, Altman, Schulz, & Ravaud, 2008; Perepletchikova, Treat, & Kazdin, 2007). Unyielding standardisation can however result in participants receiving a treatment that is not ideally suited to their presenting problems or preferences and restrains the clinical reasoning process that clinicians typically apply in practice (Delitto, 2005; Jones & Rivett, 2004).

Developing a standardised yet flexible treatment protocol for complex multimodal interventions such as FR is a challenging exercise but one that has been identified as an important research priority (Foster et al., 2009). Researchers have noted the unique potential for multimodal treatments to influence the full array of biopsychosocial problems that influence people with a complex disorder such as DHR (Chou, Loeser et al., 2009; Daffner, 2010; Jull & Moore, 2010). It is unrealistic to expect that a single treatment modality will benefit all aspects of a person's condition, hence the selection

of multiple treatment components is popular in clinical practice and increasingly common in research trials (Jull & Moore, 2010).

It was suggested in the previous chapter that traditional FR programs may require some modification in order to be suitable for the specific pathoanatomical condition of DHR. The logic surrounding this assumption was that FR has traditionally been applied to people with subacute and chronic non-specific LBP where the degree of ongoing physical pathology is assumed to be minimal, whereas significant pathophysiological processes can be ongoing beyond the acute stage in people with DHR. In developing a FR protocol specifically for people with DHR, the current chapter considers treatment components based on a number of different literature sources. These include the systematic review (Chapter 3), the case series (Chapter 4), traditional components of FR (Section 4.1.1) and known or hypothesised pathophysiological mechanisms involved in DHR (Sections 2.2, 2.3 & 2.4). Selecting and justifying treatment components for trial protocols based on a range of existing research including mechanisms of effect was a key recommendation in a guideline produced by an international group of LBP researchers (Helmhout et al., 2008) and is also supported by the Cochrane Collaboration (Higgins & Green, 2006). Previous treatment protocols for trials involving people with LBDs and other musculoskeletal disorders have been developed and justified using a combination of methods, including literature review, expert opinion, observational studies, mechanisms of effect and consideration of existing clinical practice (Dorey, Glazener, Buckley, Cochran, & Moore, 2009; Dziedzic, Stevenson, Thomas, Sim, & Hay, 2009; Hansen et al., 2010; Molsberger, Mau, Gotthardt, Schneider, & Drabik, 2004; Williamson, Williams, Hansen, Joseph, & Lamb, 2009).

5.2 Process of developing a functional restoration protocol for a trial involving people who have disc herniation with associated radiculopathy

The development of the FR protocol to be used in the RCT utilised a number of methods. Existing protocols for the application of FR to people with pathoanatomical LBDs had been developed by a musculoskeletal physiotherapist based on clinical experience informed by evidence from the literature (Ford & Bennell, 2000). These protocols had been taught to several physiotherapists who treated people with subacute and chronic LBDs in private practice, allowing modifications to be made based on their own perspectives (Ford, Hahne, & Chan, 2011; Ford, Surkitt, & Hahne, 2011). The

existing protocols were further scrutinised, operationally defined and modified for people with DHR based on the findings of the systematic review (Chapter 3) and the case series (Chapter 4), as well as consideration of the mechanisms of effect given the literature relating to the pathophysiology and healing processes involved in DHR (Chapter 2). Once a draft version of the protocol had been developed, a full day workshop was attended by 13 physiotherapists who had expressed an interest in treating participants in the trial. The physiotherapists who attended the workshop had been working in clinical practice for between 0.5 and 12 years. The workshop was used to gain feedback from the physiotherapists to ensure that the final version of the treatment protocol reflected their clinical practice and was able to be comprehended by practitioners with a variety of experience levels. While the workshop was facilitated by the musculoskeletal physiotherapist who began developing the protocols in his clinical practice, open discussion among all those in attendance was encouraged and anonymous voting was undertaken whenever consensus was lacking.

5.3 Description and justification of the functional restoration protocol for disc herniation with associated radiculopathy

The final FR treatment protocol for the RCT is described and justified below. This discussion is divided into a general overview of the treatment approach, a more detailed presentation of the individual components and a description of the electronic "clinical notes" that outlined the protocol for treating physiotherapists on a session-by-session basis while allowing them to record clinical information. As the full treatment protocol involved a 120 page manual, 21 participant information sheets and 30 pages of electronic clinical notes for each participant, this thesis presents a summarised version of the protocol.

5.4 Overview of the functional restoration protocol

The FR protocol involved 10 x 30-minute sessions over a ten week timeframe. The basis of the program utilised the key principles of FR described in Chapter 4, adapted for the presence of significant pathology seen in DHR. Consistent with the approach of a traditional FR program (Section 4.1.1) and the approach utilised by physiotherapists in the case series (Section 4.3.2), the program involved multiple treatment components including supervised functional exercises and a cognitive-behavioural approach. The program focussed on active management rather than passive treatment modalities (such

as electrotherapy, manual therapy or massage) in order to promote participant independence and to avoid the development or reinforcement of unrealistic expectations for a rapid recovery (Blyth, March, Nicholas, & Cousins, 2005; Hansen et al., 2010; Harding & Williams, 1995; May, 2010). As part of this active approach, self-management skills were taught to participants to ensure they would be equipped to continue managing their condition upon conclusion of the ten week program (Blyth et al., 2005; Bodenheimer, Lorig, Holman, & Grumbach, 2002; Morris, 2004; van Hooff et al., 2010). Aspects of the FR program that were adapted for the presence of DHR included the provision of specific pathoanatomical information, a conservative approach to exercise progression that respected the reporting of symptoms by participants, strategies for the management of inflammation, posture management to minimise stresses on the disc, implementation of mechanical loading strategies based on theories of nuclear migration within the disc, and the incorporation of specific motor control training as a means of providing support for the healing disc.

While a focus on pathoanatomical treatment components was necessitated by the presence of significant pathology, the psychological and social elements of DHR were not discounted. For this purpose, a cognitive-behavioural approach was utilised throughout the FR program (Grazebrook & Garland, 2005; Nicholas, 2008). Cognitive restructuring was utilised whenever an unhelpful belief was expressed by the participant, such as catastrophizing (the irrational thought that a situation is worse than it actually is, or that the worst possible outcomes will eventuate in the future) (Hansen et al., 2010; Sullivan et al., 2001; Turner & Aaron, 2001). The aim in these cases was to replace the unhelpful cognition with a more constructive and accurate perception (Hansen et al., 2010; Harding & Williams, 1995). Behavioural modification was used in the form of positive reinforcement of desirable behaviour through verbal praise, as well as avoiding the reinforcement of undesirable behaviour such as underactivity (Bunzli, Gillham, & Esterman, 2011; Harding & Williams, 1995; Lindstrom, Ohlund, Eek, Wallin, Peterson, Fordyce et al., 1992). Specific treatment components that involved the strongest cognitive-behavioural emphasis included pacing, goal setting, relaxation training and management of an increase in pain.

In order to find a suitable balance between standardisation of treatment and flexibility to adapt the program to individual participants, the protocol was divided into a series of mandatory and optional treatment components. There was scope for physiotherapists to

select optional treatment components when they were deemed appropriate for the individual while ensuring that all participants received the major aspects of treatment. The selection of optional treatment components was guided by algorithms which incorporated key clinical reasoning principles (Jones & Rivett, 2004; Maitland, Hengeveld, Banks, & English, 2005). These aimed to ensure that even the optional treatment components were selected and applied by different physiotherapists in a standardised and justified manner. Further scope for physiotherapists to tailor the treatment to individual participants was provided within the delivery of treatment components, where algorithms again guided physiotherapists through clinical reasoning processes that informed critical decisions such as when to commence and cease a particular treatment component.

While this section has provided a general overview of the FR program, a more detailed description and justification of all mandatory and optional treatment components is presented below.

5.4.1 Mandatory treatment components for all participants

Mandatory treatment components were to be applied to all participants throughout the course of the FR program. Where participant information sheets (PISs) were used to convey standardised information, these were actively presented by the physiotherapist reading through the sheets with each participant, applying the information to the participant's situation, and encouraging questions and engagement with the information. Each participant was given a display folder to store all of their PISs and they were advised to read over them between physiotherapy sessions and bring the folder to each session.

5.4.1.1 Pathoanatomical information

Surveys have shown that 92% of physiotherapists who treat people with back pain and radiating leg pain provide information regarding the physical cause of their pain (Poitras, Blais, Swaine, & Rossignol, 2005) and the provision of such information is recommended in guidelines relating to DHR (Health Council of the Netherlands, 1999). In addition, qualitative studies have shown that patients typically desire this type of information from healthcare providers (Liddle, Baxter, & Gracey, 2007; Ong, Konstantinou, Corbett, & Hay, 2011; Underwood, Harding, & Klaber Moffett, 2006; Verbeek, Sengers, Riemens, & Haafkens, 2004). A PIS was therefore provided to participants outlining the anatomy and function of the intervertebral disc, the

pathophysiology of DHR and its typical symptoms, the healing potential of DHR and the generally favourable prognosis for achieving improvement (based on the information in Chapter 2).

5.4.1.2 Information regarding treatment options

The available treatments for DHR (Chapter 4) were outlined on a PIS. By discussing the content of the PIS, the physiotherapists aimed to compare and contrast the FR program with other treatments that participants may have undertaken or heard about previously. This included information about the role of injections and surgery (based on the information in Section 3.1), as well as the limitations of passive treatment modalities for DHR given its extended recovery timeframes (Blyth et al., 2005; Hansen et al., 2010; Harding & Williams, 1995; May, 2010). The known or hypothesised mechanisms by which FR has a therapeutic effect for DHR were also summarised based on the information in Section 4.1.4. Providing explanation of the content and rationale for a treatment approach is considered essential to engage participants and gain their commitment to the program (Slade, Molloy, & Keating, 2009a).

5.4.1.3 Information regarding program timeframes

A PIS was presented to participants outlining the structure of the FR program across the ten week treatment period. An expectation was established that optimal recovery, if it occurred, would be likely to take at least 6 months of ongoing exercise. Based on the complex healing processes that occur over an extended timeframe in DHR (Chapter 2), this information was considered important to avoid the unrealistic expectation of a rapid recovery and to maximise compliance both within the treatment period and beyond discharge.

5.4.1.4 Posture management and taping

A range of strategies were employed to encourage participants to maintain a neutral spine position during activities (McKenzie & May, 2003). A PIS advised participants to avoid repeated or sustained lumbar flexion and to maintain the lumbar lordosis by sitting with a lumbar roll (McKenzie & May, 2003; Williams, Hawley, McKenzie, & van Wijmen, 1991). This advice was based on evidence of posterior nuclear migration (Alexander et al., 2007; Bogduk, 2005; Kolber & Hanney, 2009), increased intradiscal pressure (Harrison, Harrison, Croft, Harrison, & Troyanovich, 1999; Nachemson, 1981; Wilke, Neef, Caimi, Hoogland, & Claes, 1999) and increased pressure from a disc herniation on compressed nerve roots (Schnebel et al., 1989) during activities that

involve flexion of the spine (including slouch sitting and forward bending). Participants were particularly cautioned against flexion activities in the early morning based on studies showing that rehydration of the disc in a recumbent position overnight renders it more prone to injury at this time of day (Adams, Dolan, Hutton, & Porter, 1990; Adams et al., 2010; Beattie, 2008). In addition, one RCT has shown some positive benefits among participants with LBDs who were advised to restrict early morning lumbar flexion (Snook, Webster, & McGorry, 2002; Snook, Webster, McGorry, Fogleman, & McCann, 1998).

A further postural strategy was the application of strapping tape to the lumbar spine of each participant by their treating physiotherapist (Baquie, 2002; Hammill, 1988; McKenzie & May, 2003). Taping was used on 61% of participants in the case series (Chapter 4) and theoretically could have provided proprioceptive feedback and a physical restriction to lumbar flexion movements. The protocol for applying tape is outlined in Appendix E. Taping was to be applied by the physiotherapist at each session during the first four weeks of the program and was to be worn for at least three days prior to removal. The decision to wean and then cease taping was guided by an algorithm that considered the stability of symptoms, the presence of inflammatory signs, the perceived benefit of the tape and the tolerance of taping by the participant (Appendix E). Once ceased, taping could be resumed if an exacerbation in pain or inflammatory signs occurred.

5.4.1.5 Specific motor control training

According to a model proposed by Panjabi, the protection, stability and support of the spine is dependent on three subsystems (Panjabi, 1992a, 1992b). The passive subsystem includes the vertebrae and spinal ligaments that offer some inherent stability. The active subsystem involves muscles that play a role in supporting the spine and controlling movements. The control subsystem includes the brain and nervous system which coordinates the active subsystem to ensure optimal spinal stability for a given task or situation (Panjabi, 1992a, 1992b; Richardson et al., 2004). The various muscles that comprise the active subsystem have different structures and roles, which has led to their division into “global” and “local” muscles (Bergmark, 1989; Richardson et al., 2004). In the spine, global muscles are located superficially, span several joints, do not tend to attach to vertebrae and are mainly concerned with generating movement (Bergmark, 1989; Richardson et al., 2004). Examples of global

muscles include rectus abdominis, external oblique and the superficial portions of the erector spinae group (Bergmark, 1989; Richardson et al., 2004). Local muscles are located deeply and for this reason are sometimes called “core” muscles (Hodges, 2003). They typically attach to vertebrae, with their fibres spanning only 1-2 joints (Bergmark, 1989; Richardson et al., 2004). The primary role of the local muscles is the control of movement and stability of the spine (Bergmark, 1989; Richardson et al., 2004). Examples of local muscles include the lumbar multifidus and transversus abdominis (Bergmark, 1989; Richardson et al., 2004).

Experimental and anatomical studies have shown that the transversus abdominis and lumbar multifidus are local muscles that are anatomically and functionally suited to provide stability and control for the lumbar spine (Barker, 2004, 2006; Hodges, Kaigle et al., 2003; Kaigle, 1998; Panjabi, 1992a; Tesh, 1987). The role of these muscles in spinal stability can be deduced from studies showing that they are activated in anticipation of postural perturbation or movement (Cresswell, 1994; Hodges, Cresswell, & Thorstensson, 1999; Hodges & Richardson, 1997a) regardless of the direction of force or movement (Cresswell, Grundstrom, & Thorstensson, 1992; Hodges et al., 1999; Hodges & Richardson, 1997b; Wallwork, Stanton, Freke, & Hides, 2009). In the presence of pain or pathology, the structure and function of these muscles has been shown to alter, including evidence of reduced cross-sectional area in multifidus (Danneels, Vanderstraeten, Cambier, Witvrouw, & De Cuyper, 2000; Hides, Gilmore, Stanton, & Bohlscheid, 2008) and delayed or reduced activation of all local muscles in response to movement and postural perturbation (Dickx, Cagnie, Parlevliet, Lavens, & Danneels, 2010; Ferreira, Ferreira, & Hodges, 2004; Hodges, Moseley, Gabrielsson, & Gandevia, 2003; Hodges & Richardson, 1996, 1998; Kiesel, 2008; Leinonen et al., 2001; MacDonald, Moseley, & Hodges, 2009). While most of this evidence relates to people with LBP, studies have shown that multifidus wasting (Hyun, Lee, Lee, & Jeon, 2007; Kulig et al., 2009) and delayed activation (Leinonen et al., 2001) also occurs in people with DHR. In addition, an experimental study showed that rapid reduction in multifidus cross sectional area occurred in response to experimentally induced disc and nerve lesions in pigs (Hodges, Holm, Hansson, & Holm, 2006).

Poor motor control around the lumbar spine as a result of the changes in the local muscles discussed above has been hypothesised as a contributing factor to delayed

recovery and recurrence of symptoms in people with LBDs (Hodges, Moseley et al., 2003; Richardson et al., 2004). Consequently, considerable research has been devoted to retraining these muscles in people with LBDs. Experimental studies have shown that training programs involving targeted conscious activation of these muscles can reverse some of these changes in people with LBDs (Hodges, 2008; Tsao, Druitt, Schollum, & Hodges, 2010; Tsao & Hodges, 2008; Tsao & Hodges, 2007). Furthermore, these deficits do not appear to resolve spontaneously (Hides, Richardson, & Jull, 1996; MacDonald et al., 2009), nor do they resolve following less specific training such as general exercise, abdominal bracing, or sit-ups (Hall, Tsao, MacDonald, Coppieters, & Hodges, 2009; Hodges, 2008; Tsao & Hodges, 2007). In addition to this significant body of experimental evidence, clinical trials have shown that specific motor control training is effective for reducing pain, activity limitation and recurrence in people with LBDs (Costa, Maher et al., 2009a; Ferreira, Ferreira, Maher, Herbert, & Refshauge, 2006; Hides, Jull, & Richardson, 2001; Macedo et al., 2009). In relation to DHR, the highest effect size achieved by any study in the systematic review (Chapter 3) related to the comparison of lumbar stabilising exercises to a waiting list control, with significant effects found in favour of stabilising exercises for pain intensity at short term follow-up (Bakhtiary et al., 2005). Conscious motor control training of the local muscles was undertaken in one case series and one case report that described FR for people with DHR (see Chapter 4) (Hahne & Ford, 2006; Saal & Saal, 1989). In addition, precise motor control training was used for 100% of the participants with DHR in the original case series presented in this thesis (Chapter 4).

Based on the above justification, specific motor control training of the transversus abdominis, lumbar multifidus and pelvic floor was a mandatory component of the FR protocol for all participants. While the full protocol for delivering the specific motor control training was extensive, the key elements and their justification are presented in Table 5.1.

Table 5.1: Description and justification of the key principles involved in the specific motor control training utilised in the functional restoration protocol

Principle of training	Justification
Provision of information	
The anatomy, normal function and dysfunction of the core muscles were described, along with key points regarding training and recovery of these muscles.	Understanding the background of the specific motor control training program may enhance motivation, compliance and exercise performance (Slade et al., 2009a).
Commencement	
Commenced in Session 2, unless uncontrolled inflammation was present, or a directional preference in response to mechanical loading strategies was identified.	Pain has an inhibitory effect on core muscle activation (Dickx et al., 2010; Hodges, Moseley et al., 2003; Kiesel, 2008), hence motor control training was delayed until pain reduced through control of inflammation or implementation of directional preference management (when applicable).
Starting position	
Training commenced in unloaded positions, with a preference for side-lying.	Unloaded positions are generally associated with minimal pain, allowing full relaxation of the global muscles and optimal activation of the core muscles (Hides et al., 2006; Richardson et al., 2004; Urquhart, Hodges, Allen, & Story, 2005).
A neutral lumbar spine position was established.	There is evidence that the core muscles are more effectively activated in a neutral spine position (O'Sullivan et al., 2006; Reeve & Dilley, 2009).
Activation instructions	
Transversus abdominis: "slowly and gently draw your lower stomach in towards your spine".	The drawing in maneuver of the lower abdominal wall has been shown to preferentially activate the transversus abdominis (Hides et al., 2006; Urquhart et al., 2005).
Multifidus: "slowly and gently swell the muscle under my finger without moving your back".	Aim to achieve an isolated contraction of the multifidus relative to the global erector spinae muscles (Hides et al., 2010; Richardson et al., 2004).
Pelvic floor: "slowly and gently stop the flow". "draw up the front part of the pelvic floor".	Activation of the anterior aspect of the pelvic floor was targeted (Hides et al., 2010).
"Keep breathing".	It is important to maintain respiration during the activation of the core muscles (Richardson et al., 2004; Tsao & Hodges, 2007).

Continued

Table 5.1 continued: Description and justification of the key principles involved in the specific motor control training utilised in the functional restoration protocol

Principle of training	Justification
Co-contraction Participants were taught to contract the core muscles concurrently (pelvic floor, multifidus and transversus abdominis).	The core muscles typically work together as an integrated system to provide spinal stability and each muscle has been shown to facilitate the activation of the others (Richardson et al., 2004).
Therapist evaluation and feedback The physiotherapist palpated the core muscles to ensure correct activation, with feedback provided accordingly.	A correct transversus abdominis contraction should produce a feeling of gentle deep tension upon palpation just medial to the anterior superior iliac spines of the pelvis (Hides, Scott, Jull, & Richardson, 2000). Gentle expansion under the thumb or finger upon palpation adjacent to the spinous process indicates a correctly isolated contraction of multifidus (Hides et al., 2000).
The physiotherapist observed the abdominal wall for an inward movement of the lower abdomen without movement of the trunk or excessive activation of global muscles.	A targeted contraction of the transversus abdominis at an intensity of less than 30% maximum voluntary contraction was sought without movement of the spine indicative of excessive global muscle substitution (Richardson et al., 2004; Tsao & Hodges, 2007).
Participant awareness and monitoring Participants were encouraged to develop an internal awareness of the correct activation. They could also use visual feedback with a mirror (once in a standing position), or self-palpation in some cases.	Development of an internal kinesthetic awareness, visual observation and self-palpation provided important feedback regarding performance (Richardson et al., 2004).
Dosage Once the core muscles could be activated sufficiently, they were prescribed to be practiced at home 4 times per day, with each session requiring 5 x 5-second contractions and then increasing to 10 x 10 seconds. The duration of holds was then increased with the repetitions reducing until the contraction could be held for 1-2 minutes with integrated breathing.	The dosages were based on the recommendations of other researchers (Hides et al., 2010; Richardson et al., 2004; Tsao & Hodges, 2008) as well as consensus among physiotherapists who attended the one-day workshop to assist with the RCT protocol development.

Continued

Table 5.1 continued: Description and justification of the key principles involved in the specific motor control training utilised in the functional restoration protocol

Principle of training	Justification
Progression of positions Once 10 x 10 second contractions could be performed with good quality, the starting position was progressed to upright and loaded positions (standing and walking).	Upright positions are more functionally relevant once the basic concept of the muscle activation has been grasped. Loading may also facilitate activation of the core muscles (Mew, 2009).
Once a good quality contraction could be performed whilst walking, the motor control exercises were integrated into task-specific functional exercises.	The integration of specific motor control training into functional activities aimed to restore correct motor control during tasks relevant to the participant (Richardson et al., 2004), which is described further in the next section.

5.4.1.6 Functional exercises

Some specific motor control training programs have been criticised for failing to progress to higher level functional activities and integrate with training of the global muscles (McGill, 2007; van Dieen, Cholewicki, & Radebold, 2003). However, optimally delivered specific motor control training is intended to form part of an overall intervention that progresses to more complex tasks involving global muscles (Hodges, 2008; Richardson et al., 2004). The protocol in the RCT therefore attempted to firstly correct maladaptive patterns of activation in the core muscles before integrating the improved pattern into tasks with higher functional demands. Consistent with other trials, exercises did not progress to more advanced functional activities (such as heavier weights or complex exercises) until the correct motor control patterns had been established (Cairns, Foster, & Wright, 2006; Costa, Maher et al., 2009a; Ferreira et al., 2007; Hides et al., 2010; O'Sullivan, Twomey, & Allison, 1997).

In addition to the correction of motor control patterns during functional activities, as well as the reversal of deconditioning described previously in Section 4.1.4, there are other mechanisms by which functional exercises may assist with the recovery from DHR. As the dispersion of fluid and molecules through the disc is aided by movement (see Section 2.2) intermittent loading and motion of the spine may assist with the transport of nutrients to, and the removal of waste products from, the healing disc (Adams et al., 2010; Beattie, 2008; Freemont, 2009; Hendrick et al., 2010; Holm &

Nachemson, 1983). There is also some evidence that a modest intensity and gradual progression of mechanical loading may stimulate the disc, particularly its outer annulus, to adapt and strengthen to the imposed demand (Adams & Dolan, 1997; Adams et al., 2010; Iatridis, Mente, Stokes, Aronsson, & Alini, 1999; Puustjarvi, Lammi, Helminen, Inkinen, & Tammi, 1994; Videman, Levalahti, & Battie, 2007).

While functional exercises are hypothesised to benefit people with DHR, there is also evidence that they are likely to be safe if administered appropriately. Studies have shown that a variety of exercises and activities, including weight lifting and treadmill running, do not place excessive forces on discs (Beattie, 2008; Potvin, McGill, & Norman, 1991). However, it has been advised that certain precautions be taken to minimise the load placed on discs during exercise, particularly when dealing with a damaged disc that has reduced ability to distribute forces (Beattie, 2008). These recommendations based on experimental studies include avoiding sustained or excessive mechanical loading, avoiding exercises that move the spine into flexion (particularly to the end of range), progressing exercise intensity gradually, and monitoring symptoms both at the time of exercise and the following day (Adams et al., 2010; Beattie, 2008; Freemont, 2009; Iatridis et al., 1999; Potvin et al., 1991; Puustjarvi et al., 1994; Raj, 2008; Videman et al., 2007). It has been suggested in one review that core stabilisation exercises pose a low risk to the lumbar spine and may increase the ability of the spine to tolerate loading in the presence of a damaged disc (Beattie, 2008).

To ensure that the recommended principles for safe exercise in people with disc injuries were adhered to, the functional exercises in the RCT were supervised by a physiotherapist. Participants did complete additional exercise sessions at home between visits, although only after performing them under supervision and having the intensity of exercise progressions documented in a diary. The supervision of participants also allowed the physiotherapists to provide feedback regarding the accuracy of core muscle activation, the maintenance of correct posture and the achievement of appropriate lumbo-pelvic kinematics during functional exercises (Dankaerts & O'Sullivan, 2010; O'Sullivan, 2005). In addition to ensuring safety, a meta-analysis of RCTs investigating exercise for LBDs concluded that a key factor distinguishing successful from unsuccessful programs was the provision of supervision during exercise sessions (Hayden, van Tulder, & Tomlinson, 2005).

To determine the functional exercises that would be prescribed in the RCT, a review of the relevant literature was conducted. The final list of functional exercises was determined from studies describing FR for LBP (Lindstrom, Ohlund, Eek, Wallin, Peterson, Fordyce et al., 1992; Pengel et al., 2007; Roche et al., 2007), a case series and case report describing FR for DHR (Hahne & Ford, 2006; Saal & Saal, 1989) and the case series outlined in this thesis (Chapter 4). All exercises adhered to the safety principles described above based on experimental studies. The exercises are listed in Table 5.2 along with typical starting dosages and exercise goals by the end of the ten week program (which were individualised for each participant). In addition to these standard exercises, physiotherapists had scope to add other activities in the later stages of the FR program that met the goals and functional demands of individual participants. This was another means of tailoring the program to each participant.

Table 5.2: List of functional exercises used in the treatment protocol, along with typical starting dosages and progressions by the end of the ten week program

Exercise	Typical starting dosage	Typical exercise goal by program end
Basic functional exercises		
Treadmill walking	3 x 3 minutes @ 3.0 kph	3 x 5 minutes @ 6.0 kph
Dumbbells: bicep curls	3 x 10 @ 2kg	3 x 15 @ 5kg
Dumbbells: forward raises	3 x 10 @ 1kg	3 x 15 @ 3kg
Dumbbells: side raises	3 x 10 @ 1kg	3 x 15 @ 3kg
Step-ups	3 x 10	3 x 25
Advanced functional exercises		
Lunges	3 x 10 (2kg)	3 x 10 (3kg)
Squats	3 x 10 (2kg)	3 x 10 (3kg)
Lifting a box from floor to waist height	3 x 5 (5kg)	3 x 5 (10kg)
Erector spinae	3 x 5 (lift legs)	3 x 5 (lift trunk)
Abdominal crunches	3 x 5	3 x 15

Abbreviations: kph=kilometres per hour; kg=kilograms

5.4.1.7 Goal setting

The establishment of activity goals that were important to the participant was assisted by the use of a specific PIS that was administered in Session 2. Participants identified four SMART (specific, measurable, attainable, realistic and timely) goals (Doran, 1981; Lazarus, 2004) relating to activities they wished to resume or increase. Graded

exercise goals were then established by the physiotherapist that would facilitate achievement of these activity goals, with progress that had been made towards achieving these goals reviewed and positively reinforced in subsequent sessions (Butler & Moseley, 2003; Hansen et al., 2010; Harding & Williams, 1995; Sowden et al., 2006). Goal setting facilitated the selection and progression of functional exercises that were most suitable for the participant, which was one of the primary means of tailoring the FR program to the individual. This goal-orientated approach also aimed to increase the motivation and compliance of participants with their exercises, as it was thought that achieving goals that were important to them would increase engagement and motivation with the program (Filoramo, 2007).

5.4.1.8 Pacing

Related to the concept of goal setting, pacing strategies were implemented to assist participants to find a balance between underactivity and overactivity (Butler & Moseley, 2003; Hansen et al., 2010; Harding & Williams, 1995; Sowden et al., 2006). Overactivity in people with a significant pathology such as DHR can lead to exacerbation of pain or the injury (Adams et al., 2010), whereas underactivity is often attributable to the avoidance of feared activities and is hypothesised to result in deconditioning (Hansen et al., 2010; Harding & Williams, 1995; Mayer et al., 1985). In both circumstances, the participant's baseline tolerance was established for individual activities, followed by education regarding the level of safety of the activity and the rate at which it could be progressed (Butler, 2000; Butler & Moseley, 2003; Hansen et al., 2010; Sowden et al., 2006). The importance of making gradual progressions beyond the baseline level was emphasised as a safe and necessary means of increasing the activity (Butler, 2000; Butler & Moseley, 2003; Hansen et al., 2010). The concept of planning ahead and breaking up activities into manageable portions consistent with the pathology and current tolerances was also discussed (Butler, 2000; Butler & Moseley, 2003; Sowden et al., 2006).

5.4.1.9 Discharge planning

The final session for each participant involved a PIS relating to discharge planning. The achievements made by the end of the program were positively reinforced by the treating physiotherapist. The typical healing timeframes for DHR were reviewed to reassure participants that a full recovery would not be expected by discharge in most cases. Participants were encouraged to continue to apply the information, skills and exercises they had been taught for at least another 3-6 months in order to facilitate

further improvements. Finally, long term exercise goals and progressions were written down for each participant to work towards (Sowden et al., 2006). Exercises could be continued either at home or at a local gymnasium depending on the participant's goals. Careful discharge planning was considered essential given the severity of DHR and the long duration of healing for this pathology, along with the considerable risk of ongoing pain and recurrence (see Chapters 2 & 3). Further justification for discharge planning was provided by a qualitative study that showed most participants who completed a core stabilisation exercise program ceased their exercises at the end of the supervised sessions (Sokunbi, Cross, Watt, & Moore, 2010), as well as from a systematic review that found those with LBP who do continue with exercises following discharge have a lower likelihood of recurrence (Choi, Verbeek, Tam, & Jiang, 2010).

5.4.2 Optional treatment components used when applicable

While the previous treatment components were mandatory for all participants, those presented below were applied only when indicated. Guidelines and decision making algorithms outlined in the trial manual guided physiotherapists in their selection of suitable optional treatment components for each participant.

5.4.2.1 Management of inflammation

As discussed in Chapter 2, inflammation is considered to be a major mechanism implicated in the pathophysiology of DHR (Bogduk, 2005; Kobayashi et al., 2004; Lipetz, 2002; Rhee et al., 2006; Saal, 1995; Valat et al., 2010). Uncontrolled inflammation has the potential to cause considerable pain that may impair the ability of participants to exercise (McKenzie & May, 2003) and inhibit the activation of the local stabilising muscles (Dickx et al., 2010; Hodges, Moseley et al., 2003; Kiesel, 2008). As part of the FR protocol, an attempt was therefore made to identify and manage uncontrolled inflammation in participants during the early stage of the program (Session 1).

To identify the presence of inflammation, clinical indicators were assessed. These indicators of inflammatory LBP were identified based on classic physiotherapy textbooks (Maitland et al., 2005; McKenzie & May, 2003), an interdisciplinary survey of clinicians (Walker & Williamson, 2008), consistency with clinical indicators for rheumatoid arthritis (Grassi, De Angelis, Lamanna, & Cervini, 1998), plus preliminary evidence of concurrent validity (Foldes, Balint, Gaal, Buchanan, & Balint, 1992) and discriminant validity (Rudwaleit, Metter, Listing, Sieper, & Braun, 2006). Based on

these sources, participants were considered to have clinical evidence of inflammation if they had at least two of the following three indicators: i) constant pain; ii) morning stiffness in the back lasting for more than 60 minutes; and iii) night waking due to pain that required rising from bed.

Strategies for managing inflammation were outlined in a PIS. The physiotherapist reviewed the participant's medication and recommended they consult with a pharmacist for over-the-counter NSAIDs if none were being taken. In cases of severe inflammation, or when weaker NSAIDs proved ineffective, the participant was referred to see their general medical practitioner with a letter recommending a medication review for consideration of prescription NSAIDs or systemic corticosteroids. A regular (2-4 times per day) walking program within pain limits was also prescribed to participants with uncontrolled inflammation. As discussed previously, it is hypothesised that gentle exercise such as walking leads to rhythmic movement and mechanical loading of the spine which might aid the circulation of nutrients into the disc and the removal of inflammatory by-products (Adams et al., 2010; Beattie, 2008; Freemont, 2009; Hendrick et al., 2010; Holm & Nachemson, 1983).

5.4.2.2 Directional preference management

Directional preference management (DPM) refers to a range of strategies initially developed by Robin McKenzie for people with LBDs (McKenzie & May, 2003). The method involves assessing the effect of repeated lumbar movements and positions (known as mechanical loading strategies) on symptom response (Petersen et al., 2003; Wetzel & Donelson, 2003). A positive response is indicated by centralisation of referred symptoms, reduced pain intensity, or improvement in range-of-motion in response to mechanical loading strategies (McKenzie & May, 2003; Wetzel & Donelson, 2003). The direction of movements or positions that leads to a positive benefit is called the "directional preference" (DP) (McKenzie & May, 2003; Werneke, 2009; Werneke et al., 2011; Wetzel & Donelson, 2003) and this lends itself to a range of management strategies utilising the movements and positions that match the DP (McKenzie & May, 2003; Wetzel & Donelson, 2003). It is hypothesised that a DP occurs in some discogenic LBDs based on nuclear migration in response to movements and positions of the spine (Kolber & Hanney, 2009; Petersen et al., 2003; Wetzel & Donelson, 2003). As discussed in Chapter 2, extension movements have been shown to promote anterior movement of the nucleus pulposus within the disc (Alexander et al.,

2007; Bogduk, 2005; Kolber & Hanney, 2009). Chapter 2 also discussed that nuclear migration is less consistent in damaged or symptomatic discs (Kolber & Hanney, 2009) but two experimental studies have shown evidence of nuclear migration occurring in a proportion of herniated discs (Scannell & McGill, 2009; Schnebel et al., 1989). A DP could therefore theoretically be expected to be observed in some, but not all, people with DHR (Donelson, 2011; Wetzel & Donelson, 2003). Indeed, clinical studies have shown that approximately 50% of people with DHR exhibit a DP in response to mechanical loading strategies (Alexander, Jones, & Rosenbaum, 1992; Donelson, 2011; Kopp, Alexander, Turocy, Levrini, & Lichtman, 1986; Wetzel & Donelson, 2003). This is consistent with the baseline assessment findings of the case series in this thesis (Chapter 4), where 39% of participants exhibited a DP.

Given that only a proportion of people with DHR appear to exhibit a DP in response to mechanical loading strategies, this was assessed at baseline in all participants enrolled in the RCT (next chapter). In those who exhibited a DP in response to assessment of mechanical loading strategies, a trial of DPM was initiated. Since all trial participants required a posterior, lateral, or posterolateral disc herniation to be included, flexion based mechanical loading strategies were not assessed due to the potential for exacerbation and the low likelihood that a flexion based DP would be present. Participants unresponsive to mechanical loading strategies at baseline assessment were reassessed later in the program if inflammatory indicators reduced, with DPM commenced at that stage if a DP had emerged (see decision making algorithm in Appendix F). This decision was justified based on data showing that in a sample of participants with radiculopathy who did not exhibit a DP at baseline assessment, 41% developed a DP following epidural steroid injection to reduce inflammation (Donelson, 2011). The components of DPM implemented in the trial included repeated extension movements every 1-2 hours (with or without a lateral shift of the pelvis depending on the DP) and reinforcement of the postural strategies described previously relating to maintenance of the lumbar lordosis during seated and dynamic tasks (McKenzie & May, 2003; Werneke, 2009; Werneke et al., 2011; Wetzel & Donelson, 2003). Although no RCTs have evaluated the effectiveness of DPM for people with DHR, several trials have demonstrated significant short-term pain and activity limitation outcomes favouring DPM over other treatments in LBP populations (Browder, Childs, Cleland, & Fritz, 2007; Long, Donelson, & Fung, 2004; Machado, de Souza, Ferreira, & Ferreira, 2006; Paatelma et al., 2008). The DPM approach was therefore considered

worth implementing for participants who exhibited a DP in an attempt to expedite improvements during the early stages of the program.

5.4.2.3 Pain management strategies

For participants who had higher levels of pain or activity limitation (Oswestry > 35%), or who described difficulty controlling their pain, two PISs could be used to provide strategies for managing pain. The first PIS provided information regarding the various pharmaceuticals that are available for the management of pain, including NSAIDs, systemic corticosteroids, simple analgesics, opioids, anti-depressants, muscle relaxants and neuropathic pain medication. This was aimed at informing participants of the availability and indications for these medications, however the PIS stressed that the advice of a pharmacist or medical practitioner must be sought before taking them. The second PIS suggested a range of non-pharmaceutical techniques for self-managing pain, including heat, ice, hydrotherapy and relaxation (Blyth et al., 2005; Crowe, Whitehead, Jo Gagan, Baxter, & Panckhurst, 2010; French, Cameron, Walker, Reggars, & Esterman, 2006).

5.4.2.4 Sleep strategies

A systematic review has estimated that sleep disturbance affects 58.7% of people with LBDs (Alsaadi, McAuley, Hush, & Maher, 2010). That review, along with others, also found that sleep disturbance is only weakly associated with pain intensity, hence other factors appear to be involved (Alsaadi et al., 2010; Naughton, Ashworth, & Skevington, 2007). While the management of inflammation was one strategy aimed at assisting with sleep, it was anticipated that some participants would report sleep disturbance in the absence of inflammation, or that normal sleep might not be restored after active inflammation had been managed. Sleep disturbance was identified based on questioning participants with regards to their sleep quality and quantity (including ease of falling asleep initially and any waking during the night). When sleep disturbance was identified, a PIS was presented to participants that suggested several techniques including the development of consistent sleep routines, adoption of suitable body positioning, and management of stress and anxiety before sleep times (Harding & Williams, 1995; McKenzie & May, 2003).

5.4.2.5 Relaxation strategies

Treating physiotherapists were advised to assess the need for implementing relaxation strategies in participants with higher pain and activity limitation scores (Oswestry >

35%), or when participants raised any issues relating to stress or anxiety. This decision was also assisted by checking the participant's response to the depression and anxiety questions on their baseline Orebro Musculoskeletal Pain Questionnaire (Linton & Boersma, 2003; Linton & Hallden, 1998). When higher scores had been selected on these questions, or when stress or anxiety was openly reported by participants, a PIS was to be presented that outlined relaxation strategies. The pain-stress cycle was firstly discussed to demonstrate the potential benefit of managing stress and anxiety (Burns, 2006; Indahl, Velund, & Reikeraas, 1995; Lundberg et al., 2002; Nicholas, 2008). Strategies were then taught including passive relaxation such as listening to music or performing enjoyable activities, as well as the active relaxation techniques of relaxed breathing and progressive muscle relaxation (Hansen et al., 2010; Linton & Andersson, 2000; Nicholas, 2008; Sowden et al., 2006; Turner, 1982).

5.4.2.6 Management of increased pain

When participants reported an increase in their back or leg symptoms between treatment sessions, physiotherapists used an algorithm to decide if the physical pathology had been exacerbated or if the increased pain represented expected fluctuation in symptoms (see Appendix G). This required questioning of the participant regarding the cause of the increased pain, observation of their level of discomfort and reassessment of key assessment findings if necessary. In cases where the increase in pain appeared to be unrelated to any specific cause, or where no deterioration of key assessment findings was found, general reassurance was provided and the program continued in order to avoid positively reinforcing behaviour (complaining of increased pain) that may have been based on catastrophizing or fear avoidance beliefs (Hansen et al., 2010; Harding & Williams, 1995; Indahl et al., 1995). In cases where the pain was related to a considerable overloading event, or where exacerbation of physical signs was apparent, a PIS was given to the participant. This provided reassurance that the exacerbation was likely to settle over the following days and strategies were reviewed to assist with this process (pain management, pacing, posture, taping and management of inflammation). The intensity of exercise was also able to be temporarily reduced to accommodate a significant physical exacerbation (Sowden et al., 2006).

5.4.2.7 Management of work issues

Facilitating optimal engagement with work for trial participants was considered essential based on substantial evidence regarding the biopsychosocial benefits of work (Waddell & Burton, 2006). For participants off work, or unable to perform their full

work duties, the physiotherapist aimed to assist them to overcome barriers. Where the barrier was purely physical, suggestions for modifying the workplace or work tasks were made, while specific exercises were designed to target the physical requirements of the participant's occupation. If unhelpful or inaccurate beliefs presented a barrier to work (such as a fear of undertaking any work due to pain), cognitive restructuring was utilised to overcome them (Harding & Williams, 1995; Main, Foster, & Buchbinder, 2010; Nicholas, 2008). If work conflict unrelated to the participant's physical condition was apparent, problem solving skills were employed to assist with a resolution.

5.4.2.8 Pain versus function

For participants who appeared frustrated regarding a lack of rapid pain reduction during the program, the "pain versus function" PIS was used. This involved firstly reinforcing the timeframes of the program to dispel any unrealistic expectation of a rapid resolution of their condition. Participants were also advised to avoid focusing exclusively on pain as an indicator of progress, with any improvements in function or exercise intensity identified as an early sign that progress was occurring in other domains (Butler & Moseley, 2003).

5.4.3 Electronic clinical notes outlining the functional restoration protocol

The previous sections have provided an overview of the key approaches used in the FR program, followed by a more detailed description and justification of individual treatment components. This section outlines how the above components were compiled into 10 x 30-minute physiotherapy consultations.

The treating physiotherapists in the RCT were all provided with a 30-page Microsoft Word[2] electronic file called the "clinical notes". Embedded in the formatted document was a step-by-step guide outlining how to conduct each of the ten consultations. A list of all mandatory and optional treatment components available for each session was listed with check-boxes, while prompts were provided regarding important decision making algorithms that needed to be considered. References to the trial manual were made at various stages. The clinical notes required the treating physiotherapists to document assessment and reassessment findings, clinical reasoning/decision making rationale, treatment provided and response to treatment during each individual session. As an example, the Session 1 clinical notes have been presented in Appendix H.

[2] Microsoft Corp, One Microsoft Way, Redmond, WA 98052-6399

While it is not practical to present all 30 pages of clinical notes in this thesis, a summary of the content and timing of the ten treatment sessions through various phases of the FR program is presented in Table 5.3.

Table 5.3: Summary of the content and timing of the different phases of the functional restoration program

Phase of treatment	Timing of sessions	Content
Phase 1: Preparation for functional restoration	Weeks 1-2 (2 sessions per week)	• Participant explanations and background information • Postural management and taping • Management of inflammation and directional preference (if applicable) • Commencement of non-weight bearing specific motor control training unless adequate control demonstrated in functional positions • Address any additional issues via optional treatment components (eg. sleep management, work management, relaxation strategies, pain management strategies, management of increases in pain)
Phase 2: Functional restoration establishment	Weeks 2-3 (1-2 sessions per week)	• Ongoing review and reinforcement of Phase 1 strategies • Commencement of basic supervised functional exercises • Address any additional issues as above
Phase 3: Functional restoration progression	Weeks 3-6 (1 session per week)	• Greater focus on increasing exercise dosage based on functional activity goals • Progress to more advanced functional exercises • Address any additional issues as above, consider all possible contributing factors for participants failing to progress
Phase 4: Transfer to independence	Weeks 7-10 (1 session per week to one session per fortnight)	• Review of progress and positive reinforcement of gains made • Strategies for independent progression of exercises • Preparation for treatment completion and long term exercise/self management

5.5 Chapter summary

In this chapter, a protocol was presented outlining a specific physiotherapy FR program for people with DHR. The program was consistent with the key principles of FR (Section 4.1.1) but modifications were made to ensure that all elements were suitable for people with DHR based on consideration of the pathophysiological and healing mechanisms associated with this condition (see Sections 2.3 & 2.4). The key concepts relating to the delivery of the program were presented, followed by description and justification of the individual treatment components. While the program was standardised to allow reproduction and consistent application by different physiotherapists, there was scope incorporated into the protocol to allow tailoring of treatment to individuals. This protocol was applied in a RCT for people with DHR that is presented in the next chapter.

CHAPTER 6: A PILOT RANDOMISED CONTROLLED TRIAL COMPARING PHYSIOTHERAPY FUNCTIONAL RESTORATION TO ADVICE FOR LUMBAR DISC HERNIATION WITH ASSOCIATED RADICULOPATHY

The previous chapters of this thesis have presented a case that DHR is a specific pathoanatomical subgroup of LBDs for which few conservative treatments are known to be effective. Preliminary evidence was provided suggesting that FR has potential to benefit people with DHR based on an existing case series, an original case series presented in this thesis (Chapter 4) and pathophysiological mechanisms of effect. The systematic review (Chapter 3) found that the effectiveness of FR has not been previously evaluated in a RCT. In the previous chapter, a treatment protocol for the application of FR to people with DHR by physiotherapists was described and justified. The current chapter presents a pilot RCT conducted to evaluate the effectiveness of the FR treatment protocol when applied to people with DHR.

6.1 Introduction

In order to undertake a RCT to evaluate a new treatment protocol, a critical decision that needs to be made relates to the comparison intervention to be used in the trial. The choice of a comparison is dependent on the type of trial that is desired and the questions that are to be answered from it (Manchikanti et al., 2008). While Chapters 4 & 5 of this thesis provided considerable justification for the FR treatment, it has been recommended that comparison interventions in a RCT should also be justified (Manchikanti et al., 2008; Mann & Djulbegovic, 2003). The most common comparison interventions used in RCTs are placebo controls, no treatment controls, and comparison to another existing treatment that is known to be effective or is commonly applied in clinical practice (Manchikanti et al., 2008).

Trials that compare an intervention to other existing treatments in their usual clinical forms are used in “pragmatic” RCTs. These trials measure “effectiveness”, that is, they measure the benefit of one treatment in comparison to another in clinical practice (Bogduk, 2004a; Li & Kaptchuk, 2011; Manchikanti et al., 2008). These trials are common in back pain research and have been encouraged by researchers (Brox et al., 2003; Manchikanti et al., 2008). Conducting a trial evaluating the effectiveness of FR in this thesis offered several advantages over a placebo or no treatment controlled trial. Firstly, comparing FR to another treatment with existing benchmarks and clinical

acceptance has potential to enhance the external validity and interpretation of trial results (Manchikanti et al., 2008). In addition, there is evidence that participants are more likely to enrol in a pragmatic trial as they receive an active treatment regardless of their allocation, assisting with recruitment efforts (Friedly et al., 2010; Manchikanti et al., 2008). The provision of a valid treatment to both arms of a RCT also has ethical advantages over placebo and no treatment controls (Manchikanti et al., 2008; Mann & Djulbegovic, 2003). The main limitation of a trial that investigates effectiveness lies with difficulties in blinding participants to the treatment they receive, hence trial results can be influenced by bias or placebo effects if participants have a higher expectation of benefit from one of the treatments (Bogduk, 2004a; Costa, Maher et al., 2009b; Manchikanti et al., 2008; Paterson & Dieppe, 2005).

Upon balancing the strengths and weaknesses of different comparison interventions, it was decided to compare FR to an existing treatment that has established benchmarks and widespread acceptance in clinical practice guidelines. An international comparison of all clinical practice guidelines relating to LBDs reported that advice was the only intervention recommended consistently in all guidelines for the management of acute and subacute LBDs (Koes et al., 2010). The two existing guidelines relating to DHR also endorse the use of advice (Health Council of the Netherlands, 1999; Wong et al., 2000). There is evidence that the recommendations relating to advice within these guidelines are generally followed in clinical practice. Firstly, a survey of general medical practitioners in the Netherlands found that the majority of those surveyed followed the recommendations in the Dutch guideline relating to lumbo-sacral radicular syndrome, which recommends advice as the primary intervention for this condition (Luijsterburg et al., 2005). In addition, of the participants with DHR who were allocated to conservative treatment in the Spine Patients Outcomes Research Trial (where physicians and participants could select their own conservative treatments), 93% received advice, education and counseling, which was the most common conservative treatment selected in the trial (Weinstein, Tosteson et al., 2006).

While clinical practice guidelines seem to justify the use of advice as an accepted treatment suitable for serving as a comparison intervention for the RCT, an estimate of the effectiveness of advice was desirable so that the trial results could be placed into context. The following evidence review was undertaken by considering studies in the following hierarchy of relevance for DHR: i) studies using advice that were included in

the systematic review of conservative treatments for DHR presented in this thesis; ii) studies evaluating advice for conditions approximating DHR that did not meet the full selection criteria for the systematic review in this thesis; and iii) studies evaluating advice for people with other LBDs.

The systematic review presented in Chapter 3 of this thesis located only two RCTs that implemented advice as one of the interventions (Osterman et al., 2006; Peul et al., 2007). These two high quality trials used advice as a comparison for the primary intervention of microdiscectomy. Meta-analysis revealed that advice was less effective than microdiscectomy surgery at short term follow-ups but equally effective at long term follow-ups. Since surgery is known to be an effective treatment for DHR, this provides some support for the use of advice for DHR given the equal long term outcomes achieved. No trials were found in the systematic review (Chapter 3) that compared advice to another conservative intervention in people with DHR.

Two trials that did not meet all of the inclusion criteria for the systematic review evaluated advice for people with conditions that approximated DHR. One trial included participants with acute radiculopathy and CT evidence of neural compression from any structure (including the disc), and compared advice with two other interventions; bed rest and physiotherapy (Hofstee et al., 2002). That trial found no difference between any of the groups for the outcomes of pain and activity limitation at 1, 2 and 6 month follow-ups (Hofstee et al., 2002). Another trial compared advice alone to physiotherapy treatment plus advice for participants with acute lumbo-sacral radicular syndrome (without radiological imaging) (Luijsterburg et al., 2008). This trial showed no differences at any follow-up time (3, 6, 12 and 52 weeks) for the outcomes of leg pain, back pain, or activity limitation. There was also no difference in the proportion of participants rating their progress as "improved" on a Global Perceived Effect scale administered at 3, 6 and 12 weeks, although a significantly higher proportion of the physiotherapy plus advice group reported improvement at the 12 month follow-up (Luijsterburg et al., 2008). The results of these two trials provided evidence that advice is equally effective to several other interventions for people with conditions approximating DHR.

There has been much more research evaluating the effectiveness of advice for people with other LBDs. One of the first RCTs to demonstrate the effectiveness of advice for

people with LBDs compared advice versus no treatment for people with subacute LBP (Indahl et al., 1995). The advice intervention involved a pathoanatomical explanation of the cause of participants' pain, reassurance regarding the favourable prognosis of their condition, advice to remain active and avoid rest, as well as demonstration of correct lifting technique. The group receiving advice achieved significantly higher return-to-work rates than the group that received no treatment (Indahl et al., 1995). Another RCT comparing advice to no treatment revealed similar results in relation to improved return-to-work rates (Hagen, Eriksen, & Ursin, 2000). In addition to improving work outcomes, systematic reviews have also shown that advice is slightly more effective than bed rest for the outcomes of pain intensity and activity limitation when administered to people with acute LBP (Dahm, Brurberg, Jamtvedt, & Hagen, 2010; Liddle, Gracey et al., 2007).

While advice has been shown to be more effective than no treatment and bed rest for people with LBP, there is also evidence that advice is equally effective to a range of other interventions (Engers et al., 2008). Advice has been shown to be equally effective to routine physiotherapy (Frost, Lamb, Doll, Carver, & Stewart-Brown, 2004), physiotherapy exercises (Pengel et al., 2007), cognitive-behavioural group therapy (Linton & Andersson, 2000), Mckenzie therapy (Cherkin, Deyo, Battie, Street, & Barlow, 1998), chiropractic care (Cherkin et al., 1998) and intensive group exercise training (Storheim et al., 2003). When advice is shown to be equally effective to other interventions, a case can be made that advice is the preferred treatment option given its lower cost and easier implementation compared to more substantial treatment approaches. This was proven by a cost-utility analysis of the Frost et al. (2004) trial, which found that one session of advice was more cost effective than up to six sessions of routine physiotherapy that achieved the same outcomes for people with LBP (Rivero-Arias, Gray, Frost, Lamb, & Stewart-Brown, 2006).

Based on the above evidence review, it was considered that advice was a suitable comparison intervention for the current RCT based on recommendations in guidelines, the common utilisation of advice in clinical practice, established evidence of the effectiveness of advice for LBDs, and preliminary evidence of the non-inferiority of advice for people with DHR when compared to other conservative interventions.

6.2 Aims and hypotheses of the study

The primary aim of the study was to determine the effectiveness of physiotherapy FR versus advice for people with DHR. A secondary aim was to report any adverse events potentially associated with either of the interventions. It was hypothesised that FR is more effective than advice at reducing back pain, leg pain and activity limitations in people with DHR. The second hypothesis was that FR is a safe treatment for people with DHR that is associated with little or no risk of serious adverse events. Given the constraints on time, funding and resources imposed by a PhD, it was acknowledged at the beginning of the study that a definitive achievement of these aims was unlikely to be possible. The study was therefore more realistically considered as a pilot study to gain a preliminary estimate of effect sizes and adverse events, along with establishing the feasibility of conducting a larger trial in the future.

6.3 Methods

An overview of the processes involved in the trial is presented in Figure 6.1.

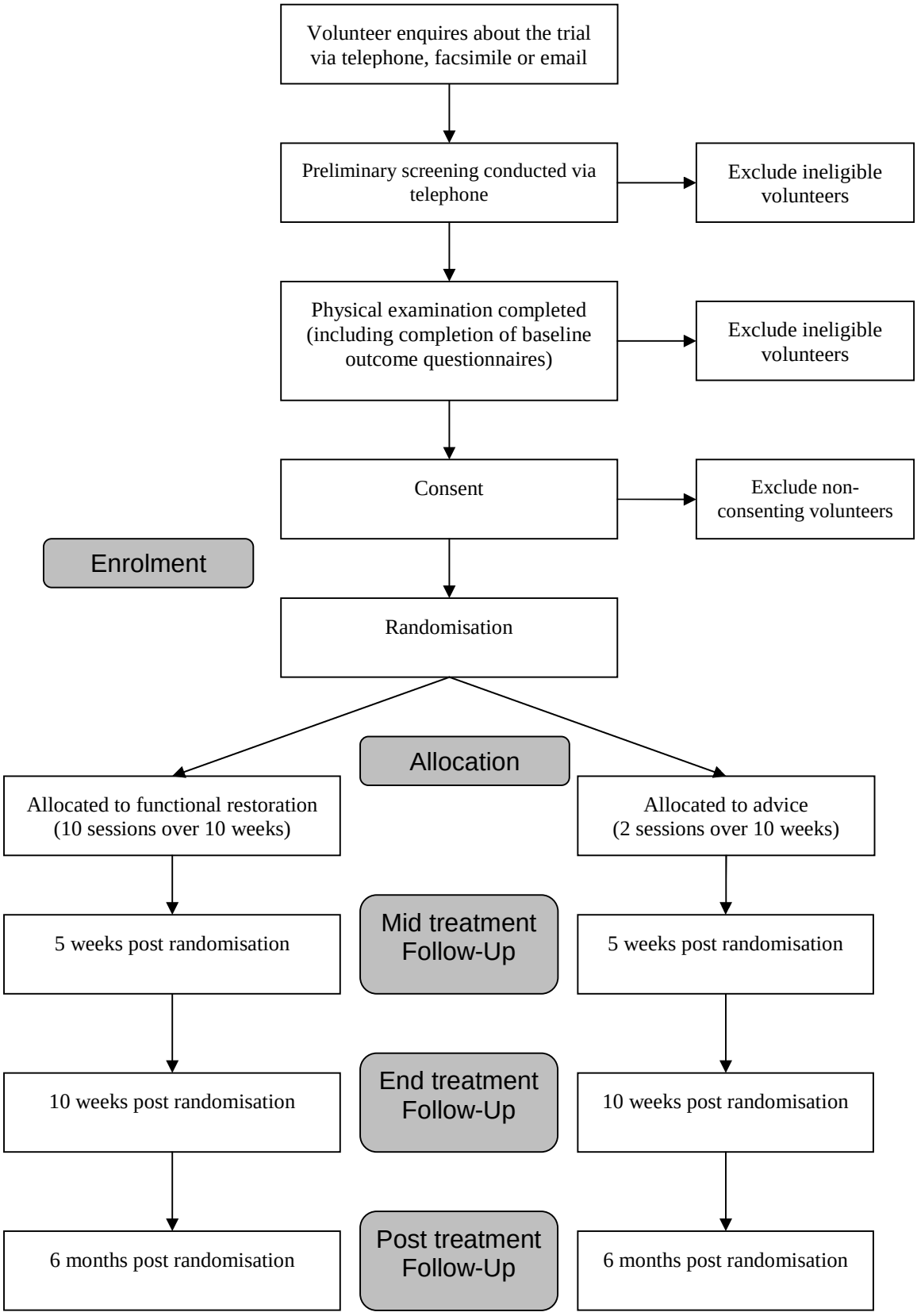


Figure 6.1: Overview of the trial processes

6.3.1 Study design

This was a pilot multi-centre parallel group randomised controlled trial.

6.3.2 Ethics and registration

The trial received ethical approval from the Faculty of Health Sciences Human Ethics Committee, La Trobe University (FHEC approval number 08/196, see Appendix I). The trial was registered with the Australian & New Zealand Clinical Trials Registry prior to enrolment of the first participant (ACTRN#12609000205235).

6.3.3 Participants

6.3.3.1 Recruitment

Recruitment of participants occurred between 25/4/2009 and 30/9/2010. Table 6.1 outlines the scope and nature of the recruitment methods used.

Table 6.1: Participant recruitment methods utilised for the trial

Recruitment method	Number	Total cost of materials to implement (AU$)
Newspaper advertising		
Leader newspapers	29	$5800
Geelong newspapers	2	$871
Community announcements section	32	Nil
Herald-sun classifieds	3	$378
The Age Green Guide (TV guide)	2	$860
MX magazine	1	$850
The Shoppers Guide	3	$1100
Council newsletter	2	Nil
Division of general practice newsletter	1	$350
TOTAL	75	$10,209
Posters / pile of flyers		
Radiology clinics	50	
Pharmacies	26	
Gymnasiums	13	
Libraries	18	
University notice boards	400	
Community notice boards	8	
Other	2	
TOTAL	517	$3000
Medical practitioner mailout		
General medical practitioners	183	
Rheumatologists	21	
Neurologists	14	
Sports Physicians	30	
Spinal surgeons	10	
TOTAL	258	$155 (stamps)
Medical practitioner visits		
General medical practitioner meeting	26	
Information left with practice manager	33 clinics (86 doctors)	
Flyers / posters placed in clinic	15 clinics	
Spinal surgeon meeting	7	
TOTAL	81	Cost of flyers and posters (see above)
Public hospital physiotherapy department presentations	9 departments (71 physiotherapists)	Cost of flyers and posters (see above)
TOTAL direct costs of marketing		**$13,364**

Abbreviations: AU$=Australian dollars

Examples of advertising material are provided in relevant appendices: newspaper advertisements (Appendix J), posters (Appendix K) and flyers (Appendix L).
All advertising material described four avenues by which potential participants could obtain more information, enquire about participating, or undergo a preliminary screening of their eligibility for the trial. These avenues were a designated trial telephone line and facsimile line, a trial website that was designed by the Information Technology Department at La Trobe University (www.stopsbackpain.com.au) and a trial email account that was checked daily (backpain@pac.com.au).

6.3.3.2 Eligibility

Potential participants who enquired about the trial were initially screened for eligibility via telephone (see Appendix M for phone screening form). Those found to be potentially eligible were invited to attend an interview and physical examination with one of the treating physiotherapists to confirm or refute their eligibility (see Appendix N for assessment content and protocols). The selection criteria for the trial are listed and justified in Table 6.2.

Table 6.2: Selection criteria that needed to be met by participants to be eligible for the trial

Criterion	Justification / elaboration
Inclusion criteria (participants needed to demonstrate ALL of the following)	
Aged between 18 and 65 (inclusive).	Symptomatic DHR is most commonly seen in the middle ages (Atlas, Deyo et al., 1996a; Rhee et al., 2006) and older people are more likely to have spinal stenosis as the primary cause of their radiculopathy (Atlas, Deyo et al., 1996b; Sugioka, Hayashino, Konno, Kikuchi, & Fukuhara, 2008).
Presence of referred leg symptoms (pain or paraesthesia), defined as predominately unilateral leg symptoms extending either below the knee or into the anterior thigh, with or without low back pain.	These features were found to possess adequate reliability and validity as diagnostic features for DHR (Section 2.5.2). In addition, this definition is consistent with large surgical trials involving people with DHR (Peul et al., 2007; Weinstein, Tosteson et al., 2006).
A duration of the current episode of leg symptoms lasting between 6 weeks and 6 months. A new episode was distinguished from recurring or chronic episodes by requiring that a 4 week period with *no leg symptoms* be present prior to the start of the current episode (de Vet et al., 2002; Stanton, Latimer, Maher, & Hancock, 2009).	This symptom duration was considered to be targeting participants in the subacute stage of DHR (Pengel et al., 2002; Woods et al., 2000). The rationale behind targeting participants in this stage of injury was due to multiple reasons. Firstly, it allowed exclusion of participants with acute symptoms that may change rapidly irrespective of the effects of treatment (Benoist, 2002; Hayden et al., 2010; Pengel et al., 2002; Pengel, Herbert, Maher, & Refshauge, 2003; Weber, 1994). Secondly, participants with chronic symptoms and consequently a poorer prognosis for improving were also excluded (Andersson, 1999; Atlas et al., 2001; Costa, Maher, McAuley et al., 2009; Pengel et al., 2002; Pengel et al., 2003). Finally, there has been limited research into the management of people with LBDs in the subacute stage of injury (Pengel et al., 2002), hence developing effective treatments for this group represented an opportunity to prevent the critical transition to chronic symptoms (Frank et al., 1996; Pengel et al., 2002).
Evidence of radiculopathy in the leg where the primary symptoms were reported.	The presence of radiculopathy was defined as at least one positive physical examination finding (reduced dermatomal sensation, reduced myotomal strength, reduced or absent ankle jerk or knee jerk reflex, usual leg symptoms reproduced at any angle during passive SLR, or usual anterior thigh symptoms reproduced at any angle during the prone knee flexion test). These features were found to possess adequate reliability and validity as diagnostic features for DHR (Section 2.5.2). Similar or identical definitions of radiculopathy have been used in other RCTs to identify people with DHR (Carette et al., 1997; Dincer et al., 2007; Genevay et al., 2010; Osterman et al., 2006; Weinstein, Tosteson et al., 2006).

Continued

Table 6.2 continued: Selection criteria that needed to be met by participants to be eligible for the trial

Criterion	Justification / elaboration
A radiologist's report from a MRI or CT scan confirming a lumbar disc herniation according to the definition adopted in this thesis (Section 2.1) (Fardon & Milette, 2001).	Disc herniations (or protrusions, prolapses, extrusions or sequestrations) could be central, posterolateral, or lateral in direction but bulges were excluded. The imaging test must have been undertaken during the period of the participant's current episode of leg symptoms. Potential participants who had radiculopathy without a current MRI or CT scan were given the option of obtaining one through their medical practitioner but they were not included without imaging confirmation of a disc herniation. Disc herniations depicted on imaging were found to possess adequate reliability and validity as diagnostic features of DHR (Section 2.5.2).
Concordance between the distribution and side of leg symptoms, the physical examination findings and the imaging results.	Combining multiple features of DHR is known to increase the specificity for diagnosing this condition (as discussed in Section 2.5.2.1).
Fluency in English	English language skills needed to be sufficient to complete outcome questionnaires and to enable understanding of the intervention by participants.
Agreeing to refrain from other interventions wherever possible for the 10 week treatment period of the trial.	This agreement aimed to minimise co-interventions so that the treatments in the trial could be compared without confounding factors. Consultations with medical practitioners, use of medication and any exercises that were already being performed prior to the trial were permitted.
Exclusion criteria (participants were excluded if they had ANY of the following)	
An active compensation claim for their injury.	Neither of the treatment protocols to be compared in the trial were designed to be able to deal with the full range of complexities that can arise when managing compensable injuries (Atlas et al., 2007).
Presence of other potential pathoanatomical causes of radiculopathy confirmed via radiological imaging.	These included spondylolisthesis, retrolisthesis, osseous or ligamentous stenosis, or spinal tumours. This trial focussed on people with disc herniation as the most likely source of their radiculopathy, hence these other conditions were excluded.
Active cancer under current treatment.	The treatment of the cancer may have interfered with the participant's ability to comply with treatment in the trial.
Signs of cauda equina syndrome based on reports of bladder or bowel dysfunction and/or imaging (Domen, Hofman, van Santbrink, & Weber, 2009).	This condition may require urgent surgery (Domen et al., 2009).

Continued

Table 6.2 continued: Selection criteria that needed to be met by participants to be eligible for the trial

Criterion	Justification / elaboration
Pregnancy or childbirth within the last 6 months.	Pregnancy or recent childbirth may have impaired participants' ability to undertake certain exercises and could also account for back and leg symptoms not related to the disc herniation.
Spinal injections within the last 6 weeks.	The therapeutic effects of spinal injections have been demonstrated to last for up to 6 weeks (see Section 3.1.3) (Abdi et al., 2007; Armon et al., 2007; DePalma et al., 2005) and this may have confounded the effects of the treatments being evaluated in the trial.
Any history of lumbar spine surgery.	There is already considerable research evaluating the effectiveness of post-surgical rehabilitation programs (Ostelo, Costa, Maher, de Vet, & van Tulder, 2009).
A low intensity of leg pain indicated by a score of less than 2/10 on a 0-10 numerical rating scale.	The trial focussed on participants who had baseline symptoms of sufficient intensity to allow clinically significant changes to be identified.
Minimal activity limitation, indicated by a participant being capable at baseline to undertake all of the following activities: walk > 60 minutes, sit > 60 minutes, stand > 60 minutes and sleep without any disturbance at night.	These activities were chosen based on four representative questions from the Oswestry Disability Index (Fairbank, 2007) that were easily administered via telephone, where no limitation on all of these activities was likely to result in a very low final Oswestry score. Again, the trial focussed on participants who had scope for significant change to be detected.
Participants who had already completed more than five sessions of physiotherapy with any of the treating trial physiotherapists prior to enrolment.	These physiotherapists were likely to have already used many components of the trial treatment protocol on their usual client caseload. Up to five sessions were allowed in order to allow trial physiotherapists to refer their own clients into the trial after initial contact.
Inability to walk safely, such as severe foot drop causing regular tripping.	The interventions in the trial included walking for most participants which may not have been safe for people with a high risk of tripping.
A planned absence of more than one week during the treatment period (such as overseas or interstate holidays).	This would have interrupted the treatment program and made it difficult to complete all allocated sessions within the 10 week treatment period.

Some of the decisions required to determine eligibility for the trial were quite technical and complex, such as whether the level of a neurological deficit was consistent with the radiological imaging results. For this reason, a standardised Microsoft Excel[3] spreadsheet was designed with decision rule algorithms that consistently assessed whether a participant was eligible after all relevant examination and questionnaire data had been entered. In addition to this automatic system, the spreadsheet was manually checked by a researcher prior to enrolment of every participant in the trial to confirm that the participant was eligible.

6.3.4 Randomisation and allocation

All volunteers were given a participant information sheet regarding the trial prior to their attendance at the physical examination (Appendix O). Those who were found to be eligible at the assessment were invited to sign a consent form indicating that they had agreed to participate in the trial (Appendix P). Those who consented were randomised into one of two treatment groups: advice or FR. A randomisation schedule was prepared in advance by a researcher who had no contact with any participants throughout the trial and was not involved in the recruitment, screening, assessment, enrolment or treatment processes. The randomisation sequence was generated using an internet based randomisation program (http://www.randomization.com) with the sequences transferred to a computer spreadsheet. Permuted block randomisation with random block lengths was used to avoid unequal group sizes (Altman & Bland, 1999). Randomisation was stratified for treatment centre by generating a separate schedule for each treatment centre.

Allocation of participants in accordance with the randomisation schedule was undertaken by an administrative assistant located external to the treatment centres and university. The administrative assistant was not involved in the recruitment, screening, assessment, consenting, or treatment of participants (Altman & Schulz, 2001; Moher et al., 2010). To enrol a participant, the treating physiotherapist emailed the consenting participant's name and date of birth to the administrative assistant. These details were then entered into the allocation spreadsheet and the next treatment allocation and participant identification number was emailed back to the treating physiotherapist.

[3] Microsoft Corp, One Microsoft Way, Redmond, WA 98052-6399

6.3.5 Interventions

6.3.5.1 Setting

The treatments in the trial were conducted at eleven private physiotherapy practices that were part of the Spinal Management Clinics of Victoria network throughout metropolitan Melbourne, Australia. This network was chosen for several reasons, including convenience given that several members of the La Trobe University Back Research Team worked within the network and had established contacts. Treatment clinics were located across a wide geographical area of metropolitan Melbourne, providing sufficient scope for recruitment of participants. In addition, Spinal Management Clinics of Victoria (and its physiotherapists) agreed to provide the allocated treatment free of charge to all trial participants, which made the trial possible on a modest budget.

6.3.5.2 Treating physiotherapists

Ten physiotherapists from Spinal Management Clinics of Victoria provided the treatment for both groups in the trial. All physiotherapists had at least one year of experience working for that organisation, which required them to read a 120 page manual and complete a training program relating to the management of spinal disorders prior to commencing work. They had all been engaged in clinical mentoring and education programs that included inservices and regular meetings with senior physiotherapists. None of the physiotherapists had post-graduate qualifications. The treating physiotherapists comprised nine males and one female, with a mean (SD) age of 30.4 (4.9) years, a mean (SD) of 8.7 (4.9) years experience as physiotherapists and a mean (SD) of 6.5 (4.1) years working for Spinal Management Clinics of Victoria.

6.3.5.3 Comparison intervention: physiotherapy advice

Participants allocated to the physiotherapy advice intervention attended 2 x 30-minute physiotherapy sessions with one of the treating physiotherapists over a 10 week period. The intervention followed the approach described by Indahl et al. (1995), which was endorsed in the Australian Clinical Practice Guidelines for LBP (Bogduk, 1999). The key content of the advice intervention is presented in Table 6.3. This content is consistent with a summary of international LBP guidelines (Koes et al., 2010), as well as with guidelines relating to the management of DHR (Health Council of the Netherlands, 1999; Wong et al., 2000). The first session was scheduled shortly after randomisation. In that session, two participant information sheets were presented to

participants by their treating physiotherapist. The first was the same information sheet provided to the FR group outlining the anatomy and pathophysiology of DHR (see Chapter 5). The second outlined key principles for the self-management of LBDs (points 2-7 of Table 6.3). While the advice intervention could have been administered in one session, a follow-up session is often advised to allow reinforcement of the information and monitoring of progress (Bogduk, 1999; Indahl et al., 1995; Luijsterburg et al., 2008). This second session was scheduled 4-5 weeks following the first, and involved working through the same two participant information sheets with questions posed to participants regarding their progress with each of the recommendations.

Table 6.3: Outline of the content of the advice intervention

1. A pathoanatomical explanation of DHR was provided via the same participant information sheet that was used for the functional restoration group (see Chapter 5). This included a brief outline of the anatomy and pathophysiology of DHR, explanation of the common symptoms, and reassurance regarding the generally favourably prognosis for the achievement of improvements over time.

2. Participants were advised to avoid worrying about their condition. This included an explanation of how stress and worrying can increase the tension in back muscles which further increases pain in a stress-pain cycle.

3. Advice was given to remain as active as possible. General exercise of the participant's choice was recommended, with walking identified as one example of a potentially useful means of remaining active. The concept of goal setting in relation to increasing exercise was covered, although no specific goals or quotas were recommended.

4. Participants were advised to avoid activities requiring sustained activity of the back muscles, such as long periods of unsupported sitting or sustained forward flexion of the lumbar spine.

5. Information was discussed regarding the management of acute attacks of pain. It was discussed that these exacerbations were rarely an indicator of further damage, hence they could generally be managed by continuing with light activity or general stretches.

6. Participants were advised to move as freely as possible and a demonstration of normal relaxed walking was performed.

7. Discussion, demonstration and practice of correct lifting technique occurred. The key concepts covered were a recommendation to avoid twisting and bending of the back when lifting, and to allow the leg muscles to perform the primary motion during the lift.

6.3.5.4 Primary intervention: physiotherapy functional restoration

Participants allocated to the physiotherapy functional restoration intervention attended 10 x 30-minute physiotherapy sessions with one of the treating physiotherapists over a 10 week period. The FR treatment protocol used in the trial was outlined and justified previously in Chapter 5.

6.3.5.5 Blinding

Given the nature of the interventions it was not possible to blind participants or physiotherapists to the treatments. However, all physiotherapists and participants were informed that both treatment approaches were valid interventions that had a realistic chance of being beneficial and that neither approach was known to be more effective than the other. Physiotherapists were also instructed to treat participants in both groups with the same degree of attentiveness, enthusiasm and optimism (Paterson & Dieppe, 2005; Turner, Deyo, Loeser, Von Korff, & Fordyce, 1994). Although blinding of participants and physiotherapists was not possible, the trial did utilise blinded scoring and data entry of self-administered outcome questionnaires that were completed by participants and mailed back to the researchers (Colditz et al., 1989; Juni et al., 2001; Schulz et al., 1995; van Tulder et al., 2003; Wood et al., 2008).

6.3.5.6 Standardisation and integrity of treatment protocols

Several strategies were employed to facilitate and assess treatment integrity for both the specific physiotherapy treatment group and the advice group (Borrelli et al., 2005; Perepletchikova et al., 2007). These methods were designed to ensure that all participants received treatment from trial physiotherapists that was standardised, accountable and reproducible (Borrelli et al., 2005; Boutron et al., 2008; Perepletchikova et al., 2007).

Prior to the commencement of the trial, all participating physiotherapists attended a one-day training program led by a senior musculoskeletal physiotherapist where all assessment and treatment protocols were taught and practiced. The treatment protocols (described in Chapter 5) were outlined in a 120 page manual that contained standardised descriptions of how to deliver the treatment, along with decision making algorithms to assist with key management choices. All trial procedures were also outlined in the manual, such as the procedure for reporting adverse events. Key information conveyed to participants was standardised by the use of participant information sheets that were provided for each participant. While the manual was to be

used as a reference document, it was supplemented by the electronic clinical notes which contained an outline of the treatment protocol on a session-by-session basis (see Section 5.4.3). The clinical notes of all participants (in both groups) were emailed to a researcher at weeks four, seven and ten of each participant's program, which allowed feedback to be provided to the treating physiotherapist during the treatment period of each participant. The review of clinical notes therefore provided a means of assessing the treatment integrity / compliance of the physiotherapists with the treatment protocols (Borrelli et al., 2005; Perepletchikova et al., 2007).

For the duration of the trial a monthly teleconference was conducted for 60 minutes involving all treating physiotherapists. These meetings were used to review specific cases in the context of the treatment protocols and to anonymously discuss any common issues that emerged from reviewing the clinical notes throughout the trial.

6.3.5.7 Clinical equipoise

A strong case can be made that this trial satisfied the requirement for clinical equipoise based on the selection of the two treatment approaches to be compared (Freedman, 1987). There is preliminary evidence to support the effectiveness of both advice (see Section 6.1) and FR (see Chapter 4) for people with DHR. These two interventions have not been previously compared for people with confirmed DHR but trials comparing advice with generic physiotherapy treatment for conditions approximating DHR have shown no differences in outcomes (Hofstee et al., 2002; Luijsterburg et al., 2008). While it was hypothesised that FR would be shown to be more effective than advice for people with DHR, genuine uncertainty existed regarding the relative effects of these two treatment approaches in this population.

6.3.6 Outcome assessment

Outcomes were assessed via self-administered questionnaires that were mailed to participants prior to randomisation (Appendix Q) and at each follow-up point (5 weeks, 10 weeks and 26 weeks post randomisation: Appendix R). Participants returned completed follow-up questionnaires via mail marked only with their participant identification number. The outcomes that were measured in the trial are discussed below and summarised in a table at the end of this section (Table 6.3).

6.3.6.1 Primary outcomes

Activity limitation was evaluated using nine questions from the Oswestry Disability Index version 2.1 (Fairbank, 2007), with the 10th item relating to "sex life" being replaced by a question relating to "work/housework" (Davidson, 2008; Fritz & Irrgang, 2001). Rasch analysis has shown that this modified version performs as well as the original Oswestry (Davidson, 2008) but it is aimed at preventing missing responses to the "sex life" question. This questionnaire consists of ten questions relating to pain and activity performance, where participants select the degree of limitation they experience on a six point scale (scored 0-5) (Davidson, 2008; Fritz & Irrgang, 2001). The total score out of 50 is then converted to a percentage, with higher scores indicating a greater degree of activity limitation due to the participant's LBD (Davidson, 2008; Fritz & Irrgang, 2001). The Oswestry has been shown to be a reliable, valid and responsive instrument for measuring activity limitation in people with LBP and referred leg pain (Davidson & Keating, 2002; Frost, Lamb, & Stewart-Brown, 2008; Lauridsen et al., 2006) and it has been specifically validated on a cohort of people with DHR (Hakkinen, Kautiainen, Jarvenpaa, Arkela-Kautiainen, & Ylinen, 2007). The psychometric properties of the Oswestry have outperformed other questionnaires that measure activity limitation (Davidson & Keating, 2002; Frost et al., 2008; Rocchi et al., 2005).

Separate 0-10 numerical rating scales (NRSs) were used to measure the average intensity of back pain and leg pain over the past week, with anchor descriptors of "no pain" (scored 0) and "worst pain possible" (scored 10) (Ostelo & de Vet, 2005; Pengel et al., 2007). The NRS has demonstrated good reliability (Ferraz et al., 1990; Lundeberg et al., 2001), responsiveness (Childs, Piva, & Fritz, 2005; Grotle, Brox, & Vollestad, 2004; Lauridsen et al., 2006; Pengel, Refshauge, & Maher, 2004) and validity (Bijur, Latimer, & Gallagher, 2003; Jensen, Turner, Romano, & Fisher, 1999) for a wide range of health conditions including LBDs. The NRS has also been shown to be easier to use, preferable to patients and less likely to yield invalid responses when compared to a visual analogue scale (Dworkin et al., 2005; Williams, Davies, & Chadury, 2000). Average pain scores over the past week were assessed in order to measure pain intensity over a longer period of time (Deyo et al., 1998), with studies showing that weekly average scores give an accurate indication of the true mean score if pain were rated on a daily basis for seven days (Bolton, 1999; Jamison, Raymond, Slawsby, McHugo, & Baird, 2006). The decision to rate back and leg pain on separate

scales was made based on knowledge that these symptoms are commonly distinct in people with DHR due to back and leg symptoms resulting from different pain mechanisms (Sections 2.1 & 2.3) (Bogduk, 2009).

6.3.6.2 Secondary outcomes

While the NRS provided a measure of back and leg pain intensity, it is a uni-dimensional tool that does not account for the other elements and complexities of pain (Smith & Grimmer-Somers, 2010). In Chapter 2 the common symptoms of DHR in addition to pain were described, including leg numbness, weakness and pins & needles (Grovle et al., 2010). To limit the assessment of outcomes in people with DHR to leg pain intensity would potentially miss the impact of treatment on these other leg symptoms. For this reason, the Sciatica Frequency and Bothersomeness Scale was used to assess the "frequency" and "bothersomeness" of a range of leg symptoms including leg pain, numbness or tingling, and weakness in the leg or foot (Patrick et al., 1995). For the frequency sub-section of the scale, the frequency of five symptoms are rated on a 0-6 scale ranging from "not at all" (scored 0) to "always" (scored 6) for a total score ranging between 0 and 30 (Grovle et al., 2008; Patrick et al., 1995). For the other sub-section of the scale, the bothersomeness of the same five symptoms are rated on a 0-6 scale ranging from "not bothersome" (scored 0) to "extremely bothersome" (scored 6) for a total score between 0 and 30 (Grovle et al., 2008; Patrick et al., 1995). The two sub-sections are typically analysed separately rather than as a combined score (Atlas et al., 2001; Grovle et al., 2008, 2010; Patrick et al., 1995; Peul et al., 2007; Weinstein, Lurie et al., 2006; Weinstein, Tosteson et al., 2006). One or both sub-sections of the scale have been used in a number of trials focussing on people with DHR (Atlas et al., 2001; Peul et al., 2007; Weinstein, Lurie et al., 2006; Weinstein, Tosteson et al., 2006). The scale has been shown to be reliable (Grovle et al., 2008; Patrick et al., 1995), responsive and valid (Grovle et al., 2008, 2010) in several samples of participants with sciatica.

Global rating of change was measured using a 7-point likert scale, with participants rating their overall change from baseline as "completely recovered", "much improved", "slightly improved", "no change", "slightly worsened", "much worsened", or "vastly worsened" (Beurskens, de Vet, & Koke, 1996; Kamper, 2009). This scale is considered to be valid, reliable and responsive when applied to people with musculoskeletal

conditions including LBDs (Kamper, 2009; Kamper, Maher, & Mackay, 2009; Kamper et al., 2010).

In addition to global rating of change, participants rated their satisfaction with physiotherapy care, their satisfaction with the *results* of physiotherapy care and their satisfaction with the prospect of enduring their current symptoms for life, on separate 5-point Likert scales. Ratings from "very satisfied" to "very dissatisfied" were available for selection (Bombardier, 2000; Deyo et al., 1998; Hudak & Wright, 2000). These scales have demonstrated good reliability, validity and responsiveness in people with LBDs (Ferrer et al., 2006; Mannion et al., 2005).

Interference with work due to DHR was assessed in two ways. Firstly, at each assessment point participants recorded the number of work days missed due to their back/leg condition over the previous 30 days (Bombardier, 2000; Deyo et al., 1998). Secondly, participants rated the degree of interference with work (employment or housework) caused by their back/leg condition over the previous week on a 4-point scale ranging from "not at all" (scored 0) to "extremely" (scored 3) (Bombardier, 2000; Deyo et al., 1998). These measurement methods have demonstrated good reliability, validity and responsiveness in people with LBDs (Ferrer et al., 2006; Mannion et al., 2005).

The Orebro Musculoskeletal Pain Questionnaire was used as a measure of psychosocial risk factors (Linton & Boersma, 2003; Linton & Hallden, 1998). This questionnaire consists of 21 questions relating to risk factors that are known to be predictive of a poorer future outcome in people with musculoskeletal disorders (Linton & Boersma, 2003; Linton & Hallden, 1998). Each question is rated on a 0-10 scale, with a total score ranging between 0 and 210 (Linton & Boersma, 2003; Linton & Hallden, 1998). Higher scores are associated with a greater risk of poor future outcome (Grotle, Vollestad, & Brox, 2006; Hockings, McAuley, & Maher, 2008; Linton & Boersma, 2003; Linton & Hallden, 1998). Although it is more commonly used as a prognostic screening tool at one point in time (Hockings et al., 2008), in the current trial the Orebro was also administered at each follow-up point to detect changes in psychosocial risk factors over time. This appeared justified given that the Orebro has good test-retest reliability and internal consistency in LBD populations (Grotle et al., 2006; Linton &

Boersma, 2003), although its responsiveness as an outcome measure has not been evaluated.

Health related quality of life was measured with the EuroQol-5D (EuroQol-Group, 1990). This consists of five items relating to different dimensions of quality of life that are scored on a three point scale consisting of no problems, some problems and severe problems (EuroQol-Group, 1990). Validated algorithms were used to transform the questionnaire results into overall health status scores ranging from -.594 to 1.0, with negative values considered to represent a health state worse than death (Dolan, 1997; Silverplats et al., 2011). The EuroQol-5D has demonstrated good reliability and responsiveness across a range of health conditions (Hurst, Kind, Ruta, Hunter, & Stubbings, 1997; Linde, Sorensen, Ostergaard, Horslev-Petersen, & Hetland, 2008; Solberg, Olsen, Ingebrigtsen, Hofoss, & Nygaard, 2005), is a recommended outcome measure for LBP research (Deyo et al., 1998) and has been used in several other LBP trials (Rivero-Arias et al., 2005; Rivero-Arias et al., 2006; van der Roer, van Tulder, van Mechelen, & de Vet, 2008).

A summary of all outcome measures used in the trial is presented in Table 6.4.

Table 6.4: Summary of outcome measures

Outcome measure	Measurement point (weeks post randomisation)
Primary outcome measures	
1. Oswestry Disability Index V2.1 with "sex life" question replaced by a "work/housework" question	0, 5, 10, 26
2. Numerical rating scale for back pain (0-10)	0, 5, 10, 26
3. Numerical rating scale for leg pain (0-10)	0, 5, 10, 26
Secondary outcome measures	
1. Global rating of change scale (7-point Likert scale)	5, 10, 26
2. Satisfaction with physiotherapy treatment (5-point likert scale)	5, 10, 26
3. Satisfaction with *results* of physiotherapy treatment (5-point likert scale)	5, 10, 26
4. Satisfaction with the prospect of enduring current symptoms for life (5-point likert scale)	5, 10, 26
5. Number of work days missed in the last 30 days	0, 5, 10, 26
6. Interference with work or housework in the past week (5-point likert scale)	0, 5, 10, 26
7. Quality of life (EuroQol-5D)	0, 5, 10, 26
8. Orebro musculoskeletal pain questionnaire	0, 5, 10, 26
9. Sciatica frequency scale	0, 5, 10, 26
10. Sciatica bothersomeness scale	0, 5, 10, 26

6.3.7 Participant compliance and co-interventions

The number of physiotherapy treatment sessions attended by each participant was obtained by reviewing the clinical notes at the end of the program. The FR group participants also completed an exercise chart that was checked by their physiotherapist at each session (see Appendix S). Information regarding the type and extent of co-interventions, as well as medication usage, was obtained from participants via questions on each follow-up outcome questionnaire (see Appendix R, questions 8 & 18).

6.3.8 Adverse events

Adverse events were measured in both groups using two methods. Firstly, physiotherapists recorded any adverse events that occurred during the treatment period on their clinical notes for each participant. In addition, an open question on all follow-up questionnaires asked participants to describe any adverse, harmful or unpleasant effects that they attributed to the intervention.

6.3.9 Minimising loss to follow-up

It has been suggested that RCTs should employ intentional methods aimed at minimising drop-outs and missing outcomes at follow-up (Altman, 2009). This trial utilised several methods aimed at achieving this important goal and they are outlined in Table 6.5.

Table 6.5: Methods employed to minimise drop-outs and loss to follow-up

Method	Reference(s)
Informing participants during the consent process that they were expected to return all outcome questionnaires under all circumstances.	(Sprague et al., 2003)
Developing treatment protocols with minimal risk of harm or adverse events.	(Strusberg et al., 2005)
Physiotherapists providing a good level of explanation of the interventions to ensure participant understanding.	(Sprague et al., 2003; Strusberg et al., 2005)
Educating participants regarding the aims and processes of the RCT.	(Sprague et al., 2003)
Being flexible with unsatisfied participants with regards to their right to seek co-interventions.	(Liu, Wei, & Zhang, 2006)
Reviewing clinical notes of all participants at weeks four, seven and ten to identify any emerging compliance issues or upcoming absences / travel.	
Obtaining several contact methods for each participant (home phone, mobile phone, work phone, postal address, email address).	(Sprague et al., 2003)
Conducting reminder calls for participants who had not returned questionnaires, including outside normal working hours and on weekends.	(Sprague et al., 2003)
Obtaining the details of two alternative contact people for each participant (eg. friends, relatives).	(Sprague et al., 2003)
Informing participants who withdrew from treatment that their data were still required and continuing to collect their data.	(Altman, 2009; Liu et al., 2006)
Offering monetary incentive (in the form of $20 shopping vouchers) to participants reluctant to return questionnaires.	(Gates et al., 2009)
As a last resort obtaining outcomes via telephone if it appeared unlikely that the participant would return them via mail.	(Sprague et al., 2003)

The above strategies in Table 6.5 are self-explanatory but elaboration will be made regarding the procedure for obtaining some outcomes via telephone. While every effort was made to obtain written questionnaires from every participant at all follow-ups, a contingency plan was established to obtain missing outcomes via telephone if it became obvious that a participant was not likely to return their questionnaires. This was considered a better alternative than predicting scores via data imputation methods. When outcomes were obtained via telephone, the primary outcomes were first obtained followed by as many secondary outcomes as possible. There is evidence that the NRS remains reliable and valid when administered verbally (such as via telephone) (Bijur et al., 2003; Paice & Cohen, 1997). While a review article concluded that the Oswestry Disability Index can be administered via telephone (Roland & Fairbank, 2000), no studies were located that have evaluated the reliability and validity of verbal administration of the Oswestry.

6.3.10 Sample size

A sample size analysis estimated that 128 participants (64 in each group) were required to detect the MCID between groups of 10/100 points on the Oswestry (Davidson & Keating, 2002; Lauridsen et al., 2006; Ostelo & de Vet, 2005; Ostelo et al., 2008) assuming a standard deviation of 20 (two tailed hypothesis, alpha=.05, power=80%) (Carlin & Doyle, 2002). Allowing for 15% of the outcomes to be absent (and assuming no data imputation methods were to be used) required an increase in sample size to 148 (74 participants per group). This sample size provided *more than* 80% power to detect the MCID of 2/10 on the other primary outcomes, the NRS pain scales, assuming a standard deviation of 3.0 (Hagg, Fritzell, & Nordwall, 2003; Lauridsen et al., 2006; Ostelo & de Vet, 2005; Ostelo et al., 2008). This sample size also provided at least 80% power to detect a SMD effect size of 0.5 (which indicates that the between group difference is half the size of the pooled standard deviation of the scores) on both the Oswestry and the NRS pain scales. Studies have shown that clinically important differences on many health outcome assessment scales tend to be evident when between group SMD values reach 0.5 or more (Cohen, 1988; Norman, Sloan, & Wyrwich, 2003), making it desirable to detect an effect size of this magnitude (Slade & Keating, 2006).

The estimated values for standard deviations of the Oswestry and the NRS pain scales were obtained from several sources. Firstly, in the case series undertaken in this thesis that involved participants with DHR undertaking FR (Chapter 4), the standard deviation of the Oswestry was 20.1 at discharge from the program (mean of 8.7 months following the start of treatment). In addition, the four trials that used the Oswestry in the systematic review included in this thesis (Chapter 3) reported standard deviation scores for the Oswestry ranging from 4.9 to 16.0 at various timepoints (Dincer et al., 2007; Osterman et al., 2006; Unlu et al., 2008; Veihelmann et al., 2006), so a value of 20.0 was a conservative estimate. With regards to the NRS pain scales, several studies included in the systematic review used either the NRS or a visual analogue scale to measure pain intensity, with their reported standard deviations ranging from 0.9 to 3.0 (Bakhtiary et al., 2005; Bonaiuti et al., 2004; Buchner et al., 2000; Dincer et al., 2007; He et al., 2006; Kanayama et al., 2005; Osterman et al., 2006; Ozturk et al., 2006; Peul et al., 2007; Santilli et al., 2006; Sherry et al., 2001; Unlu et al., 2008; Veihelmann et al., 2006). Taking the highest value of 3.0 was therefore considered a conservative approach to estimating the standard deviation for the current trial.

During the planning stages of the trial, it was considered unlikely that this number of participants could be recruited in the context of a PhD. Limiting factors were the lack of major funding for advertising and the focus of the trial on a specific subgroup of participants with DHR which is known to be rarer than other LBDs. A latest possible recruitment date was therefore set for 30/9/2010 to allow for this thesis to be submitted in a timely manner with 6 month follow-up data for all participants. This trial was therefore considered a pilot study that could be used to gain an indication of feasibility and likely effect sizes for future funding applications to undertake a larger trial. The aim was however to recruit as many participants as possible within the available timeframes.

6.3.11 Data analysis

6.3.11.1 Data entry and integrity

All questionnaire data were scored and entered into a formatted computer spreadsheet by a researcher blinded to the group allocation of the participant.

6.3.11.2 Data screening

Data sets for each group were screened for all continuous outcomes at each follow-up. Histograms, QQ plots and boxplots were used to determine whether the data sets possessed the appearance of a normal distribution, with significance testing undertaken using the Shapiro-Wilk statistic to determine if the data deviated significantly from a normal distribution (Oman, 1995; West, 2009).

6.3.11.3 Descriptive statistics

Descriptive statistics were obtained from the physical examination and baseline questionnaires for participants in each group to describe their baseline characteristics. Differences between groups at baseline were not subjected to statistical comparisons, as this is now discouraged in the revised CONSORT statement (Moher et al., 2010). The number of participants from the two groups treated by each physiotherapist and at each treatment centre was also recorded.

6.3.11.4 Analysis of outcomes

In order to test the null hypothesis that FR is no more effective than advice, data analysis focussed on between group differences (with 95% confidence intervals) at each of the follow-up periods (5 weeks, 10 weeks and 26 weeks following randomisation). Within group changes were also analysed to see whether either or both groups improved at each follow-up relative to baseline. Data analysis was conducted using PASW Version 18[4], with alpha set at .05 using a two-tailed hypothesis.

Interval level data was analysed using linear mixed models (with the group x time interaction estimating the treatment effect). These were chosen for their strength in analysing longitudinal biological data and accounting for correlations associated with repeated measurements (Demidenko, 2004; Hamer & Simpson, 2009; Krueger & Tian, 2004). The mixed models were adjusted for the baseline score of the outcome being assessed. The inclusion of treatment centre as a random effect was planned in order to account for the potential clustering of outcomes within treatment centres (Boutron et al., 2008; Lee & Thompson, 2005). Other fixed factors were also considered based on evidence of their prognostic value (Moher et al., 2010), including participant gender (Peul, Brand, Thomeer, & Koes, 2008) and the baseline Orebro Musculoskeletal Pain

[4] SPSS Inc., 11th Floor, 233 Wacker Drive, Chicago, IL 60606.

Questionnaire score (Hockings et al., 2008). Between group effects were analysed at each follow-up, while an overall model was also fitted to determine the relative rate of improvement between groups across all time periods.

In addition to the mixed model analysis, between group differences on continuous outcomes were also presented as Hedges adjusted-g SMDs with 95% confidence intervals, in accordance with the systematic review in Chapter 3 (Deeks & Higgins, 2007; Hedges & Olkin, 1985). Mean between group differences and pooled standard deviations at the follow-up time of interest were used for these calculations. Positive SMD values indicated treatment effects favouring the FR group. Consistent with the systematic review (Chapter 3), standardised mean differences of 0.2, 0.5 and 0.8 were considered thresholds for small, moderate and large effect sizes, respectively (Cohen, 1988). This alternative analysis method was applied to provide a standardised method for comparing the size of treatment effects measured on different outcomes (Higgins & Green, 2006; White & Thomas, 2005). The use of SMD values also facilitated comparison of the results in the current trial with other trials included in the systematic review (Chapter 3).

For ordinal data, medians and 25^{th} to 75^{th} percentiles were reported, with significance testing conducted using the Mann Whitney U test (Brotz et al., 2010; Ilfeld et al., 2010).

6.3.11.5 Linear mixed model fitting and regression diagnostics

To determine which model parameters and covariance structure produced the best fitting linear mixed model, goodness of fit measures were evaluated for each model (Garson, 2011; West, 2009). Models that achieved the lowest Aikaike's Information Criteria (AIC) were considered to provide the best fit for the data (Garson, 2011; Lamb et al., 2010; West, 2009), although models that failed to converge were always rejected and refitted with revised parameters (Garson, 2011). Fixed and random covariates were only maintained in the model if they resulted in a substantially lower AIC (Garson, 2011; West, 2009).

Once the best fitting model was identified, diagnostics were performed to ensure that the assumptions of the mixed model had been met (particularly that the residuals were normally distributed) and to check if the model was sensitive to outliers (Oman, 1995;

West, 2009). The procedures described in two papers were followed for this purpose (Oman, 1995; West, 2009). Firstly scatter-plots of residuals versus their predicted values were produced to ensure a random pattern of residuals with no major outliers. A histogram plot of the residuals was then created to check that they were normally distributed and the Shapiro-Wilk test was used to statistically test for deviations from normality. The influence of significant outliers (defined as those outside the 99th percentile of the residuals) was assessed by refitting the mixed model with those outliers omitted.

6.3.11.6 Clinical relevance of outcomes

While the presentation and analysis of effect sizes, 95% confidence intervals and statistical significance of outcomes was determined a-priori as described above, guidelines were also established a-priori in relation to the interpretation of the clinical significance of the findings (Ostelo et al., 2008; van Tulder et al., 2007). This was perhaps even more important for a pilot study, as the determination of the feasibility of a larger trial would be based more on the clinical significance of the outcomes than the statistical significance due to low power resulting from the limited number of participants.

One way of assessing clinical significance is to compare the between group differences on continuous outcomes to published values of the MCID (Ostelo et al., 2008). This recommendation has been further extended to suggest that the lower band of the 95% confidence interval should exceed the MCID (van Tulder et al., 2007). Therefore, evaluating between group differences and their confidence intervals, in relation to the MCID, was one method of assessing the clinical significance of outcomes in the trial.

The methods described above have, however, received some criticism (Ferreira & Herbert, 2009; Ferreira & Herbert, 2008). This is because MCID values are designed to determine the clinical significance of changes in individual participants, so translating these values to group mean scores (or extrapolating even further to between group differences and the lower band of the 95% confidence interval) may not be valid (Ferreira & Herbert, 2009; Ferreira & Herbert, 2008; Ostelo et al., 2008). It has therefore been recommended that the changes in outcomes achieved by *individual* participants be compared to the MCID to determine the proportion of participants in each group who benefited significantly from the treatment (Baker, 2010; Busse &

Guyatt, 2009; Guyatt, Juniper, Walter, Griffith, & Goldstein, 1998; Ostelo et al., 2008; Smith & Grimmer-Somers, 2010). This was achieved by dichotomising participants as either "responders" or "non-responders" based on whether they achieved the MCID of the outcome or not, then the risk ratio, risk difference and number needed to treat were calculated (Altman, 1998; Busse & Guyatt, 2009; Cook & Sackett, 1995; Guyatt et al., 1998; Hildebrandt et al., 2006; Moher et al., 2010). Statistical significance was evaluated using Chi-square analysis. For these purposes, the MCID was defined as 10/100 for the Oswestry (Davidson & Keating, 2002; Lauridsen et al., 2006; Ostelo & de Vet, 2005; Ostelo et al., 2008), 2/10 for the NRS pain scales (Hagg et al., 2003; Lauridsen et al., 2006; Ostelo & de Vet, 2005; Ostelo et al., 2008), at least "much improved" on the global rating of change scale (Ferreira, Ferreira, Herbert, & Latimer, 2009; Ostelo & de Vet, 2005) and "very satisfied" on the treatment satisfaction scales (Ostelo & de Vet, 2005). It has been argued that these values for the MCID of continuous outcomes may be too low in some contexts (Carragee, 2010), hence these analyses were repeated using a threshold of 50% reduction in Oswestry scores and NRS pain scores based on empirical validation studies suggesting that this provides a more suitable threshold for important differences (Fritz, Hebert, Koppenhaver, & Parent, 2009; Lauridsen et al., 2006).

6.3.11.7 Intention to treat and missing outcomes

All data were analysed using an intention to treat approach, in that all participants were analysed in the treatment group to which they were initially allocated regardless of their compliance with that treatment (Altman, 2009; Hollis & Campbell, 1999; Moher et al., 2010). All participants who withdrew from treatment for any reason were contacted for follow-up assessments and informed that their data were still required (Altman, 2009; Liu et al., 2006). The primary method of analysis did not attempt to impute missing data (Altman, 2009; Ferreira et al., 2007). This was justified as all methods of data imputation have limitations (Altman, 2009; Moher et al., 2010) and the linear mixed model analysis that was employed for continuous data inherently accounts for missing data in a more effective and less biased manner than many other data imputation methods (Hamer & Simpson, 2009; Krueger & Tian, 2004; Lane, 2008; Liu et al., 2006; Siddiqui et al., 2009). However, given the popularity of simple data imputation methods (Altman, 2009; Hamer & Simpson, 2009; Moher et al., 2010) a secondary sensitivity analysis was undertaken to determine whether the results differed

if missing data were replaced using the last observation carried forward method (Altman, 2009; Liu et al., 2006).

A separate but related issue to missing outcomes was the handling of missing individual items within multi-item outcome questionnaires. The method for handling this was determined a-priori, based on recommendations in the literature. Missing items on multi-item questionnaires were therefore replaced by the mean score of the remainder of the items for the Oswestry (Davidson, 2008; Davidson & Keating, 2002; Fairbank & Pynsent, 2000), the Sciatica Frequency and Bothersomeness scales (Grovle et al., 2010) and the Orebro Musculoskeletal Pain Questionnaire (Linton, 1999).

6.4 Results

6.4.1 Participants

Between 25/4/09 and 30/9/2010, a total of 810 potential participants enquired about the trial, with 36 (4.4%) found to be eligible and consenting to participate. Eighteen participants were randomly allocated to each treatment group. The flow of participants through the trial is presented in a CONSORT flow-diagram (Figure 6.2).

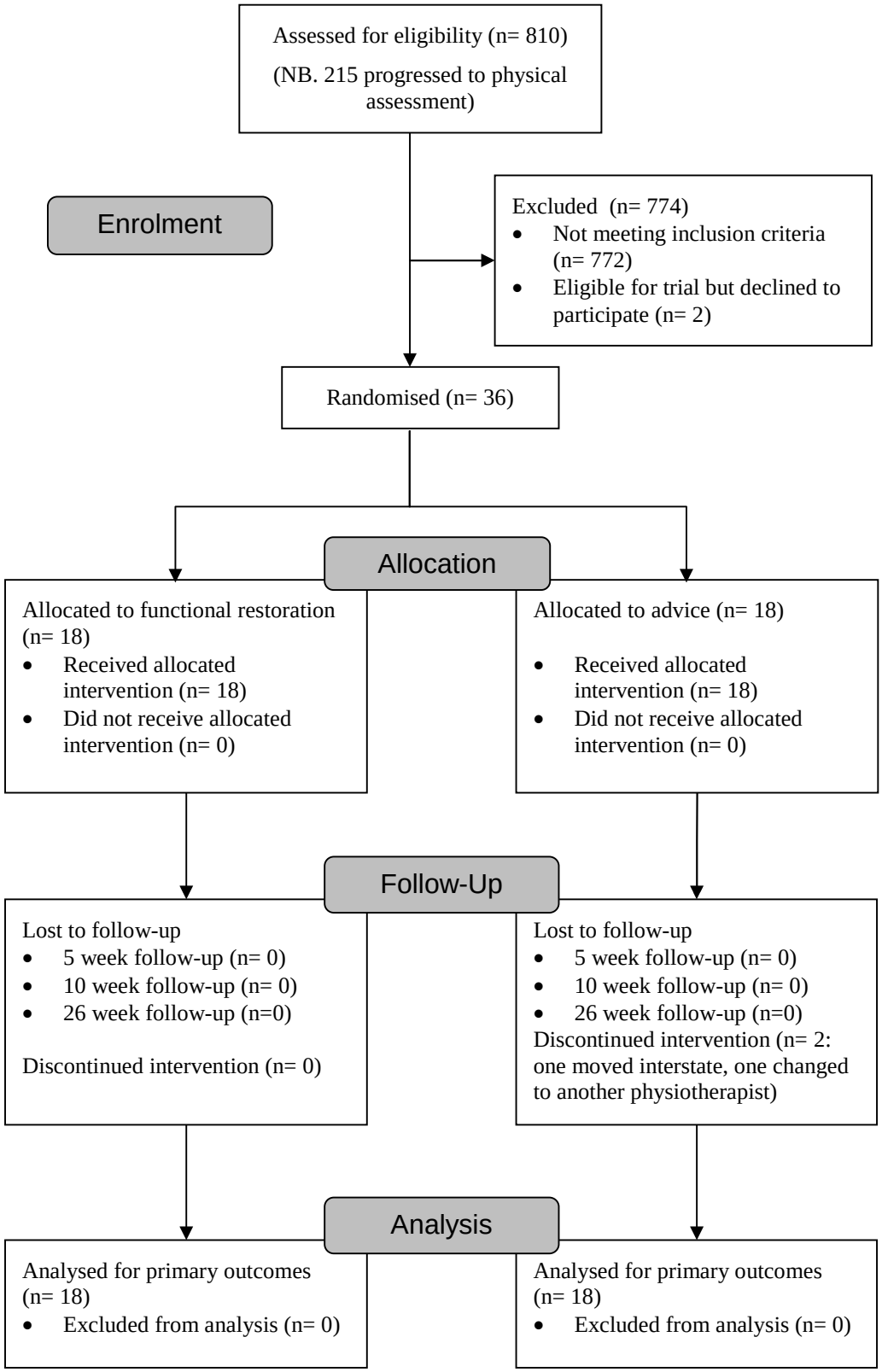


Figure 6.2: CONSORT diagram showing flow of participants through the trial

Table 6.6 provides the reasons for ineligibility at each stage of the recruitment process.

Table 6.6: Reasons for ineligibility of potential participants who enquired about the trial

Reason for ineligibility	n (% of total ineligible volunteers)
Phone screening: 517/810 (63.8%) ineligible	
Symptoms > 6 months	286 (37.0%)
CT / MRI known to be negative	35 (4.5%)
> 65 years old	32 (4.1%)
Symptoms < 6 weeks	27 (3.5%)
No lumbar or leg pain	20 (2.6%)
Minimal activity limitation	20 (2.6%)
Low pain intensity (< 2/10)	18 (2.3%)
Could not be contacted	14 (1.8%)
Compensable claim for back condition	12 (1.6%)
Could not commit to time required	12 (1.6%)
Pregnancy	8 (1.0%)
Insufficient English	7 (0.9%)
Surgical procedure immanent	4 (0.5%)
Previous lumbar spine surgery	3 (0.4%)
Had spinal injection < 6 weeks ago	3 (0.4%)
Did not wish to cease current treatment	3 (0.4%)
Overseas trip immanent	3 (0.4%)
Other	10 (1.3%)
Physical examination: 255/293 (87.0%) ineligible	
Did not satisfy the diagnostic features of DHR	143 (18.5%)
Declined or failed to attend physical examination	80 (10.4%)
Symptoms found to be > 6 months duration upon obtaining full history of condition	18 (2.3%)
Significant spinal stenosis found on imaging	5 (0.6%)
No pain by the time of assessment	2 (0.3%)
Other	7 (0.9%)

Table 6.7 presents the sources of recruitment for the 36 included participants. This table shows that a similar number of participants in each group were recruited via the various sources.

Table 6.7: Sources of recruitment for the participants included in the trial

Source of recruitment	n (% of total enrolled participants)	Number in advice group	Number in FR group
Newspaper advertising			
Leader newspapers	18 (50%)	11	7
The Age Green Guide (TV section)	1 (3%)	1	0
Public flyers / posters			
Radiology clinics	5 (14%)	2	3
Medical practices	2 (6%)	2	0
University campuses	2 (6%)	0	2
Public hospitals	1 (3%)	0	1
Gymnasiums	1 (3%)	0	1
Treating physiotherapist referring their own client	3 (8%)	1	2
Word of mouth / friend	2 (6%)	1	1
Direct referral from General Medical Practitioner	1 (3%)	0	1

The baseline characteristics of the included participants are outlined in Table 6.8. The two groups appeared comparable on all baseline features. Table 6.9 presents the mean baseline score of each outcome measure for the two treatment groups. Again, the two groups were relatively comparable on all outcome measures at baseline.

Table 6.8: Baseline characteristics of participants, presented as n (%) unless otherwise indicated

Characteristic	Advice group	FR group
Male	9/18 (50%)	10/18 (56%)
Age in years: *mean (SD)*	49.6 (12.7)	44.8 (13.2)
Smoker	0/18 (0%)	3/18 (17%)
Area of leg symptoms		
Below the knee only	17/18 (94%)	15/18 (83%)
Anterior thigh only	0/18 (0%)	0/18 (0%)
Both	1/18 (6%)	3/18 (17%)
Leg / foot paraesthesia	12/18 (67%)	15/18 (83%)
Duration of leg symptoms in weeks: *mean (SD)*	13.4 (6.6)	15.3 (6.0)
Duration of back symptoms in weeks: *mean (SD)*	21.1 (24.5)	16.0 (10.2)
Participants reporting a previous episode of back/leg pain	13/18 (72%)	14/18 (78%)
Previous treatment prior to assessment		
Medical practitioner	16/18 (89%)	17/18 (94%)
Spinal surgeon	5/18 (28%)	5/18 (28%)
Other medical specialist	3/18 (17%)	2/18 (11%)
Epidural injections	1/18 (6%)	0/18 (0%)
Physiotherapy	11/18 (61%)	10/18 (56%)
Chiropractic	6/18 (33%)	3/18 (17%)
Osteopathy	4/18 (22%)	4/18 (22%)
Massage	7/18 (39%	4/18 (22%)
Acupuncture	7/18 (39%)	6/18 (33%)
Type of herniation		
Herniation / protrusion / prolapse	15/18 (83%)	15/18 (83%)
Extrusion	2/18 (11%)	2/18 (11%)
Sequestration	1/18 (6%)	1/18 (6%)
Level of primary disc herniation		
L5/S1	12/18 (67%)	13/18 (72%)
L4/5	6/18 (33%)	4/18 (22%)
L3/4	0/18 (0%)	1/18 (6%)
Direction of disc herniation		
Postero-lateral	18/18 (100%)	14/18 (78%)
Central	0/18 (0%)	3/18 (16%)
Lateral	0/18 (0%)	1/18 (6%)
Nerve root involvement		
Compression	8/18 (44%)	6/18 (33%)
Displacement	3/18 (17%)	3/18 (17%)
Contact	3/18 (17%)	6/18 (33%)
None	4/18 (22%)	3/18 (17%)
Examination findings		
Straight leg raise positive	16/18 (89%)	16/18 (89%)
Straight leg raise angle affected side: *mean (SD)*	49.7° (19.6°)	54.2° (20.6°)
Straight leg raise angle non-affected side: *mean (SD)*	72.2° (11.8°)	72.5° (17.8°)
Number with comparable sensory deficit	7/18 (39%)	8/18 (44%)
Number with comparable motor weakness	6/18 (33%)	10/18 (56%)
Number with comparable reflex impairment	11/18 (61%)	7/18 (39%)
Number with 0/3 neurological signs	4/18 (22%)	3/18 (17%)
Number with any 1/3 neurological signs	6/18 (33%)	7/18 (39%)
Number with any 2/3 neurological signs	6/18 (33%)	6/18 (33%)
Number with 3/3 neurological signs	2/18 (11%)	2/18 (11%)
Directional preference identified	6/18 (33%)	7/18 (39%)

Abbreviations: FR= functional restoration; SD= standard deviation

Table 6.9: Baseline status of participants on outcome measures

Outcome measure	Advice group	FR group
Primary outcomes		
Activity limitation on the Oswestry: *mean (SD)*	40.8 (16.0)	38.5 (14.4)
Leg pain intensity: *mean (SD)*	6.1 (2.2)	6.1 (2.3)
Back pain intensity: *mean (SD)*	5.4 (2.4)	4.7 (2.5)
Secondary outcomes		
Orebro musculoskeletal pain questionnaire: *mean (SD)*	115.0 (32.1)	105.8 (26.0)
Sciatica frequency scale: *mean (SD)*	18.9 (6.0)	19.1 (5.6)
Sciatica bothersomeness scale: *mean (SD)*	17.6 (5.8)	16.8 (7.8)
Number of work days missed in the last 30 days: *median (25^{th} to 75^{th} percentile)**	1.0 (0.0 to 5.5)	0.0 (0.0 to 1.0)
Interference with work or housework in the past week (5-point likert scale): *median (25^{th} to 75^{th} percentile)**	3.0 (2.0 to 3.0)	3.0 (1.3 to 3.0)
Quality of life (EuroQol-5D utility score): *median (25^{th} to 75^{th} percentile)**	0.6 (0.1 to 0.7)	0.6 (0.5 to 0.7)

Note: the global rating of change scale and the three satisfaction scales were not measured at baseline as they were based on ratings of change at each follow-up.
Abbreviations: FR= functional restoration; SD= standard deviation
*These outcomes were not normally distributed, hence they were treated as ordinal data (see Section 6.4.3.1).

Table 6.10 shows that each trial physiotherapist and treatment centre appeared to treat an equal distribution of participants from each group, although some treated more overall trial participants than others.

Table 6.10: Distribution of participants in each group between treating clinics and physiotherapists

	Advice group	FR group
Clinic		
A	3	3
B	4	3
C	1	0
D	0	1
E	2	3
F	3	2
G	0	1
H	2	2
I	2	2
J	0	1
K	1	0
Physiotherapist		
1	3	3
2	5	3
3	0	1
4	2	3
5	0	1
6	3	2
7	0	1
8	2	2
9	2	2
10	1	0

Abbreviations: FR= functional restoration

6.4.2 Treatment content and integrity

The content of the treatment delivered to each participant in the trial was assessed by reviewing the clinical notes recorded by their physiotherapist. This revealed that all 18 participants allocated to the advice group had been managed in accordance with the protocol, with all receiving both mandatory participant information sheets (pathoanatomical information and the key principles for the self-management of LBDs).

For the FR group, the review of clinical notes revealed that all 18 participants allocated to that intervention received all mandatory treatment components, with many participants also receiving optional treatment components when indicated. The frequency of utilisation for each treatment component in the FR group is presented in Table 6.11.

Table 6.11: Treatment components received by the 18 participants allocated to functional restoration according to review of their clinical notes

Treatment component	Number (%) of participants receiving component (n=18)
Mandatory components	
Pathoanatomical information:	18 (100%)
Treatment options:	18 (100%)
Program timeframes:	18 (100%)
Posture advice:	18 (100%)
Taping:	18 (100%)
Specific motor control training:	18 (100%)
Functional exercises	
Basic:	18 (100%)
Advanced:	18 (100%)
Goal setting:	18 (100%)
Pacing:	18 (100%)
Discharge planning:	18 (100%)
Optional components	
Management of inflammation	
When inflammation present at start of program:	10 (56%)
When inflammation appeared later:	1 (6%)
Total:	11 (61%)
Directional preference (DP) management	
DP present at start of program:	7 (39%)
DP present after management of inflammation:	3 (17%)
Total:	10 (56%)
Pain management strategies	
Pharmacological:	9 (50%)
Non-pharmacological:	9 (50%)
Sleep strategies:	5 (28%)
Relaxation strategies:	6 (33%)
Management of increased pain:	12 (67%)
Management of work issues:	6 (33%)
Pain versus function:	7 (39%)

Abbreviations: DP=directional preference

6.4.3 Outcomes

All primary outcomes were obtained for 100% of participants at all follow-up points (as shown in Figure 6.2). Primary outcomes were obtained via the mailed questionnaires for all participants at 5 weeks, 35 (97%) participants at 10 weeks and 34 (94%) participants at 6 months, with the remainder obtained via telephone. All secondary outcomes were obtained at the five week follow-up for all participants, although some secondary outcomes were missing at the ten week and six month follow-ups. The missing secondary outcomes were due to one participant (2.8%)

omitting individual questions in the outcome questionnaire booklets, as well as the inability to obtain all secondary outcomes via telephone for 2 participants (5.6%).

6.4.3.1 Data screening, regression diagnostics and linear mixed model fitting

The obtained data for all primary outcome measures (activity limitation, leg pain intensity and back pain intensity) were found to be sufficiently normally distributed to justify parametric analysis using the planned linear mixed models. For secondary outcomes, data from the Orebro Musculoskeletal Pain Questionnaire, the sciatica frequency scale and the sciatica bothersomeness scale were found to be normally distributed, hence these were also subjected to parametric analysis. While it was initially planned to use linear mixed models and standardised mean differences to analyse data from the EuroQol-5D and the number of work days missed, these data were found to deviate significantly from a normal distribution hence they were treated as ordinal data and analysed using the Mann Whitney U test.

With all linear mixed models, a suitable group x time model was able to be fitted using the baseline score of the outcome as the only covariate. The inclusion of baseline score was found to improve the fit of the models based on substantially lower values for the AIC (Garson, 2011; West, 2009). None of the additional planned fixed or random covariates were found to improve model fit (based on the AIC) so they were omitted from the final models. Residuals of the mixed models were found to be sufficiently normally distributed. Removal of significant outliers that were identified in each mixed model had only a minimal effect on the size of between group differences and the statistical significance of all analyses remained unchanged.

6.4.3.2 Primary outcomes

The results of the primary outcome analyses are presented in Table 6.12 for back pain intensity, leg pain intensity and activity limitation. The overall time effect in the linear mixed models was significant for all primary outcomes, indicating that trial participants improved over time irrespective of the treatment they received. Figure 6.3 shows that participants in both groups improved over time on each of these primary outcomes, a finding that was confirmed by statistically significant within group changes in both groups at each follow-up for all outcomes except for back pain intensity at 10 weeks in the advice group (Table 6.12). Two between group comparisons achieved statistical significance in the linear mixed models, with the FR group demonstrating a significantly greater rate of reduction in activity limitation scores than the advice group

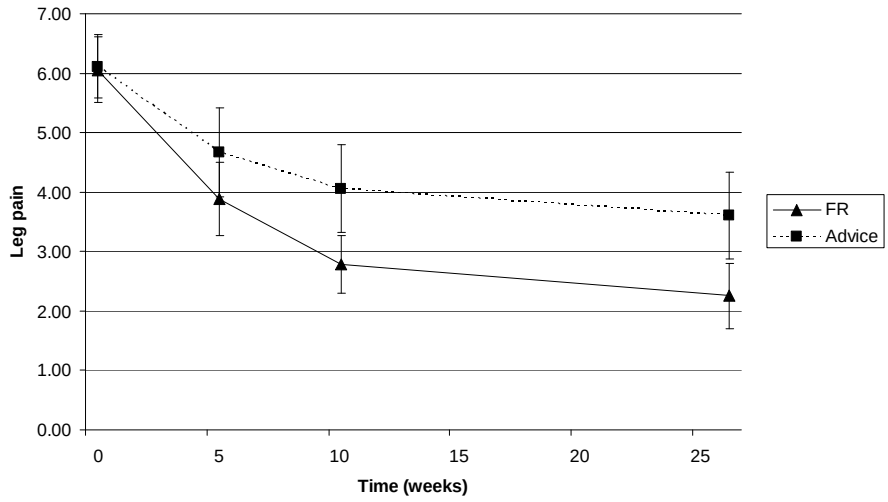
across the whole follow-up period (F (3,102)=2.8; *p*=.04), and the FR group achieving a significantly greater improvement in back pain scores at the 10 week follow-up (adjusted between group difference 1.6 (0.1 to 3.0), t(102)=2.1; *p*=.04). All other between group comparisons approached, but did not achieve, statistical significance at the 10 week and 26 week follow-up points.

Table 6.12: Effects of functional restoration versus advice on primary outcomes

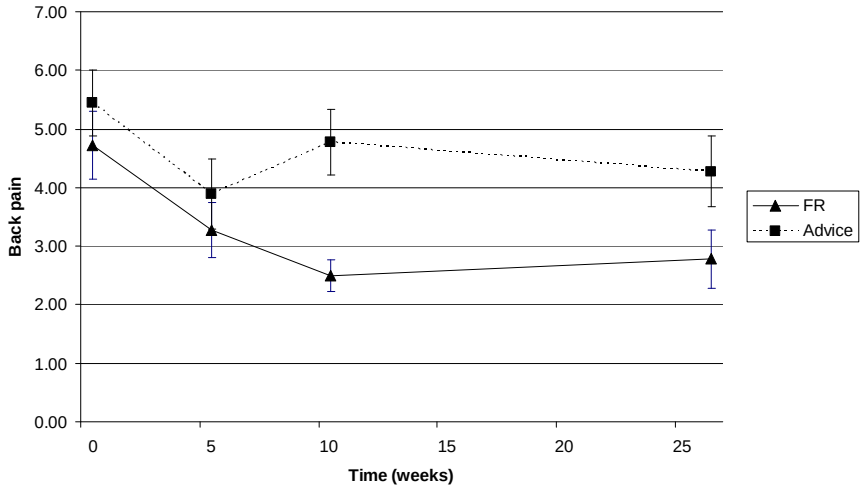
Outcome	Unadjusted mean score (SD)		Unadjusted SMD (95%CI)	Adjusted between group difference (95%CI)*	*p*-value
	FR	Advice			
Leg pain intensity (NRS)					
Baseline	6.1 (2.3)	6.1 (2.2)			
5 weeks	3.9 (2.6) ‡	4.7 (3.2) ‡	0.3 (-0.4 to 0.9)	0.7 (-1.0 to 2.4)	.40
10 weeks	2.1 (2.1) ‡	4.1 (3.1) ‡	0.5 (-0.2 to 1.1)	1.2 (-0.5 to 2.9)	.16
6 months	2.3 (2.3) ‡	3.6 (3.1) ‡	0.5 (-0.2 to 1.2)	1.3 (-0.4 to 3.0)	.13
Overall time model				F (3,102)=20.9; p< .001	
Overall group x time model				F (3,102)=1.0; p=.41	
Back pain intensity (NRS)					
Baseline	4.7 (2.5)	5.4 (2.4)			
5 weeks	3.3 (2.0) ‡	3.9 (2.5) ‡	0.3 (-0.4 to 0.9)	-0.1 (-1.6 to 1.3)	.88
10 weeks	2.5 (1.2) ‡	4.8 (2.4)	**1.2 (0.5 to 1.9)**	**1.6 (0.1 to 3.0)**	**.04**
6 months	2.8 (2.1) ‡	4.3 (2.6) ‡	0.6 (-0.0 to 1.3)	0.8 (-0.7 to 2.2)	.29
Overall time model				F (3,102)=8.5; p< .001	
Overall group x time model				F (3,102)=2.3; p=.09	
Activity limitation (Oswestry)					
Baseline	38.5 (14.4)	40.8 (16.0)			
5 weeks	29.0 (13.5) ‡	29.5 (18.8) ‡	0.0 (-0.6 to 0.7)	-1.8 (-10.1 to 6.5)	.67
10 weeks	21.5 (11.8) ‡	31.8 (21.8) ‡	0.6 (-0.1 to 1.2)	8.0 (-0.3 to 16.3)	.06
6 months	18.3 (12.7) ‡	27.8 (21.5) ‡	0.5 (-0.1 to 1.2)	7.2 (-1.1 to 15.5)	.09
Overall time model				F (3,102)=23.1; p< .001	
Overall group x time model				**F (3,102)=2.8; p=.04**	

Note: N=36 for all analyses (FR=18, advice=18), figures in bold represent between group differences that were statistically significant.
Abbreviations: FR=functional restoration; NRS=Numerical rating scale; Oswestry=Oswestry Disability Index
*Adjusted analyses were linear mixed models adjusted for baseline score, with *p*-values obtained from these adjusted linear mixed models. Positive values represent greater improvement in the FR group relative to the advice group.
‡ Indicates statistically significant (p < .05) within group change from baseline measured with a linear mixed model

6.3 (a)



6.3 (b)



6.3 (c)

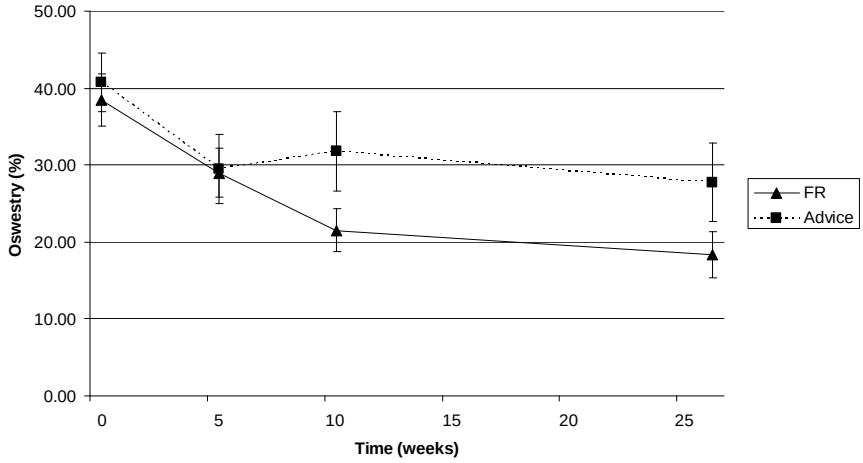


Figure 6.3: Graphs showing group mean scores at each measurement point for the primary outcomes of: a) leg pain intensity; b) back pain intensity; and c) activity limitation (error bars represent standard errors)

6.4.3.3 Secondary outcomes

Results of secondary outcome analyses are presented in Table 6.13 for continuous data and in Table 6.14 for ordinal data. Graphs for secondary continuous outcomes are presented in Appendix T. For continuous data, improvements were achieved by both groups relative to baseline on the Sciatica Frequency and Bothersomeness Scales, as well as on the Orebro Musculoskeletal Pain Questionnaire, although there were no significant between group differences (Table 6.13). For ordinal data (Table 6.14), there were statistically significant between group differences in favour of FR for the outcomes of global rating of change (10 weeks and 6 months), satisfaction with physiotherapy care (all follow-ups), satisfaction with results (10 weeks and 6 months), satisfaction with enduring current symptoms for life (6 month follow-up) and number of work days missed in the previous 30 days (10 week follow-up).

Table 6.13: Effects of functional restoration versus advice on continuous secondary outcomes

Outcome	Number included (FR / advice)	Unadjusted mean score (SD)		Unadjusted SMD (95%CI)	Adjusted* between group difference (95%CI)	*p*-value
		FR	Advice			
Sciatica frequency score						
Baseline	18 / 18	19.1 (5.6)	18.9 (6.0)			
5 weeks	18 / 18	11.7 (5.2) ‡	13.9 (8.0) ‡	0.3 (-0.3 to 1.0)	2.3 (-2.3 to 6.9)	.32
10 weeks	18 / 17	9.5 (5.6) ‡	13.5 (8.4) ‡	0.6 (-0.1 to 1.2)	4.2 (-0.5 to 8.8)	.08
6 months	18 / 15	7.7 (5.1) ‡	11.4 (7.9) ‡	0.6 (-0.1 to 1.3) †	3.8 (-1.0 to 8.5) †	.12
Overall time model					F (3,99)=24.0; p< .001	
Overall group x time model					F (3,99)=1.3; p=.28	
Sciatica bothersomeness score						
Baseline	18 / 18	16.8 (7.8)	17.6 (5.8)			
5 weeks	18 / 18	10.8 (5.3) ‡	12.6 (7.5) ‡	0.3 (-0.4 to 0.9)	1.0 (-3.6 to 5.7)	.66
10 weeks	18 / 17	8.6 (6.0) ‡	12.9 (8.6) ‡	0.6 (-0.1 to 1.3)	3.7 (-1.0 to 8.4)	.13
6 months	18 / 15	7.8 (5.0) ‡	11.1 (8.7) ‡	0.5 (-0.2 to 1.2)	2.3 (-2.4 to 7.1)	.33
Overall time model					F (3,99)=16.4; p< .001	
Overall group x time model					F (3,99)=0.9; p=.45	
Psychosocial status (Orebro)						
Baseline	18 / 18	105.8 (26.0)	115.0 (32.1)			
5 weeks	18 / 18	92.9 (22.4) ‡	96.2 (29.6) ‡	0.1 (-0.5 to 0.8)	-5.9 (-21.7 to 9.9)	.46
10 weeks	18 / 17	79.5 (21.9) ‡	93.6 (35.3) ‡	0.5 (-0.2 to 1.1)	6.8 (-9.2 to 22.7)	.40
6 months	18 / 15	73.0 (29.1) ‡	84.8 (40.9) ‡	0.3 (-0.4 to 1.0)	4.2 (-12.1 to 20.5)	.61
Overall time model					F (3,99)=20.6; p< .001	
Overall group x time model					F (3,99)=0.9; p=.42	

Abbreviations: FR=functional restoration

*Adjusted analyses were linear mixed models adjusted for baseline score, with *p*-values obtained from these adjusted linear mixed models. Positive values represent greater improvement in the FR group relative to the advice group.

†Using last observation carried forward method for missing data created a different result for this comparison, with the SMD becoming significant: SMD=0.7 (0.0 to 1.4) and the mixed model becoming significant: adjusted between group difference 4.9 (0.3 to 9.4), p=.04.

‡ Indicates statistically significant (p < .05) within group change from baseline measured with a linear mixed model

Table 6.14: Effects of functional restoration versus advice on ordinal secondary outcomes

Outcome	Number included (FR / advice)	Median (25^{th} to 75^{th} percentile) FR	Advice	*p*-value *
Global rating of change (1-7 scale with lower scores indicating greater improvement)				
5 weeks	18 / 18	3.0 (2.0 to 3.0)	3.0 (2.0 to 4.0)	.45
10 weeks	18 / 18	2.0 (2.0 to 2.8)	3.0 (2.0 to 4.0)	**<.01**
6 months	18 / 18	2.0 (2.0 to 2.0)	3.0 (2.0 to 4.0)	**.01**
Satisfaction with physiotherapy care (0-4 scale with higher scores greater satisfaction)				
5 weeks	18 / 18	4.0 (3.0 to 4.0)	2.0 (0.0 to 3.8)	**<.01**
10 weeks	18 / 16	4.0 (3.4 to 4.0)	2.0 (2.0 to 2.5)	**<.01**
6 months	18 / 16	4.0 (3.3 to 4.0)	2.0 (1.0 to 2.3)	**<.01**
Satisfaction with results of physiotherapy care (0-4 scale with higher scores greater satisfaction)				
5 weeks	18 / 18	3.0 (2.0 to 4.0)	2.0 (1.0 to 3.0)	.08
10 weeks	18 / 16	3.0 (3.0 to 4.0)	2.0 (2.0 to 3.0)	**<.01**
6 months	18 / 16	4.0 (3.0 to 4.0)	2.0 (1.0 to 3.0)	**<.01**
Satisfaction with enduring current symptoms for rest of life (0-4 scale with higher scores greater satisfaction)				
5 weeks	18 / 17	0.0 (0.0 to 1.0)	0.0 (0.0 to 1.0)	.87
10 weeks	18 / 17	1.0 (0.0 to 1.0)	0.0 (0.0 to 1.0)	.52
6 months	18 / 17	2.0 (0.3 to 3.0)	0.0 (0.0 to 1.0)	**.02**
EuroQol-5D (utility score)				
Baseline	18 / 18	0.61 (0.52 to 0.68)	0.61 (0.12 to 0.69)	
5 weeks	18 / 18	0.69 (0.66 to 0.73)	0.69 (0.62 to 0.79)	.87
10 weeks	18 / 17	0.75 (0.69 to 0.79)	0.69 (0.59 to 0.80)	.43
6 months	18 / 15	0.76 (0.69 to 1.0)	0.80 (0.62 to 0.90)	.70
Interference with work in the past week (0-4 scale with higher scores greater interference)				
Baseline	18 / 18	3.0 (1.3 to 3.0)	3.0 (2.0 to 3.0)	
5 weeks	17 / 18	2.0 (1.0 to 2.0)	1.0 (0.0 to 2.0)	.20
10 weeks	18 / 18	1.5 (1.0 to 2.0)	1.0 (1.0 to 3.0)	.56
6 months	18 / 17	1.0 (1.0 to 2.0)	1.0 (1.0 to 2.0)	.47
Work days missed last 30 days (for employed participants only)				
Baseline	15 / 12	0.0 (0.0 to 1.0)	1.0 (0.0 to 5.5)	
5 weeks	15 / 12	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.8)	.33
10 weeks	15 / 12	0.0 (0.0 to 0.0)	0.0 (0.0 to 2.0)	**.04**
6 months	15 /12	0.0 (0.0 to 0.0)	0.0 (0.0 to 1.3)	.22

Note: figures in bold represent statistically significant results.
Abbreviations: FR=functional restoration.
* *p*-values = significance value of the Mann Whitney U test

6.4.3.4 Dichotomous outcomes and clinical relevance

Table 6.15 presents dichotomous outcomes relating to the proportion of participants in each group who achieved the MCID, or a 50% improvement, on various outcome measures. Several statistically significant between group differences emerged that indicated participants in the FR group were more likely to achieve clinically important improvements than those in the advice group. Data are also presented graphically for the primary outcome measures (Figures 6.4 & 6.5), while graphs for the secondary outcome measures appear in Appendices U and V.

Table 6.15: Effects of functional restoration versus advice on clinically important changes in outcomes (dichotomous secondary outcomes)

Outcome	FR N (%)	Advice N (%)	Risk difference (95% CI)	Relative risk (95% CI)	*p*-value*	NNT
Reduced leg pain by at least 2/10 on the NRS from baseline						
5 weeks	12/18 (67%)	5/18 (28%)	**39% (6% to 62%)**	**2.4 (1.1 to 5.4)**	**.02**	3
10 weeks	15/18 (83%)	9/18 (50%)	**33% (3% to 57%)**	**1.7 (1.0 to 2.8)**	**.03**	3
6 months	16/18 (89%)	10/18 (56%)	**33% (4% to 57%)**	**1.6 (1.0 to 2.5)**	**.03**	3
Reduced back pain by at least 2/10 on the NRS from baseline						
5 weeks	8/18 (44%)	8/18 (44%)	0% (-30% to 30%)	1.0 (0.5 to 2.1)	1.0	n/a
10 weeks	10/18 (56%)	6/18 (33%)	22% (-9% to 48%)	1.7 (0.8 to 3.6)	.18	5
6 months	9/18 (50%)	4/18 (22%)	28% (-3% to 53%)	2.3 (0.8 to 6.0)	.08	4
Reduced Oswestry score by at least 10/100 points from baseline						
5 weeks	10/18 (56%)	9/18 (50%)	6% (-25% to 35%)	1.1 (0.6 to 2.1)	.74	18
10 weeks	14/18 (78%)	8/18 (44%)	**33% (2% to 57%)**	**1.8 (1.0 to 3.1)**	**.04**	3
6 months	14/18 (78%)	9/18 (50%)	28% (-3% to 53%)	1.6 (0.9 to 2.6)	.08	4
Reduced leg pain by at least 50% from baseline on the NRS						
5 weeks	8/18 (44%)	5/18 (28%)	17% (-14% to 43%)	1.6 (0.6 to 4.0)	.30	6
10 weeks	12/18 (67%)	8/18 (44%)	22% (-9% to 48%)	1.5 (0.8 to 2.8)	.18	5
6 months	14/18 (78%)	9/18 (50%)	28% (-3% to 53%)	1.6 (0.9 to 2.6)	.08	4
Reduced back pain by at least 50% from baseline on the NRS						
5 weeks	6/18 (33%)	6/18 (33%)	0% (-29% to 29%)	1.0 (0.4 to 2.5)	1.0	n/a
10 weeks	9/18 (50%)	4/18 (22%)	28% (-3% to 53%	2.3 (0.8 to 6.0)	.08	4
6 months	9/18 (50%)	5/18 (28%)	22% (-9% to 48%)	1.8 (0.8 to 4.3)	.17	5
Reduced Oswestry score by at least 50% from baseline						
5 weeks	3/18 (17%)	4/18 (22%)	-6% (-31% to 21%)	0.8 (0.2 to 2.9)	.67	-18
10 weeks	8/18 (44%)	6/18 (33%)	11% (-19% to 39%)	1.3 (0.6 to 3.1)	.50	9
6 months	11/18 (61%)	7/18 (39%)	22% (-10% to 49%)	1.6 (0.8 to 3.1)	.18	5

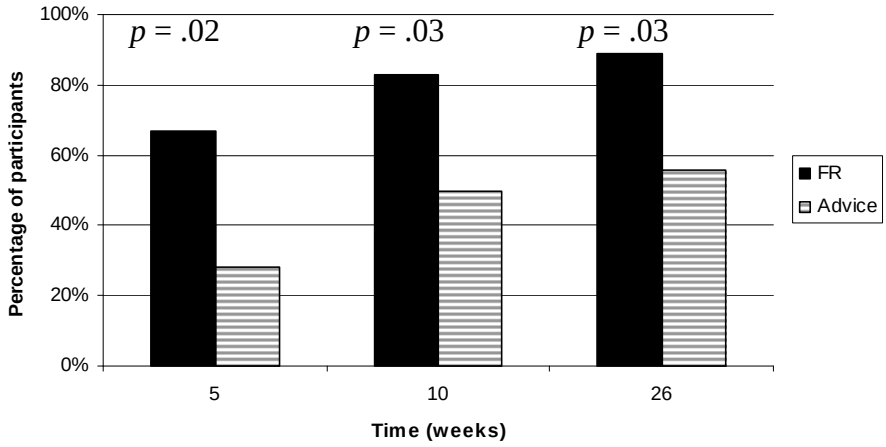
Continued

Table 6.15 continued: Effects of functional restoration versus advice on clinically important changes in outcomes (dichotomous secondary outcomes)

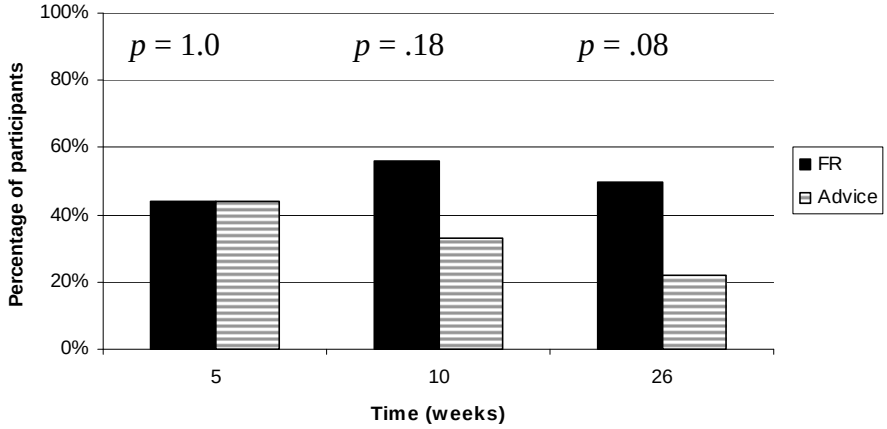
Outcome	FR N (%)	Advice N (%)	Risk difference (95% CI)	Relative risk (95% CI)	*p*-value*	NNT
Global rating of change "much improved" or "completely recovered"						
5 weeks	8/18 (44%)	7/18 (39%)	6% (-25% to 34%)	1.1 (0.5 to 2.5)	.74	18
10 weeks	13/18 (72%)	6/18 (33%)	**39% (6% to 62%)**	**2.2 (1.1 to 4.4)**	**.02**	3
6 months	14/18 (78%)	7/18 (39%)	**39% (7% to 62%)**	**2.0 (1.1 to 3.8)**	**.02**	3
"Very satisfied" with physiotherapy care						
5 weeks	12/18 (67%)	5/18 (28%)	**39% (6% to 62%)**	**2.4 (1.1 to 5.4)**	**.02**	3
10 weeks	13/18 (72%)	4/16 (25%)	**47% (14% to 69%)**	**2.9 (1.2 to 7.1)**	**<.01**	2
6 months	13/18 (72%)	1/16 (6%)	**66% (29% to 78%)**	**11 (1.6 to 73)**	**<.01**	2
"Very satisfied" with results of physiotherapy care						
5 weeks	6/18 (33%)	3/18 (17%)	17% (-12% to 42%)	2.0 (0.6 to 6.8)	.25	6
10 weeks	6/18 (33%)	2/18 (13%)	21% (-8% to 46%)	2.7 (0.6 to 11.4)	.15	5
6 months	11/18 (61%)	1/18 (6%)	**55% (23% to 74%)**	**10 (1.4 to 67)**	**<.01**	2
"Very satisfied" to endure current symptoms for rest of life						
5 weeks	1/18 (6%)	1/17 (6%)	0% (-22% to 20%)	0.9 (0.1 to 14)	.97	-306
10 weeks	1/18 (6%)	1/17 (6%)	0% (-22% to 20%)	0.9 (0.1 to 14)	.97	-306
6 months	4/18 (22%)	1/17 (6%)	16% (-9% to 40%)	3.8 (0.5 to 31)	.17	6

Note: The risk differences and relative risks are both expressed in terms of an increased or decreased risk of the labelled event occurring in the FR group relative to the advice group.
Figures in bold represent statistically significant results.
Abbreviations: FR=functional restoration; NNT=number needed to treat; NRS=numerical rating scale; Oswestry=Oswestry Disability Index.
* *p*-value =significance value of the chi square test

6.4 (a)



6.4 (b)



6.4 (c)

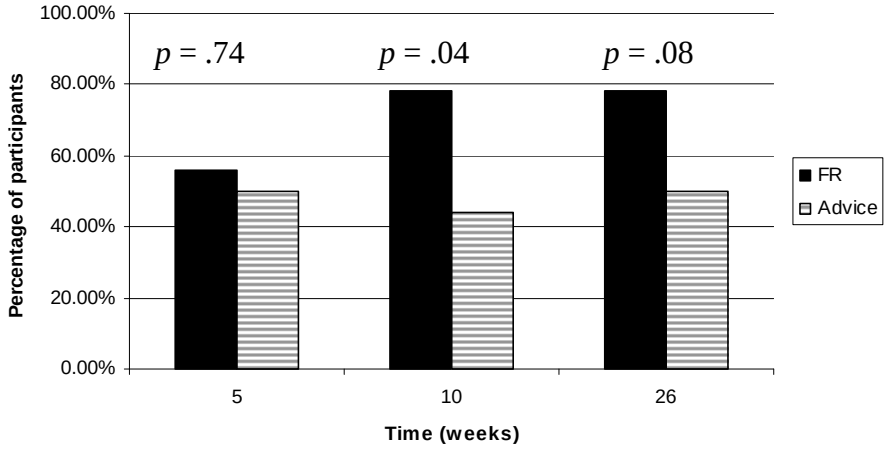
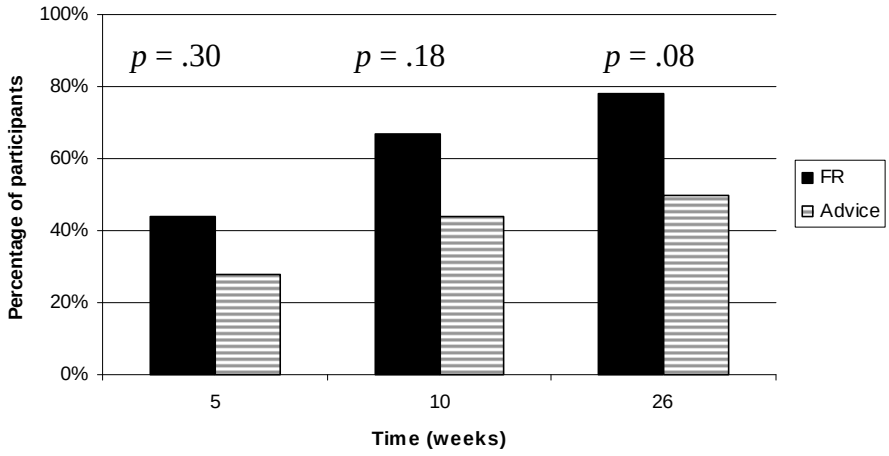
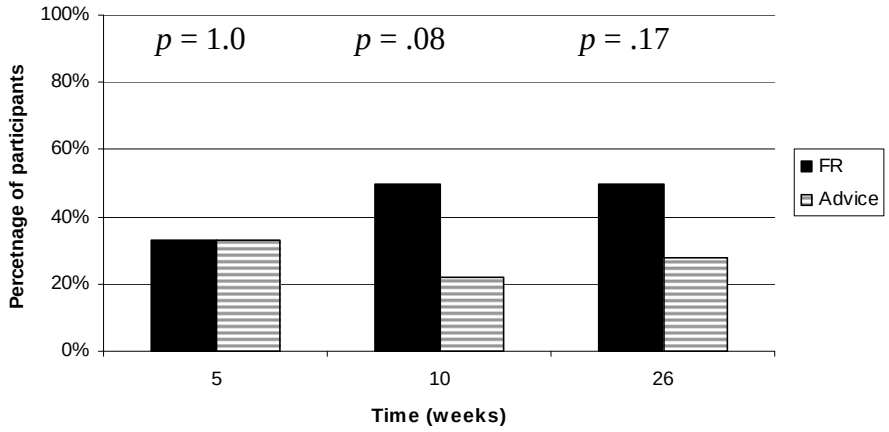


Figure 6.4: Graphs showing the proportion of participants in each group who improved by at least the minimum clinically important difference at each follow-up for the outcomes of: a) leg pain; b) back pain; and c) activity limitation

6.5 (a)



6.5 (b)



6.5 (c)

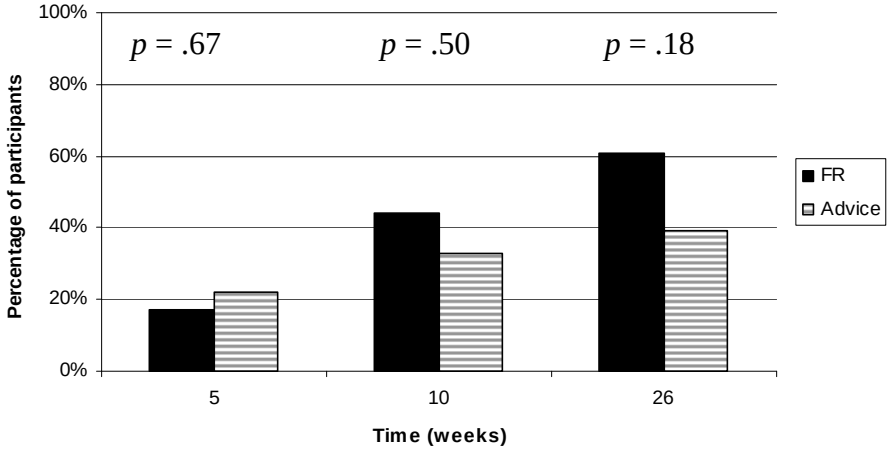


Figure 6.5: Graphs showing the proportion of participants in each group who improved by at least 50% at each follow-up for the outcomes of: a) leg pain; b) back pain; and c) activity limitation

6.4.3.5 Sensitivity analysis

As there were no missing data for any primary outcomes, the planned sensitivity analysis utilising the last observation carried forward method of imputing missing data was not required. Given the small amount of missing data in the secondary outcomes, this alternative analysis method generally made no difference to the results. Only one comparison demonstrated a different result in terms of statistical significance when the last observation carried forward method was employed, with the 6 month comparison of sciatica frequency scores becoming significant in favour of the FR group (see Table 6.11 for results).

6.4.4 Participant compliance and co-interventions

Participants in the advice group attended a mean (SD) of 1.9 (0.3) sessions, with 16 of the 18 participants (89%) attending both advice sessions. The other two participants attended the first session before withdrawing from treatment (one moved interstate for work and one ceased treatment to consult with another physiotherapist citing ineffectiveness of the advice intervention). Participants in the FR group attended a mean (SD) of 9.8 (0.5) sessions, with 16 of the 18 participants (89%) attending all 10 sessions. One participant travelled overseas following their ninth session and did not return in time to complete the final session. One participant attended eight sessions during the 10 week treatment period and did not have time to complete all sessions due to several cancelled appointments and periods of unavailability to attend appointments during the treatment program.

Table 6.16 shows co-interventions received by trial participants in each group during the 10 week treatment program, as well as between the end of treatment and the 26 week follow-up. This shows that the FR group participants were significantly less likely to attend additional non-medical / non-physiotherapy treatment (such as chiropractic, massage or acupuncture) compared to the advice group during the 10 week treatment program: risk difference -28% (95%CI: -51% to -1%). Advice group participants also attended a significantly higher median number of non-physiotherapy treatment sessions than the FR group during the 10 week treatment period (U=114.5, p= .03), as well as a higher median number of both non-physiotherapy treatment sessions (U=88.5, p= .03) and total healthcare sessions (U=82.5, p= .02) at the 26 week follow-up. Nobody in either group underwent surgery at any stage during the trial but

one advice group participant received a spinal injection during the 10 week treatment period.

Table 6.16: Proportion of participants receiving co-interventions, and the number of co-intervention sessions attended, during the 10 week treatment period and at 6 month follow-up

Intervention	Proportion of participants receiving			Sessions attended: median (25^{th} to 75^{th} percentile)		
	FR	Advice	Risk difference	FR	Advice	*p**
General practitioner visit						
10 weeks	7/18 (39%)	9/18 (50%)	-11% (-39% to 20%)	0.0 (0.0 to 1.0)	0.0 (0.0 to 1.8)	.45
6 months	2/18 (11%)	4/16 (25%)	-14% (-34% to 12%)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.5)	.24
Specialist or surgeon consultation						
10 weeks	4/18 (22%)	3/18 (17%)	6% (-21% to 31%)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	.82
6 months	1/18 (6%)	1/16 (6%)	-1% (-23% to 20%)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	.93
Additional physiotherapy						
10 weeks	2/18 (11%)	4/18 (22%)	-11% (-36% to 14%)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	.32
6 months	3/18 (17%)	4/16 (25%)	-8% (-35% to 19%)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.8)	.45
Surgery						
10 weeks	0/18 (0%)	0/18 (0%)	0% (-18% to 18%)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	1.0
6 months	0/18 (0%)	0/16 (0%)	0% (-19% to 18%)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	1.0
Injections						
10 weeks	0/18 (0%)	1/18 (6%)	-6% (-26% to 13%)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	.32
6 months	0/18 (0%)	0/16 (0%)	0% (-19% to 18%)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	1.0
Other non-medical and non-physiotherapy treatment						
10 weeks	1/18 (6%)	6/18 (33%)	**-28% (-51% to -1%)**	0.0 (0.0 to 0.0)	0.0 (0.0 to 1.8)	**.03**
6 months	5/18 (28%)	8/16 (50%)	-22% (-49% to 10%)	0.0 (0.0 to 0.0)	1.0 (0.0 to 5.0)	**.03**
Any healthcare intervention						
10 weeks	8/18 (44%)	7/18 (39%)	6% (-25% to 34%)	0.0 (0.0 to 2.0)	2.0 (0.3 to 3.5)	.07
6 months	7/18 (39%)	10/16 (63%)	-24% (-50% to 9%)	0.0 (0.0 to 1.8)	4.0 (0.0 to 7.3)	**.02**

Note: The risk differences are expressed in terms of an increased or decreased risk of the labelled co-intervention being received by a participant in the FR group relative to the advice group.
Figures in bold represent statistically significant results.
Abbreviations: FR=functional restoration.
* *p*-values are based on the Mann Whitney U test

There were no statistically significant between group differences in the proportion of participants taking various types of medication at each follow-up point (Table 6.17).

Table 6.17: Proportion of participants taking various medications at each outcome point during the trial

Medication type	Proportion taking medication		Risk difference (95% CI)
	FR	Advice	
Paracetamol			
Baseline	6/18 (33%)	8/18 (44%)	
5 week	4/18 (22%)	8/18 (44%)	-22% (-48% to 8%)
10 weeks	3/18 (17%)	8/18 (44%)	-28% (-52% to 2%)
6 months	4/18 (22%)	3/16 (19%)	4% (-24% to 30%)
Codeine			
Baseline	4/18 (22%)	5/18 (28%)	
5 week	2/18 (11%)	4/18 (22%)	-11% (-36% to 14%)
10 weeks	1/18 (6%)	2/18 (11%)	-6% (-28% to 16%)
6 months	2/18 (11%)	2/16 (13%)	-1% (-26% to 22%)
Opioids			
Baseline	1/18 (6%)	0/18 (0%)	
5 week	0/18 (0%)	1/18 (6%)	-6% (-26% to 13%)
10 weeks	0/18 (0%)	1/18 (6%)	-6% (-26% to 13%)
6 months	0/18 (0%)	1/16 (6%)	-6% (-26% to 13%)
NSAIDS			
Baseline	6/18 (33%)	7/18 (39%)	
5 week	9/18 (50%)	6/18 (33%)	17% (-14% to 44%)
10 weeks	9/18 (50%)	5/18 (28%)	22% (-9% to 48%)
6 months	4/18 (22%)	4/16 (25%)	-3% (-31% to 25%)
Any prescription medication			
Baseline	8/18 (44%)	4/18 (22%)	
5 week	3/18 (17%)	6/18 (33%)	-17% (-42% to 12%)
10 weeks	4/18 (22%)	6/18 (33%)	-11% (-38% to 18%)
6 months	5/18 (28%)	2/16 (13%)	15% (-13% to 40%)
Any medication			
Baseline	10/18 (56%)	11/18 (61%)	
5 week	10/18 (56%)	10/18 (56%)	0% (-30% to 30%)
10 weeks	10/18 (56%)	10/18 (56%)	0% (-30% to 30%)
6 months	7/18 (39%)	7/16 (44%)	-5% (-35% to 26%)

Note: The risk differences are expressed in terms of an increased or decreased risk of that medication being taken by a participant in the FR group relative to the advice group.
Abbreviations: FR=functional restoration.

6.4.5 Adverse events

Table 6.18 lists all adverse, unpleasant or harmful events that were reported by participants, or recorded by physiotherapists. All adverse events were minor in severity, resulting in only temporary discomfort or inconvenience, while no serious adverse events were reported. No individual adverse events were reported by more than one participant.

Table 6.18: Adverse events attributed to the treatment received in the trial that were recorded in the physiotherapists clinical notes, or on participants' outcome questionnaires

Adverse, harmful or unpleasant event	Physiotherapist recorded in clinical notes	Participant reported on outcome questionnaires
Functional restoration group		
Tape:		
• skin irritation	1*	1*
• pulled hairs when removing	1	
• too tight on one occasion	1	
Discomfort with exercises:		
• abdominal soreness from exceeding transversus abdominis dosage (1 day)	1	
• tightness in back and thighs from squats	1	
• back discomfort following FR program (5 minutes)	1	
• back discomfort following FR program (2 days)	1*	1*
• biceps discomfort from exceeding dosage of bicep curls (2 days)	1	
Missed classes at university due to physiotherapist running late		1
Advice group		
Lack of effectiveness		
• recovery was prolonged due to insufficient treatment		1
• treatment failed to help at all		1

* This adverse event occurred in one participant and was noted by both the participant and their physiotherapist.

6.5 Discussion

This pilot RCT compared physiotherapy FR to advice for people with DHR. It has provided useful insights into the conservative management of people with this condition. The discussion of the results of this pilot trial focuses on two primary intentions: i) consideration of the results achieved; and ii) the implications of these findings for the feasibility of conducting a RCT in the future with a larger sample size. The order of the discussion mirrors the presentation of the results in the previous section, followed by two additional sections that aim to consider the trial in a broader context.

6.5.1 Participants

Recruitment for this trial, requiring people with a strict diagnosis of DHR and a duration of leg symptoms between 6 weeks and 6 months, was very challenging. Only 4.4% of people who enquired about the trial met all of the eligibility criteria, meaning that 810 screenings were undertaken over a 17-month period to identify 36 eligible and consenting participants. This fell well short of the number of participants required for a fully powered trial of 148 participants. If the rate of recruitment achieved in this pilot study continued, it would take almost six years, AU$55,000 of marketing and 3330 screenings to enrol the required 148 participants. The most common reason for participants being excluded from the trial was due to a duration of symptoms greater than six months which accounted for a total of 304 (39.4%) of the 772 ineligible participants. It is not known how many of those participants would have satisfied the diagnostic criteria for DHR, as most of these were excluded based on the telephone screening prior to the physical examination. It could be argued that the low rate of eligibility (4.4%) for the trial raises questions about the external validity of the findings. However, this figure was roughly consistent with the 8.3% rate of eligibility in the case series that did not have any restrictions on the duration of symptoms (Chapter 4). In addition, the 4.4% rate of eligibility was comparable with the prevalence estimates in Section 2.6 indicating that DHR accounts for 5-12% of all LBDs (Bogduk, 2005; Deyo & Tsui-Wu, 1987; Friberg, 1954; Hart et al., 1995; Mooney, 1987). The findings of this trial are therefore generalisable to people with subacute, non-compensable DHR, which is known to represent a relatively small proportion of the total population who have a LBD.

The sources of recruitment indicated that most participants were obtained directly from the community via newspaper advertising and placement of public flyers. The participants enrolled in the trial might be more representative of clinical practice if a larger number of participants had been recruited from medical practitioner referrals. Despite the extensive marketing campaign and personal meetings with medical practitioners and spinal surgeons, only one eligible participant was referred by a general medical practitioner and none were referred by surgeons. Placing posters regarding the trial in the waiting room of medical practices (2 participants) and radiology clinics (5 participants) proved to be a more effective means of recruitment than meeting with medical practitioners personally. Previous research has shown that medical practitioners can be very difficult to engage in research studies, with reasons proposed for this including their time limitations, lack of interest in research, perceived disruption to their normal clinical routines and lack of remuneration (Herber, Schnepp, & Rieger, 2009).

While targeting a select subgroup of participants created the disadvantage of slowing recruitment for the trial, the benefit of this approach was that a homogenous group of people with a strict diagnosis of DHR were enrolled. By requiring all participants to have a combination of referred leg symptoms below the knee (or into the anterior thigh), at least one physical examination finding indicative of radiculopathy, and radiological confirmation of a lumbar disc herniation, there is a high likelihood that participants in this trial had a valid diagnosis of DHR (see Section 2.5.2). The presenting characteristics of the participants in the trial (Table 6.8) were consistent with those reported in other large trials involving people with a strict diagnosis of DHR including those evaluating discectomy surgery and epidural injections (Carette et al., 1997; Osterman et al., 2006; Peul et al., 2007; Weinstein, Tosteson et al., 2006). Thus it appeared that the participants included in the pilot RCT were representative of those typically enrolled in trials targeting people with DHR.

6.5.2 Treatment content and integrity

It has been recommended that RCTs should employ strategies to ensure that the treatments in the trial are applied consistently and according to protocol by the treating therapists (Borrelli et al., 2005; Perepletchikova et al., 2007). Furthermore, it has been recommended that treatment integrity be evaluated, as the failure of therapists to comply with the treatment protocol could confound the results of the trial and lead to

incorrect conclusions being drawn about the effectiveness of the treatment (Borrelli et al., 2005; Perepletchikova et al., 2007). As the FR treatment protocol evaluated in this thesis was multimodal and complex, the facilitation and evaluation of treatment integrity was considered to be particularly important. In this RCT, methods employed to facilitate treatment integrity included the use of a well-defined treatment protocol in a detailed manual, a training day attended by all treating physiotherapists prior to the trial commencing, a monthly teleconference involving all treating physiotherapists to reinforce the protocol via case discussions, and the use of electronic clinical notes that outlined the protocol for each session in a step-by-step manner. The primary means of assessing treatment integrity was by reviewing the clinical notes of the physiotherapists for each participant, as well as reviewing certain cases via the monthly teleconference.

As a result of reviewing the clinical notes of all trial participants, it appeared that a high degree of treatment integrity was achieved in both the advice and FR groups. All advice group participants received the two mandatory information sheets. In the FR group, each participant received all mandatory information sheets and optional treatment components had been selected when appropriate in accordance with the guidelines and algorithms in the protocol. Although there are more objective methods for assessing treatment integrity such as audio or video recording of treatment sessions (Borrelli et al., 2005; Perepletchikova et al., 2007), the clinical notes were deemed to provide sufficient evidence regarding the actual treatment delivered by the trial physiotherapists and it was considered unlikely that they would have falsely recorded information in these notes. This pilot RCT can therefore be deemed a valid comparison between FR and advice according to the protocols established for these respective treatments in Chapter 5 and Section 6.3.5.3.

The review of the clinical notes revealed that each of the optional treatment components were utilised for at least 28% of the FR participants, hence none of the components seemed redundant. In addition, none of the optional components were applied to more than 61% of participants, indicating that no components were so commonly indicated that they warranted mandatory application for all participants. These figures also indicate the degree to which the FR program was tailored to individual participants in accordance with their presenting problems. There was no suggestion from these figures that treating physiotherapists merely employed all available treatment components without assessing to see if they were indicated, nor did

they focus solely on mandatory treatments without considering other relevant components.

6.5.3 Outcomes

Before discussing the relative between group differences which test the primary hypothesis of this RCT, it is worthwhile briefly considering the absolute outcomes achieved in each group individually. For this purpose, the FR and advice groups could be considered as separate prospective cohort studies involving people with DHR who undertook FR and advice respectively. All continuous outcomes in FR participants improved by a statistically significant margin at each follow-up compared to baseline. The mean improvement on primary outcomes exceeded the MCID for FR participants by 5 weeks for leg pain and by 10 weeks for back pain and activity limitation. A total of 78% of FR participants reported that they were "much improved" by the 6 month follow-up, although only one perceived that they had "fully recovered" (achieved by 5 weeks and then maintained for 10 week and 6 month follow-ups). These findings in the FR group were consistent with previous chapters of this thesis that found: i) most people with DHR who undertake FR achieve clinically important improvements over time (Chapter 4); and ii) full recovery from DHR is likely to be rare (Sections 2.4 & 3.1).

Within group outcomes in participants who received advice also showed statistically significant improvements relative to baseline on all continuous outcomes except for back pain intensity at the 10 week follow-up. The mean improvement in primary continuous outcomes exceeded the MCID for advice participants by the 10 week point for leg pain and by 5 weeks for activity limitation, but not for back pain at any follow-up. A total of 39% of advice participants reported that they were "much improved" by the 6 month follow-up. Again, only one participant perceived that they had fully recovered by 5 weeks (this participant experienced a recurrence following this), one reported full recovery at 10 weeks (this participant also subsequently experienced a recurrence) and one perceived that they had fully recovered at 6 months. These findings were consistent with existing research showing that clinically meaningful improvements can be achieved by people with DHR or other LBDs with the provision of advice (Chapter 3 and Section 6.1).

As this was a pilot RCT with a small sample size, it was not anticipated that statistically significant between group effects would be demonstrated. The main goal of relative comparisons was therefore to gain an indication of the size of between group differences rather than to assess the precision of these estimates. The effect sizes achieved for the primary outcomes of back pain, leg pain and activity limitation were small at the 5 week follow-up, and moderate to large at the 10 week and 6 month follow-ups in favour of the FR group. The clinically important threshold of SMD=0.5 (Cohen, 1988; Norman et al., 2003) was achieved for all primary outcomes at both the 10 week and 6 month follow-ups. Despite the low sample size, statistically significant between group differences in favour of FR were found for back pain intensity at 10 weeks and for the overall rate of reduction in activity limitation scores across all time points. All other primary outcomes were very close to achieving statistical significance at the 10 week and 6 month follow-ups. If these findings were to remain consistent in a larger trial with greater power to detect between group differences, all primary outcomes would have a high chance of reaching statistical significance in favour of the FR group at the 10 week and 6 month points, although significant differences at the 5 week follow-up would remain difficult to detect.

The promising results in favour of the FR group observed on primary outcomes were supported by findings from the secondary continuous outcome measures. Moderate effect sizes of at least SMD=0.5 were achieved at 10 weeks and 6 months for both the Sciatica Frequency Scale and the Sciatica Bothersomeness scale. A moderate effect size of SMD=0.5 was also achieved on the Orebro Musculoskeletal Pain Questionnaire at 10 weeks but this had reduced to a small effect size by the 6 month follow-up. The consistent pattern and direction of findings achieved across primary and secondary continuous outcomes increases confidence in the validity of the results, as it reduces the likelihood that findings were due to random chance rather than real effects favouring FR.

Ordinal secondary outcomes also demonstrated some large effects in favour of the FR group. Statistically significant effects favouring FR over advice were achieved at 10 weeks and 6 months for the global rating of change scale, the satisfaction with physiotherapy treatment scale and the satisfaction with treatment results scale. At 6 months, participants in the FR group also rated their satisfaction to be significantly higher for the prospect of enduring their current symptoms for the rest of their life. The

scores on this later scale were however quite low for both groups, indicating that most participants in the trial desired further improvement beyond the 6 month follow-up. The other ordinal outcomes relating to work days missed in the previous 30 days, degree of interference with work, and quality of life measured on the EuroQol-5D, showed little or no difference between groups at all follow-ups, although the FR group had missed significantly less work days at the 10 week follow-up. The power to detect between group differences was even lower for work outcomes than for others, as only 15 FR participants and 12 advice participants were employed at the start of the trial, and most participants missed no work days at any stage throughout the trial. The assessment of work outcomes in a future trial may therefore not be worthwhile unless compensable participants are also included.

Given the limited power of this pilot trial to detect statistically significant effects due to the low sample size, a detailed analysis regarding the clinical significance of the outcomes was considered important to aid decisions regarding the feasibility of conducting a larger trial in the future. None of the adjusted between group mean differences in the primary outcomes exceeded the MCID for that outcome measure (10 points on the Oswestry and 2.0 points on the NRS pain scales), although the obtained differences approached these values at the 10 week and 6 month follow-ups. When considering the proportion of participants in each group who improved beyond the MCID, it was found that participants in the FR group were more likely to benefit from treatment by a clinically significant degree than the advice group (Table 6.15). Although several statistically significant results were achieved, most of these analyses were again underpowered due to the low sample size. Number needed to treat figures as low as two were achieved for some outcomes, indicating that only two participants would need to be treated with FR as opposed to advice in order for one additional participant to achieve a clinically significant improvement on that outcome. These very low NNT estimates suggested that several results of this pilot RCT were clinically meaningful and worthy of further evaluation in a larger RCT.

6.5.4 Compliance and co-interventions

The FR protocol contained many different treatment components and a significant amount of educational information (Chapter 5). This could potentially have negatively impacted upon compliance with the treatment by participants in the FR group. However, the results showed that the compliance of participants regarding their

attendance at physiotherapy sessions was good in both groups, with all but two participants in each group attending their full allocation of treatment sessions. Although participants in both groups were asked to refrain from other non-medical interventions during the 10 week treatment period in the trial, one-third of the advice participants attended other non-medical / non-physiotherapy treatment during this timeframe. Both the proportion of participants in the advice group receiving additional non-physiotherapy treatment during the 10 week treatment program, and the median number of such sessions attended by advice group participants, were greater than in the FR group by a statistically significant margin. In addition, the advice group attended a significantly greater number of both non-physiotherapy treatment sessions and total healthcare sessions between the end of the 10 week treatment period and the 6 month follow-up. In accordance with the principles of intention to treat, participants were analysed in their allocated groups regardless of co-interventions (Altman, 2009; Hollis & Campbell, 1999; Moher et al., 2010). Therefore, the additional co-interventions received by the advice group both during and after the treatment period in the trial may have led to larger improvements in the advice group than those that would have been achieved without additional treatment. The between group differences in outcomes favouring FR over advice may therefore have been underestimated by this pilot RCT.

There were no significant differences in the proportion of participants in each group taking various classes of medication throughout the trial. Differences in outcomes between groups were therefore not likely to be attributable to disproportionate use of medication by the two groups. There was a trend towards increased use of NSAIDs at 5 weeks and 10 weeks in the FR group, which was expected due to the recommendation for NSAIDs being a key strategy employed in this group to control inflammation when applicable.

In Section 3.1.2 of this thesis, it was discussed that discectomy surgery and spinal injections were two invasive interventions that are known to be effective in the short-term for the management of DHR. Previous trials investigating the conservative management of DHR have been confounded by high rates of injections and surgical co-interventions (Osterman et al., 2006; Peul et al., 2007; Weinstein, Tosteson et al., 2006), making it difficult to deduce the independent effects of conservative treatment. In this trial, participants were asked to refrain from these interventions during the 10 week treatment period so that the effects of non-surgical, non-injection treatment could

be evaluated. Only one participant in the trial underwent a spinal injection during the treatment period (advice group) and no participants in either group underwent surgery. By the 6 month follow-up, no additional participants had undergone either injections or surgery. These results indicated that DHR can be managed without surgical or injection interventions, as positive clinical outcomes can be achieved with a purely conservative approach.

6.5.5 Adverse events

The rate of adverse events attributed to the treatments in the trial was low in both groups. No two participants in either group reported the same adverse reaction. However, three FR participants described some discomfort with taping, while five FR participants reported discomfort with various exercises involved in the program. The adverse events detected in the FR group participants were consistent with those reported by participants in the case series (Section 3.3.6), although in the RCT shoulder pain was not reported by any participants compared to 3% of the case series participants. None of the described adverse effects in the RCT were either serious in nature or lasting in duration, which was confirmed by the finding that physiotherapists were more likely to document adverse events in their clinical notes than participants were to record them on their outcome questionnaires. Based on the participants enrolled in this trial, it therefore appears that both FR and advice are safe interventions for people with DHR. A larger sample size would be required to be confident that rare adverse events had not been missed in the current trial (Higgins & Green, 2006), so this finding is not conclusive.

6.5.6 Strengths and limitations

This pilot RCT had many strengths. In accordance with recommendations to target homogenous populations in RCTs (Delitto, 2005; Ford et al., 2007; Foster et al., 2009), the trial targeted a homogenous subgroup of participants with a clinical and radiological diagnosis of DHR who were all in the subacute stage of injury. The results are therefore applicable to people in the subacute stage of this pathoanatomical condition. While this does represent a small proportion of the population with LBDs, targeted research evaluating conservative interventions for people with DHR is particularly important given the high cost of inpatient management when conservative treatment fails (Australian Institute of Health and Welfare, 2009; Deyo, 2007; Friedly et al., 2010).

The utilisation of detailed treatment protocols for both the FR and advice groups was another strength of the trial. The FR protocol utilised a multimodal treatment approach to address the numerous aspects of DHR, with a series of mandatory and optional treatment components providing consistency of treatment delivery while allowing flexibility to tailor the program to the specific presenting problems of each participant. The protocols were also designed to be administered by physiotherapists with a range of experience levels. Other RCTs involving people with LBDs have allowed only highly experienced physiotherapists with postgraduate qualifications to treat participants (Long et al., 2004; Machado, Maher, Herbert, Clare, & McAuley, 2010; Paatelma et al., 2008; Thackeray, Fritz, Brennan, Zaman, & Willick, 2010). In contrast, the current RCT involved ten physiotherapists with a mean of 8.7 years of clinical experience, none of whom held postgraduate qualifications. Two of the physiotherapists who treated seven participants between them in this trial had less than 2 years of clinical experience. It is therefore likely that the treatment protocols could be administered by other physiotherapists with a range of experience levels and qualifications.

The high rate of follow-up of trial participants was another strength of this trial. It has been suggested that trials with less than 10% loss to follow-up provide the most credible results with minimal risk of bias (Altman, 2009). This RCT achieved 100% follow-up for all primary outcomes and at least 92% follow-up for all secondary outcomes. The high rate of follow-up and the low rate of dropouts in this trial suggests that the intentional strategies that were employed to maximise follow-up based on recommendations from previous research paid dividends (Table 6.5). Another finding that increases confidence in the validity of the findings was the consistency of results across different outcome measures, when using different data imputation methods (no imputation versus last observation carried forward) and with the removal of significant outliers from the mixed models. Regardless of the analysis method employed, 5 week between group effects tended to be absent to small, while 10 week and 6 month effect sizes ranged from moderate to large in favour of FR.

The absence of a placebo control, along with the different number of sessions that were provided to each group, could be perceived as limitations of the trial. However, the aim of the trial was to compare a new treatment approach to an existing treatment that is known to be beneficial (Hagen et al., 2000; Indahl et al., 1995; Liddle, Gracey et al.,

2007) and is recommended in all international LBP guidelines (Koes et al., 2010). Since advice is typically administered over 1-2 sessions (Hagen et al., 2000; Indahl et al., 1995; Liddle, Gracey et al., 2007) and FR is known to be a more intensive approach (Gatchel & Mayer, 2008; Poiraudeau et al., 2007), a different number of sessions was necessary for each group in order to reflect clinical practice. Other LBD trials that have involved a similar imbalance in the number of sessions delivered to each group have found no differences in outcomes (Frost et al., 2004; Hofstee et al., 2002; Luijsterburg et al., 2008). It has also been shown that the placebo effect (when evaluated in comparison to no treatment) typically accounts for only small standardised mean differences of approximately 0.3 for participant-reported pain outcomes, equivalent to 0.3-0.7 points on a 10 point pain scale (Hrobjartsson & Gotzsche, 2001, 2004; Kamper, Machado, Herbert, Maher, & McAuley, 2008). Since the primary 10 week and 6 month between group effect sizes exceeded these values, it is unlikely that the differences in outcomes between groups can be solely attributed to placebo effects or differences in perceptions of the treatments due to the imbalance in the number of sessions.

Given the nature of the interventions, it was not possible to blind physiotherapists or participants in this trial. This may have introduced some bias in the self-reporting of outcomes by participants if they had a strong preference for one of the treatments over the other (Colditz et al., 1989; Juni et al., 2001; Schulz et al., 1995; Turner et al., 1994; van Tulder et al., 2003; Wood et al., 2008). It was apparent that participants in the advice group were significantly less satisfied with the physiotherapy care they received in the trial compared to FR group participants (Tables 6.14 & 6.15) but this perception could have been influenced by a number of factors including lower effectiveness of the advice treatment. Although blinding of participants and treating physiotherapists was not possible, the trial did utilise blinded scoring and entry of outcome questionnaires to eliminate this additional potential source of bias (Colditz et al., 1989; Juni et al., 2001; Schulz et al., 1995; van Tulder et al., 2003; Wood et al., 2008).

A standardised assessment of the relative strengths and weaknesses of the current pilot RCT can be made by rating the trial on the PEDro scale. This scale was used to evaluate all trials that were included in the systematic review (Chapter 3). The PEDro score for the present trial was found to be 8/10 (See Table 6.19), which was equal to the highest rated trial in the systematic review.

Table 6.19: Assessment of the methodological quality of the pilot trial using the PEDro scale

Item	Description of item	Satisfied?
1	Were eligibility criteria specified?	✓
2	Were participants randomly allocated to groups?	✓
3	Was allocation concealed?	✓
4	Were the groups similar at baseline regarding the most important prognostic indicators?	✓
5	Were all participants blinded?	X
6	Was there blinding of all therapists who administered the therapy?	X
7*	Was there blinding of all assessors who measured at least one key outcome?	✓
8	Were measures of at least one key outcome obtained from more than 85% of the participants initially allocated to groups?	✓
9	Did all subjects for whom outcome measures were available receive the treatment or control condition as allocated or, where this was not the case, was data for at least one key outcome was analysed by "intention to treat"?	✓
10	Were the results of between group statistical comparisons reported for at least one key outcome?	✓
11	Did the study provide both point measures and measures of variability for at least one key outcome?	✓

Note: only items 2-11 are included in the calculation of the PEDro score.
* As discussed and justified in Section 3.2.4 of the systematic review, Item 7 of the PEDro scale was modified in this thesis so that it would assess whether the scoring and entry of outcome questionnaires had been undertaken by a person who was blinded to the group allocation of participants.

6.5.7 Comparison to existing research

The contribution that this RCT makes to the existing literature can be determined by referring back to previous research discussed in this thesis. As no trials in the systematic review (Chapter 3) utilised FR as a treatment, the current pilot RCT appears to be the first to evaluate this intervention for people with DHR in a RCT. The within group changes achieved by FR participants in this pilot RCT are consistent with the strong outcomes that have been reported previously in non-controlled trials that have

involved people with DHR undertaking FR (Chapter 4). The case series that was conducted prior to this thesis reported a 90% success rate at long-term follow-up (Saal & Saal, 1989). In addition, the case series undertaken in this thesis (Chapter 4) showed that 80% of participants treated with FR reported improvement at a mean discharge point of 8.7 months. These proportions are similar to the 78% of FR participants in the current pilot RCT who reported being at least "much improved" on the global rating of change scale at 6 months, although the proportion reporting any improvement at that follow-up was 100%. The mean within group improvement achieved by FR participants on the Oswestry Disability Index between baseline and 6 month follow-up in the current trial (20.2/100) was also similar to the case series where a 15.3/100 reduction was found (Chapter 4). Although there were differences in the populations involved in the previous case series, the case series in this thesis, and the current RCT, all of these studies provide evidence that a high proportion of people with DHR who undertake FR perceive overall improvement, while clinically significant reductions in the mean Oswestry Disability Index score are also apparent.

It is worthwhile comparing the effect sizes obtained for the primary outcomes in the current pilot RCT to those achieved by other high quality studies comparing other conservative interventions that were identified in the systematic review (Chapter 3). Although this does not allow any firm conclusions to be drawn about the relative effectiveness of the treatments due to substantial differences between all of the trials in terms of populations sampled, comparison interventions, outcome instruments and length of follow-up, it does provide a reference standard by which the results of the current trial can be compared. The SMD effect sizes for the primary outcomes at 10 week and 6 month follow-ups in the current trial were either equal to or greater than most other high quality trials included in the systematic review (see Chapter 3). The only high quality trial in the systematic review that achieved a substantially higher effect size showed that stabilisation exercises were significantly more effective than no treatment for the outcome of overall pain measured at 4 weeks: SMD = 2.7 (95% CI: 2.0 to 3.3) (Bakhtiary et al., 2005). It is notable that specific motor control training was a mandatory component of the FR intervention in the current trial that incorporated a more plausible comparison intervention and assessed a wider range of outcomes over a longer follow-up period than the trial by Bakhtiary et al. (2005).

The findings of the pilot RCT in relation to the advice intervention also contribute to the current literature relating to the conservative management of DHR. The systematic review conducted as part of this thesis (Chapter 3) found strong evidence (based on two high quality trials) that advice is less effective than discectomy surgery at short term follow-up for leg pain intensity, back pain intensity and activity limitation in people with subacute DHR but the differences were not maintained at long term follow-up (Osterman et al., 2006; Peul et al., 2007). The current pilot RCT appears to be the first to compare advice to another conservative intervention in people with DHR. The results of the current trial suggest that advice would be found to be inferior to FR in a fully powered trial. The 6 month within group outcomes achieved by advice participants in the present pilot RCT appeared to be somewhat inferior to those reported by the two previous RCTs identified in the systematic review that included an advice group (Osterman et al., 2006; Peul et al., 2007). Mean improvement in leg pain intensity between baseline and 6 month follow-up for advice participants in the current trial was 2.5/10, compared to 3.9/10 and 4.9/10 in the two previous trials respectively from the systematic review (Osterman et al., 2006; Peul et al., 2007). Mean back pain scores improved by 1.1/10 in the current trial, compared to 2.7/10 and 1.3/10 in the other trials (Osterman et al., 2006; Peul et al., 2007). However, direct comparisons between trials is confounded by the very high rate of cross-over to surgery by advice group participants in the trials by Osterman et al. (39.3%) and Peul et al. (29.8%), compared to a 0% surgery rate among participants enrolled in the current pilot RCT. Since surgery is known to be an effective treatment for DHR (Section 3.1.2), the outcomes in advice group participants in these other trials are likely to have been significantly overestimated. The advice group in the current RCT is therefore likely to provide the most accurate estimate of the outcomes associated with advice for people with DHR, although other non-surgical co-interventions were common in the current trial (see Section 6.4.4).

6.5.8 Implications for future research

The importance of developing and evaluating conservative interventions for people with DHR that are both safe and effective was discussed previously (Section 1.3). Increased utilisation of such treatments would provide an opportunity to reduce the rate of expensive hospital admissions and invasive interventions for people with this condition. This trial has provided preliminary evidence suggesting that FR may be both a safe and effective treatment option for people with DHR; however, a larger trial

would be required to demonstrate this conclusively. If the effect sizes obtained in this pilot RCT could be replicated in a larger trial, then FR would likely be shown to be more effective than advice for people with DHR on a wide range of 10 week and 6 month outcomes, including the primary outcomes of back pain, leg pain and activity limitation.

While a larger trial evaluating FR for people with DHR seems warranted, there remain some significant challenges regarding recruitment of sufficient participants for a fully powered trial on this select LBD subgroup. If the rate of recruitment achieved in this pilot RCT is representative, it would take six years to achieve the target sample size in a trial with 80% power to detect the desired effects across all primary outcome measures. It is likely that funding bodies would be hesitant to fund a trial that proposed to spend this long recruiting participants. For a larger trial to be feasible, ways of increasing the rate of recruitment would therefore be necessary. Expanding the number of major cities where the trial is conducted is one option that would increase the number of eligible participants. Another option would be to identify recruitment sources that may have a higher proportion of people with DHR as opposed to other LBDs. The largest RCT in the systematic review (Chapter 3) recruited 283 participants with DHR over a 2-year period by conducting the trial within the surgical departments of several large hospitals where people with the target condition tended to be selectively referred for surgical consideration (Peul et al., 2007). This would be an avenue worth considering for a larger trial, although significant collaborative planning would be required for this to become a reality.

Even with highly targeted recruitment sources, focussing on such a specific LBD subgroup will still result in a large percentage of ineligible participants. It might be possible to expand the inclusion criteria for a larger RCT to allow people with more chronic symptoms to be included rather than focussing exclusively on subacute participants. Functional restoration is typically applied to people with subacute and chronic symptoms so the primary intervention would remain suitable for people with chronic symptoms (Schaafsma et al., 2010; Schonstein et al., 2003; Staal et al., 2008). Advice alone may not, however, remain an adequate treatment for people with chronic LBDs (Liddle, Gracey et al., 2007), so including participants with chronic symptoms would necessitate reviewing and potentially expanding the content of the comparison intervention.

The sample size estimate of 148 for a fully powered trial (Section 6.3.10) was based on conservative estimates of standard deviation scores for the Oswestry and NRS pain scales obtained from the cases series (Chapter 4) and studies in the systematic review (Chapter 3). Given the difficulty in recruiting participants with DHR, combined with the fact that the pilot RCT provided additional data to increase confidence when estimating standard deviation scores, re-calculation of the sample size estimate was undertaken. Table 6.20 presents estimated sample sizes that would be required to provide 80% power to detect statistically significant effects on the primary outcome measures based on the actual between group differences and pooled standard deviations obtained in this trial. The estimated loss to follow-up was also reduced to 10% (rather than 15%) based on the high follow-up rate that was achieved in this trial. Only 10 week and 6 month follow-ups were included as it seemed clear that 5 week effects were either absent or not worth detecting. From this table, it can be seen that one out of six primary outcomes (back pain measured at 10 week follow-up) was already significant in the current pilot trial involving 36 participants. If the sample size was increased to the original target of 148, no additional outcomes would gain 80% power to detect the differences obtained in this pilot RCT. It would therefore be difficult to justify recruiting 148 participants in a larger trial given that this may not lead to any additional primary outcomes reaching statistical significance. A stronger argument could be mounted to target a sample size of 173 or 211, as this would provide 80% power to detect 4/6 and 5/6 of the primary outcomes respectively. It should be noted that these sample size calculations are estimates and they do not account for the higher precision of linear mixed models to detect treatment effects for continuous outcomes (Garson, 2011). Lower sample sizes may therefore be sufficient for detecting statistically significant effects (as was the case for 10 week back pain intensity outcomes in the current trial) but the figures in Table 6.20 represent a conservative estimate of the required sample size to ensure at least 80% power to detect the treatment effects. Any changes in the inclusion criteria, comparison intervention, or recruitment source in a future trial would be likely to result in changes to the parameters used to calculate sample sizes (namely the between group differences and standard deviations).

Table 6.20: Estimated sample size required to provide 80% power to detect statistically significant effects on the primary outcome measures based on the between group differences and standard deviations obtained in the pilot RCT

Outcome	Between group difference (baseline adjusted for continuous outcomes)	Estimated total sample size required for 80% power	Total sample size allowing for 10% loss to follow-up
Activity limitation			
10 weeks	8.0	153	169
6 months	7.2	192	211
Back pain			
10 weeks	1.6	**43**	**48***
6 months	0.8	278	305
Leg pain			
10 weeks	1.2	157	173
6 months	1.3	141	155

* This comparison achieved statistical significance in the pilot RCT with 36 participants.

Although a 6 month follow-up was conducted in this trial, longer term follow-ups including 12 months and 24 months may be of considerable interest for future trials investigating the conservative management of DHR. The current pilot RCT found that only one participant in each group considered themselves to be fully recovered by the 6 month follow-up, and most participants were not completely satisfied with the prospect of enduring their 6 month follow-up symptoms for the rest of their life. It would be interesting to see what degree of further improvement, rate of full recovery, and rate of recurrence, would be achieved at long term follow-ups in this population.

While this pilot RCT has provided an estimate of the likely effectiveness and safety of FR for people with DHR when compared to advice, additional research using a variety of methodologies could provide further insight into the utility of the FR intervention. A formal health economic analysis could be undertaken in a larger RCT to determine the cost-effectiveness of the FR program. Some of the data required for a formal cost-utility analysis was collected in the current trial, including utility scores from the EuroQol-5D and a range of outcomes that are required for the calculation of direct (such as healthcare products and services) and indirect (such as loss of work days) costs. Additional data would be needed in order to estimate prices for each of the healthcare services and average wages. Other RCTs have undertaken cost-utility

analyses to determine whether the outcomes of treatment are worthwhile given the associated costs (Smeets, Severens, Beelen, Vlaeyen & Knottnerus, 2009; Tosteson, Skinner, et al., 2008; van den Hout, Peul, et al., 2008; van der Roe, et al., 2008) and a similar protocol could be applied in a fully powered RCT on the topic of this thesis.

Another avenue of future research is to explore the mechanisms by which FR assists people with DHR. Chapter 4 outlined some general hypothesised mechanisms by which FR may facilitate improvement in people with DHR, such as the reversal of deconditioning and improvement in psychosocial dysfunction. In addition, the treatment protocol presented in Chapter 5 justified each component of the multimodal FR program based on previous research that included consideration of potential mechanisms of effect. However, the RCT in this thesis was not designed to empirically explore the mechanisms that contributed to the superior outcomes achieved by the FR group. It may be that the results were dependent upon the combined effects of the multiple treatment components that comprised the FR program, or alternatively one or two components may have been responsible for the majority of the treatment effect. Further research could seek to answer questions about the mechanisms of effect for people with DHR who undergo FR. Such research might include placebo controlled trials to formally distinguish treatment effects from non-specific (placebo) effects (Paterson & Dieppe, 2005; Turner et al., 1994), trials that seek to identify effect modifiers or mediators (Baron & Kenny, 1986; Hancock et al., 2009; Vlaeyen & Morley, 2005), as well as studies that correlate changes in outcomes with changes in constructs thought to be involved in the mechanisms of effect (Cowan, Bennell, Hodges, Crossley, & McConnell, 2003; Moseley, 2004; O'Sullivan & Beales, 2007). While answering these other research questions was outside the scope of this thesis, the next chapter presents an alternative method for further evaluating FR for DHR by analysing interviews that were conducted with participants who completed the FR treatment in this pilot RCT. This approach allowed participants to describe the aspects of the FR program that they perceived as being the most valuable, as well as elements of the program that they felt were either not useful or in need of modification.

6.6 Chapter summary and conclusions

This pilot RCT comparing physiotherapy FR to advice for people with DHR makes a unique contribution to the literature regarding the conservative management of this condition. Participants in both groups improved over time by a clinically important

amount. Although the trial did not have a sufficient sample size to provide a high chance of detecting between group differences, several statistically significant results were still achieved. There was a clear and consistent trend on almost all outcome measures that showed absent to small between group differences at the 5 week follow-up, with moderate to large (and sometimes statistically significant) effects in favour of FR seen at the 10 week and 6 month follow-ups. Functional restoration was shown to be superior to advice by a statistically significant amount for the outcomes of back pain intensity (10 weeks), activity limitation (overall rate of change over time), global rating of change (10 weeks and 6 months), satisfaction with physiotherapy care (5 weeks, 10 weeks and 6 months), satisfaction with treatment results (10 weeks and 6 months), satisfaction with enduring current symptoms for life (6 months) and number of work days missed due to pain in the previous 30 days (10 weeks). Several outcomes at 10 weeks and 6 months were also shown to be clinically meaningful for a greater proportion of FR group participants, with number needed to treat values as low as two. Participants in the advice group were significantly more likely to undertake non-medical / non-physiotherapy co-interventions during the 10 week treatment period, while advice participants also attended a greater number of both non-physiotherapy treatment sessions (at 10 weeks and 6 months) and total healthcare sessions (6 months). There were no significant differences in the proportion of participants using medications at any follow-up. Adverse events in both groups were rare in frequency and minor in severity. The results achieved in this pilot RCT provide strong justification for a larger trial investigating the effectiveness of FR for people with DHR but a sample size of 173 or 211 (rather than the initial estimate of 148) may be required to maximise the chance of achieving statistical significance on the greatest number of primary outcomes. Recruitment of a large sample of people with DHR who meet the selection criteria used in this pilot RCT is likely to be challenging, hence some changes to selection criteria or recruitment methods may be necessary to improve feasibility.

CHAPTER 7: THE PERSPECTIVES OF PARTICIPANTS WITH DISC HERNIATION AND ASSOCIATED RADICULOPATHY UNDERTAKING A PHYSIOTHERAPY FUNCTIONAL RESTORATION PROGRAM

The previous chapter presented the quantitative outcomes of people with DHR who were treated with either physiotherapy FR or advice. The assessment of outcomes was limited to group scores and proportions derived from standardised outcome measures. In order to explore the responses of individual participants, this chapter presents a qualitative study involving the participants of the RCT who received the specific physiotherapy FR treatment.

7.1 Introduction

When evaluating treatment programs for people with LBDs, consideration needs to be given to many factors (Sandbaek, 2006). While the effectiveness of the treatment as measured using standardised outcome measures is one important area that needs to be evaluated, other considerations include any side effects attributable to the treatment and the perception of the program by participants. If the treatment leads to unpleasant or harmful effects, or is perceived negatively by participants, then it is not likely to be sought. Evaluation of the experiences and perspectives of participants provides a means of fully evaluating the utility of interventions (Lewin, Glenton, & Oxman, 2009; Sandbaek, 2006), as well as providing avenues to potentially improve them (Slade, Molloy, & Keating, 2009b; Underwood et al., 2006; Verbeek et al., 2004). Qualitative research is often used for such purposes (Giacomini & Cook, 2000), particularly when evaluating multimodal treatment programs (Lewin et al., 2009; Miller, Druss, & Rohrbaugh, 2003). Several research teams working in the field of LBDs have combined quantitative and qualitative research methods in their evaluation of an intervention in a RCT (Evans, Maiers, & Bronfort, 2003; Slade & Keating, 2009; Underwood et al., 2006). This combined use of qualitative and quantitative research methods is known as “mixed methods” (Creswell & Plano Clark, 2011; Rauscher & Greenfield, 2009; Sandbaek, 2006).

As this thesis has presented the rationale, development and preliminary evaluation of a physiotherapy FR program for people with DHR, gaining insight from the RCT participants who were randomised to that treatment group was of primary interest. Before the FR program could be considered a feasible treatment option for people with

DHR, it was important to gain further insight into the perspectives of participants who had completed the program.

The first topic of interest related to the outcomes of the program expressed by the participants in their own words. The evaluation of quantitative outcomes in the RCT required selection of responses on key outcome instruments chosen by the researchers. This may have restricted the responses of the participants, who may have noticed improvements in other areas that were not assessed by the outcome instruments that were chosen. The use of mixed methods research has been shown to provide a more complete evaluation of outcomes, with the qualitative perspectives of individual participants expanding upon the quantitative group data obtained from validated questionnaires (Camp, Appleton, & Reid, 2000).

Another topic of interest was to gain feedback from participants relating to any harmful, unpleasant or unwanted effects that they attributed to the FR intervention. While this was assessed via open questions in the outcome questionnaires completed by all RCT participants, as well as via reviewing the treating physiotherapists' clinical notes, a one-on-one interview presented another opportunity for participants to discuss any adverse effects in an alternative setting.

Separate to the outcomes of the study, were the perspectives of the participants in relation to the content and delivery of the program. Previous research has shown that participants with LBDs typically have preferences in relation to exercise content and delivery (Slade et al., 2009a, 2009b). The treatment protocol in this trial did allow scope for tailoring the program to suit individual participants (Chapter 5), so evaluating whether this aspect of the program was positively perceived was of interest. The multiple components of the FR program also raised the question as to which elements of the program were perceived to be the most important by the participants (Lewin et al., 2009; Miller et al., 2003), while feedback regarding ways to improve the program was also considered valuable (Slade et al., 2009b; Underwood et al., 2006; Verbeek et al., 2004). This would allow an opportunity to refine the program if necessary prior to proceeding to a larger scale RCT.

The aim of this study was therefore to explore the perspectives of people with DHR who had completed a physiotherapy FR program in relation to their outcomes, adverse events, and the content and delivery of the program.

7.2 Methodology

7.2.1 Ethics

Ethical approval was obtained for this study concurrently with the RCT that was presented in the previous chapter (Faculty of Health Sciences Human Ethics Committee, La Trobe University #FHEC 08/196, see Appendix I). All participants were informed about the qualitative research methods on the participant information sheet for the RCT (Appendix O) and all signed written consent forms (Appendix P).

7.2.2 Study design

The qualitative study was conducted concurrently with the RCT in Chapter 6 to form a convergent mixed methods design (Creswell & Plano Clark, 2011). This design involves the parallel collection of quantitative and qualitative data, which are analysed separately and then combined to provide a greater understanding of the topic from different perspectives (Creswell & Plano Clark, 2011). The methodological framework used in the qualitative aspect of the study was consistent with a phenomenological approach. Phenomenology is the study of "the lived experience" (Creswell, 2007) where situations are described from the perspective of the person experiencing them (Liamputtong, 2009). In the current study, one-on-one semi-structured interviews were used to gain an understanding of how participants who had completed a FR program perceived the outcomes of their intervention, any adverse events, as well as the content and delivery of the program.

7.2.3 Sampling

Fifteen consecutive participants randomised to the physiotherapy FR intervention were invited to undertake an interview upon their completion of the 10 week treatment program. All consented to participate in the qualitative study. Once fifteen participants had been interviewed, the data were analysed to see if saturation had been achieved, as it was planned to continue interviewing if new themes were continuing to emerge (Auerbach & Silverstein, 2003; Cutcliffe, 2000; Liamputtong-Rice & Ezzy, 1999). Saturation was defined as the point where no new information was emerging from

additional transcripts, evidenced by three consecutive interviews being coded without any new themes being identified (Auerbach & Silverstein, 2003; Cutcliffe, 2000; Liamputtong-Rice & Ezzy, 1999).

7.2.4 Data collection

One-on-one semi-structured interviews took place between a researcher and the consenting participants (Giacomini & Cook, 2000). Whenever possible the researcher attempted to conduct the interviews face-to-face with the participant at the physiotherapy clinic where they had been treated. Due to logistical reasons three of the interviews were conducted via telephone. In all cases the interviews were recorded using a dictaphone. The interviews involved standard open-ended questions that were asked of each participant, as well as variable follow-up questions aimed at expanding and clarifying their responses. The interview schedule is presented in Table 7.1.

Table 7.1: Interview schedule

Topic area	Standard questions
Perceptions of the functional restoration treatment	• Could you make any comments about how you found the functional restoration program overall? • Could you describe any components of the treatment that you found were important for you and why? • Could you describe any components of the treatment that you found were un-important or un-necessary for you and why? • Can you suggest any ways that we could change the program?
Benefits and adverse effects attributable to the functional restoration treatment	• Have you noticed any changes in your condition or in yourself from participating in the treatment program? • Have you noticed any (other) benefits from the treatment program? • Have you noticed any (other) adverse or unwanted effects from the treatment program? • Can you discuss any skills for managing your condition that you learnt during the treatment program? • Can you discuss whether you are satisfied overall with the results of the functional restoration program?
Open feedback	• Is there anything else you would like to say that we haven't covered in the interview?

7.2.5 Transcription and analysis

The interviews were transcribed by the primary researcher (the PhD candidate). To verify accuracy, a copy of the transcript was sent to each participant with an invitation to correct any errors, a method known as member checking (Giacomini & Cook, 2000; Krefting, 1991; Mays & Pope, 2000). To protect the identity of the participants, their names were replaced with pseudonyms, while any physiotherapists, names or places mentioned in the interview were also changed for confidentiality.

Analysis was aided by a computer program (NVIVO Version 8)[5]. Typed transcripts were imported into the computer program. Two researchers independently assigned codes to label the content of each section of text (Greenhalgh & Taylor, 1997; Liamputtong-Rice & Ezzy, 1999). The two researchers then met to discuss and compare codes. By grouping and collapsing codes, key themes that emerged from the data were identified by consensus between the two researchers (Liamputtong-Rice & Ezzy, 1999).

In presenting the results of the study "rich, thick description" was utilised, which involved citing representative quotations from participants to illustrate the concepts being discussed (Greenhalgh & Taylor, 1997; Shepard, Jensen, Schmoll, Hack, & Gwyer, 1993; Tong, Sainsbury, & Craig, 2007). This allows the reader to make their own interpretation of the data from representative quotations (Tong et al., 2007).

7.2.6 Background of the researchers

It has been advised that for qualitative research, the background of the researchers should be presented as this may influence their interpretation and presentation of results (Greenhalgh & Taylor, 1997; Krefting, 1991; Mays & Pope, 2000; Tong et al., 2007).

The primary researcher was the author of this thesis. At the time of the study he was a full-time PhD candidate at the School of Physiotherapy, La Trobe University, Bundoora, Australia. He was also working part-time as a physiotherapist in private practice in Oak Park, Australia. He had a background working in private physiotherapy practice for ten years, and had a particular interest in the management of LBDs.

[5] QSR International, 2nd Floor, 651 Doncaster Rd, Doncaster Victoria 3108 Australia

The other researcher involved in analysis was a physiotherapist working in full-time academia with a combined role between the School of Physiotherapy, La Trobe University, Bundoora, Australia, and the Eastern Health hospital network, Australia.

The primary supervisor of the PhD candidate was a musculoskeletal physiotherapist with 20 years of clinical experience in private practice. He was also the director of the Low Back Research Team, La Trobe University. While he was not involved in data coding or primary analysis, he did provide some input into the final preparation and presentation of results.

7.3 Results

7.3.1 Participants

The sample comprised fifteen participants (nine males and six females), with a mean (SD) age of 44.9 (12.5) years and a mean (SD) duration of leg symptoms upon entering the program of 15.3 (6.7) weeks. The characteristics of these participants, along with their pseudonyms, are presented in Table 7.2. Analysis of the first fifteen participants revealed that no new themes or codes emerged from the last three interviews, so recruitment ceased at that stage based on the likelihood that data saturation had been achieved.

Table 7.2: Characteristics of participants

Pseudonym	Age	Gender	Duration of leg pain episode (weeks)*	Global rating of change (5 weeks) †	Global rating of change (10 weeks) †
Jasmine	64	F	7	Much better	Much better
George	65	M	10	Much better	Much better
Manu	36	M	8	Much better	Much better
Matt	38	M	16	Slightly better	Much better
Richard	33	M	16	Much better	Much better
Roger	40	M	7	Slightly better	Much better
Lilly	54	F	23	No change	Slightly better
Rose	50	F	16	Slightly better	Slightly better
Violet	37	F	10	Slightly better	Much better
Bryony	36	F	26	Much better	Much better
James	32	M	8	Much better	Much better
Daisy	62	F	20	Slightly better	Slightly better
Sean	36	M	20	No change	Slightly better
David	58	M	18	Much better	Much better
Bruce	32	M	25	No change	Slightly better

Abbreviations: M=male; F=female.
* Denotes duration of leg pain (in weeks) at the time of entry to the trial, which was 10-14 weeks prior to the interview.
† Global rating of change was assessed in Chapter 6.

7.3.2 Outcomes of the functional restoration program

Several themes were identified from the interview transcripts that related to participants' perceptions of the outcomes achieved following the FR program (Figure 7.1). Perceived outcomes were overwhelmingly positive and were grouped under the themes of "reduced symptoms", "improved activity performance", "physical improvements" and "psychological and social benefits". Perceived negative outcomes were described by only a few participants, with the majority stating that they perceived no adverse or negative effects from the program. Themes relating to perceived negative outcomes were labelled "discomfort from exercises", "problem not resolved" and "no negative outcomes". Each of these themes is discussed below.

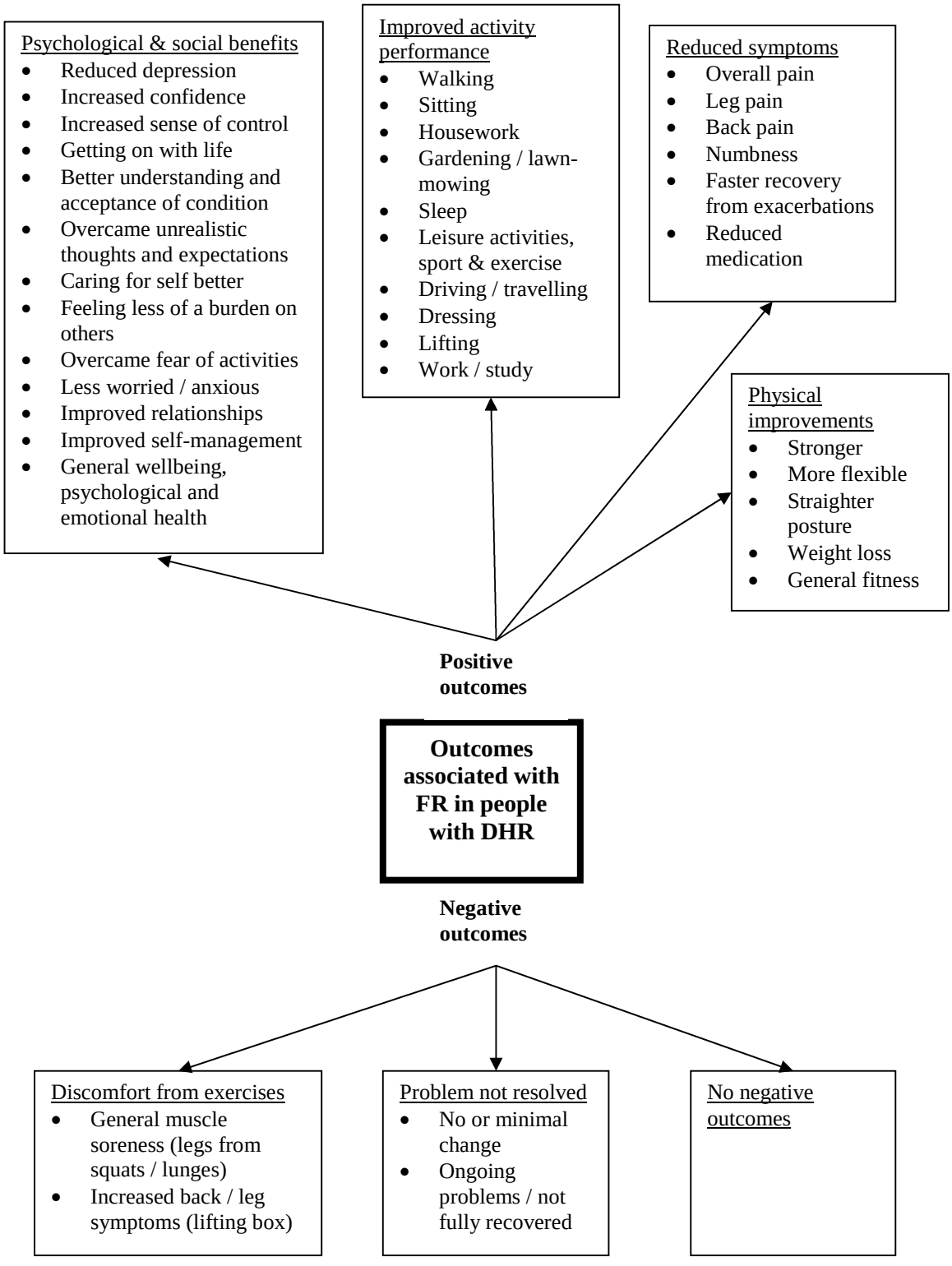


Figure 7.1: Themes derived from interviews regarding perceived outcomes of functional restoration in people with disc herniation and associated radiculopathy

7.3.2.1 Positive outcome: reduced symptoms

Most participants reported a decrease in, or total resolution of, their pain. There were descriptions of reduced leg pain, reduced back pain and reduced numbness. Some participants made a distinction between different types or areas of symptoms that had changed:

> *Jasmine: "Oh well the leg pain, you know I had the numbness and everything and that's all gone, it's just this (points to lower back)"*

Some participants reported that the improvements in their pain exceeded their initial expectations at the start of the program:

> *Bryony: "I've never had any expectation of removing all pain, which has actually caused me to be rather surprised that I've got to the stage where I am now where the pain has been so dramatically reduced, I'm happy with that!"*

Some participants identified that time may have played a part in their improvement so they were unsure of the relative benefit of the FR program on pain:

> *Daisy: "There have been some changes, the sciatic pain isn't as bad, nowhere near as bad, whether, I can't honestly say whether it was the exercises or whether it was just over time that that's happened…"*

Perceived improvements in pain were at times related to other aspects of pain management, including reduced reliance on medication and faster recovery from exacerbations:

> *Manu: "Well I haven't been on any painkillers for about, I think 7 weeks, I still have a constant pain there, ah but it is quite bearable as such, I've worked out how to keep it at a minimum"*

7.3.2.2 Positive outcome: improved activity performance

Many participants perceived improvements in their ability to perform a variety of activities. This included improved tolerances for activities, being able to return to activities that they had previously ceased due to their back condition, or improvement in the quality of activity performance:

Bryony: "…and sitting similarly, sitting's a bit like walking I can do that for longer, before I couldn't even last an hour which was making lectures and the like rather difficult, but now I'm confident I'll be able to for next semester"

Matt: "um yeah just in general I'd say that you know I can do the lawns and everything like that now, and you know I feel a bit sort of knackered afterwards but I'm not, not no where near where I sort of used to be, you know 6 months ago".

Jasmine: "Even now, friends of mine, have said to me, they notice I walk more like I used to, and I think I said that to Tony once, I said 'when I'm walking I don't feel like I'm walking like I used to' you know I just couldn't get that rhythm, but now I'm starting to walk like I normally did again".

7.3.2.3 Positive outcome: physical improvements

Perceived improvements were often noted in individual physical attributes such as muscle strength, range-of-motion and posture:

David: "certainly it's noticeable that the core muscles are stronger and that's continuing".

Richard: "My movement's probably increased 90% I'd say".

David: "Well, I'd say the posture, I'm very much more conscious of that, you know both during exercises and just in general sitting etcetera".

Improvements were also reported in the overall fitness of participants, with some citing the general benefits of engaging in a regular exercise program:

Matt: "ah, yeah I think with the exercises, also brought up a level of ah, a level of health I haven't had for a while as well so, a bit more exercise and that sort of thing."

Rose: "I'm, fitter, there's another reason! Cause I haven't really exercised for a long time, as in regular exercise".

Jasmine "And of course I've also lost a bit of weight, which helps".

7.3.2.4 Positive outcome: psychological and social benefits

A wide variety of psychological and social benefits were discussed by participants, and it was apparent that in some cases these benefits were valued by participants even more highly than the physical benefits.

There was a strong sense of improved general psychological and emotional health and wellbeing:

> *Violet: "During the program and after the program I feel very good, firstly psychologically because I was very bad I was in depression, now I feel very good my leg and my back is very good, and especially my psychology is good."*

> *Matt: "I guess the emotional side of it also you feel a bit, your head's a bit clearer about things, and you're not sort of worrying about it and its not such a conscious thing anymore so um, yeah it was good, definitely some benefits".*

Participants valued reaching a stage where they were less of a burden on others, contributing more to society and the family unit, and noting improved relationships:

> *Matt: "Plus the wife's a lot happier too, I'm getting a lot more stuff done around the house too so that's good".*

> *Manu: "Oh, I couldn't even tie my shoelaces at the start, um I had my six year old daughter and my apprentice tying my shoelaces, um I can certainly do that now"*

Several participants reported that following the FR program they felt better equipped to manage their back condition in the future and had a greater sense of control over their pain:

> *Sean: "I guess the biggest benefit really that I can think of is the fact that I feel a bit more in control of the situation, whereas before the pains would come and go and I wouldn't really know... before the program I didn't really know what the triggers were or what it was that was causing it or how I could get relief from it, it was just a matter of suffering, whereas now I sort of have a bit better idea of*

what's causing it and what I need to do to get relief. So that's the biggest benefit of the program for me, being in control".

It was noted that some psychological and social benefits such as a perceived improvement in the ability to control pain were sometimes still reported by participants who did not achieve large overall improvements in pain or activity limitation throughout the program:

Sean: "The actual symptoms that I have which Antonio knows, they are still there, like for example my right knee, I can't really bend and I can't fully extend when I'm walking. So that was there at the beginning and it's still unfortunately there at the end but what I have realised is that I'm more in control, I can sort of control my pain a little bit more now, I know what I need to do to get relief. So I feel more in control of the situation but it hasn't quite resolved and that's probably more a long term thing as well".

7.3.2.5 Negative outcome: discomfort from exercises

A small number of participants noted some minor soreness that they attributed to individual exercises that were part of the FR program. In some cases this was perceived to be muscle soreness in areas not related to the injury as Daisy noted:

Daisy: "Most of the exercises were easy except for the lunging forwards, that was hard on my thighs."

In one participant however, as the FR exercises progressed to a higher intensity level, this was considered to have temporarily aggravated their usual back and leg symptoms. This was not seen by them as a major obstacle, rather one that could be managed by adjusting the intensity of exercises:

George: "I was extending to the point where I had a little bit of lower back and little bit of more leg pain um when I was extending myself when I was doing the ah, the full exercise program that I had progressed to, but I backed off a couple of days".

7.3.2.6 Negative outcome: problem not resolved

Two participants in particular reported that their back condition had not changed considerably. Failing to perceive overall benefit was classified as a negative outcome:

Bruce: "Um unfortunately I'm still kind of at the same level I was at beforehand, you know it's going to be a long road for me to get better, but that's, I've got to deal with that".

The only other outcome classified as being negative related to several reports that the FR program failed to fully resolve participants' back conditions, or that a faster rate of recovery would be preferred. These participants typically realised however that a quick solution was an unrealistic expectation.

Daisy: "I wish he had a magic wand to have waved over my back to fix it up straight away, but yeah I know its going to take time, just slow progress"

7.3.2.7 Negative outcome: no negative outcomes

A strong theme emerged from the analysis due to most participants reiterating upon specific questioning that they did not perceive any negative outcomes from participating in the FR program:

Sean: "No, I don't think there are any adverse... no. I haven't gotten worse or anything like that, so no adverse effects".

7.3.3 Perceptions of the content and delivery of the functional restoration program

Participants perceptions of the content and delivery of the FR program were divided into several key themes (Figure 7.2). Positive themes were labelled "physiotherapist", "learning management skills", "exercises", "information / knowledge" and "overall program perceptions". Negative themes that emerged from the analysis were labelled as "difficulties with particular exercises", "program limitations" and "no negative features". These themes are discussed below.

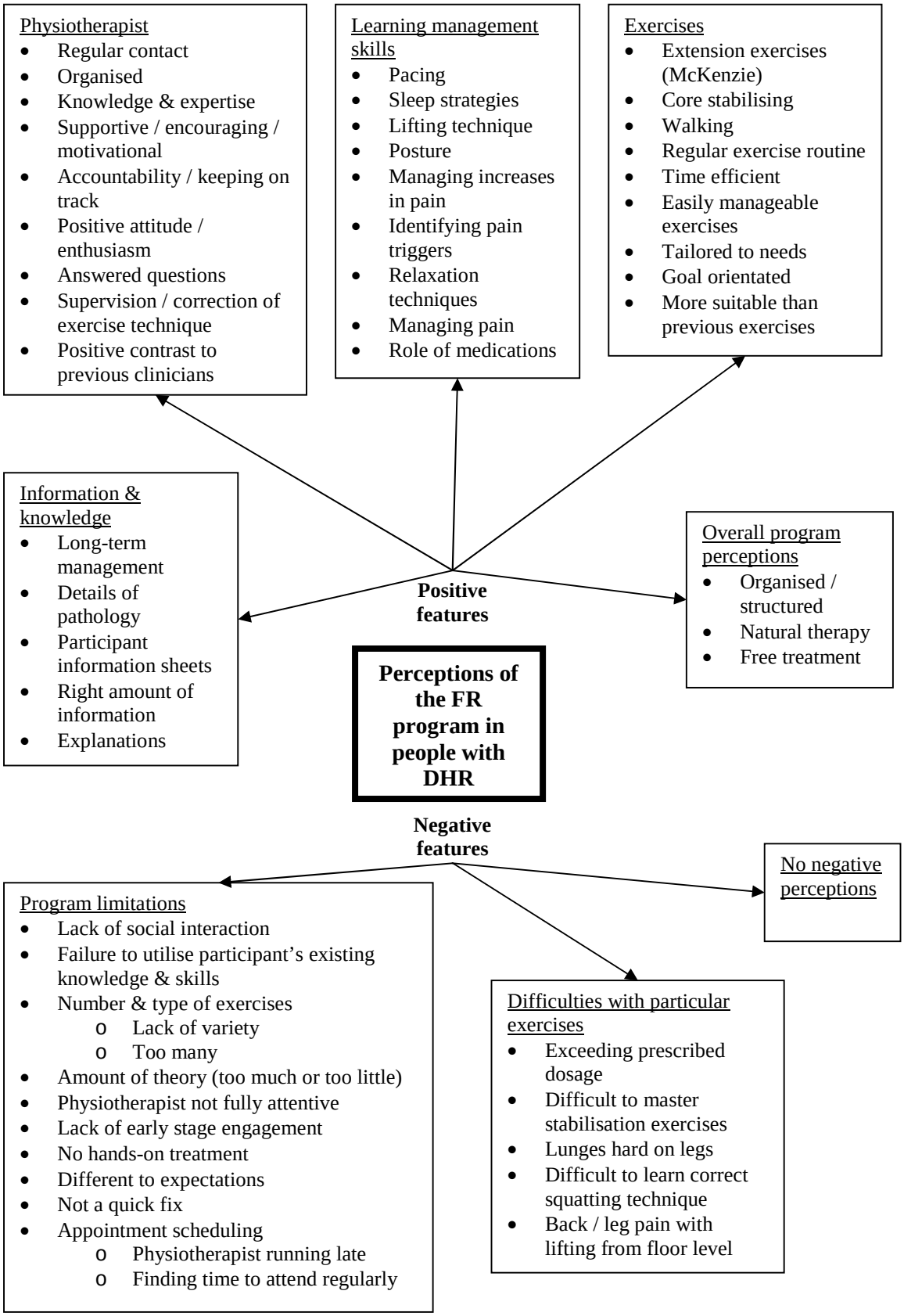


Figure 7.2: Themes derived from interviews regarding perceptions of the functional restoration program in people with disc herniation and associated radiculopathy

7.3.3.1 Positive perception: physiotherapist

Many participants provided positive comments about their treating physiotherapist. Common physiotherapist attributes cited by participants included their high level of expertise and knowledge, their enthusiasm and positive attitude and their degree of organisation:

> *George: "Oh, I found that Tim, my physiotherapist, his enthusiasm and his approach to explaining the exercises and also explaining some of the pathology of my problem because I was fortunate that I'd had advanced scans, ah CT scans and an MRI scan, and he explained more about the clinical side of that than my GP or my specialists had explained by far. So I found that inspirational you know."*

Several participants noted a positive contrast between their treating physiotherapist in the trial and other physiotherapists or medical practitioners they had seen in the past:

> *Violet: "Also you know I haven't got hope before, for being good you know, doctors and physiotherapists they all said to me I'll never be good, they all said to me 'when you die, you will be good, when you die because you can't solve this problem no-one can help', they were not optimistic, they were all saying negative things every time, that's why you know I felt very bad I was really bad, but Antonio said to me you know every time optimistic things, positive things, he praised me for doing exercises which was very important for me".*

Participants valued the regular contact with their physiotherapist during the treatment program, seeing them as an important source of accountability, encouragement and motivation:

> *James: "I've committed to someone, and someone has committed to me to get to a certain place, and even though I might think other things or be in denial of certain things at certain times when things are going good or bad, that's one of the constants, it's good to just have someone there to say 'no you're being silly or you need to do this or do that'."*

> *Violet: "he gave me (a) sheet of paper, and that helped me do regular exercise, and each time he was following up my sheet and he was asking did you do this did you do that, so I felt that was very important yeah".*

7.3.3.2 Positive perception: learning management skills

One aspect of the program that was commonly cited by participants as being an integral component of their treatment program related to the teaching of self-management skills. These included strategies to reduce pain, techniques to improve sleeping habits, pacing strategies, as well as learning correct lifting and positional skills:

> *Manu: "Greg did really seriously help me out with my sleeping and trying to get into a bit of a routine before I went to bed, um stress is a bit of an issue with me, as in you know being self-employed it's all about money, it's all about who's gonna show up in the morning if it's raining, um yeah he certainly did help with the sleeping. So and he did say that if I could sleep, it would heal a bit quicker and that that's when most of the healing took place".*

> *Matt: "I think um, it puts you straight onto the track of almost like a self-reliance type thing, it um, it's pretty much up to you and this is what you need to do, um and explaining how that all works um, yeah, I think it was fantastic, it came along at the right time for me anyway, it's just sort of something I'd been putting off and putting off for years".*

7.3.3.3 Positive perception: information / knowledge

In addition to developing self-management skills, participants valued the information and explanations that were imparted to them by their physiotherapist. Most participants found the content and flow of information to be suitable to their needs and many valued the written information sheets that reinforced their physiotherapist's explanations:

> *Matt: "Um, just the information that was in the handouts, like what was actually happening with my disc, and how the different muscle, you know different exercises and that that I'm now doing help, you know sort of which way the back works and that sort of thing, um yeah, just the general amount of information that I've been getting was such a relief because I was sort of I guess still, when I was originally seeing the physio 10-12 years ago and that, it was almost like ' just do this don't ask questions' type thing, it wasn't really overly explained or anything like that".*

Several participants felt that the educational component of the program would enable them to continue to manage their condition in the long term after the completion of the program:

Rose: "He was very thorough with all the, as I said all the things he gave me, the pamphlets that he's given me and, which is good I can always go back to them and read about it and continue the program at home".

7.3.3.4 Positive perception: exercises

The various exercises that were including in the FR program were considered to be valuable by most participants. Specific exercises that were identified as being particularly important included McKenzie exercises (as part of the directional preference management), motor control training (or "core stabilisation" exercises as most participants called them) and walking:

David: "It's really about getting a proper understanding to get the right exercises to get the core muscles strengthened, and you know getting that long term process and you know doing these exercises forever and a day basically".

In addition to the types of exercises, comments were made regarding other aspects of the exercise program, including the importance of the program being easily manageable and tailored to each participant's needs, and the value of a goal orientated approach where the exercises were related to the achievement of goals that were important to the participant.

Violet: "Antonio's suggestions of exercises were very easy, actually I found them easy, and in a very short time I could do the exercises, time is important for me, and also, they were easy exercises, not too much time".

Daisy: "Um, with my golf, I've just done it very slowly, I've gone out on the golf course with my friends and I just take a short iron and a putter and I just play the short game.....And with the exercises Alonzo's given me, that's sort of helping with the golf swing, you know strengthening my back to do that kind of stuff, so that's good"

Comments were also made contrasting the FR program to exercises that participants had undertaken previously. Again, tailoring of the program to individual participants

was an element of the FR program that may have led to better results than previous attempts at exercise, as Daisy noted:

> *Daisy: "But with the sciatica, one physio that I was going to had me doing a lot of back extensions, and I used to find after doing those the sciatic pain would be really bad and I could hardly get up off the floor, and then Alonzo pointed out to me that well that's probably bad to do that, even though they can be helpful at times in my case he said to not do any back extensions and that could be one of the reasons why the sciatic pain has eased as well, he helped me there, he said down the track they might be a good exercise to do, but he said that at the moment with me he said to avoid it, so that was very helpful too. Whereas left on my own I would have kept doing back extensions because I know that that is helpful for the back, but with my case not at the moment".*

7.3.3.5 Positive perception: overall program perceptions

The overall perceptions of the program were positive for the majority of participants, with most valuing the structure and organisation of the program as an overall treatment package:

> *Matt: "I think that, as an overall together, everything just sort of slotted in, yeah, I think every part of it was pretty much, you know, good information for me to know, and, and to learn, which will help you know over the rest of my life sort of thing".*

This holistic treatment approach was valued by participants who had previously found little benefit from interventions that were more unidimensional:

> *David: "I thought it was very good, it was basically what I'd been looking for, something that was focused on long term management, because I've been to physiotherapists many times in the past and you'd go through, you know normal procedures, you know whacking needles in you and ultrasound and all the rest of it, and its really just an attempt to deal with the symptoms rather than managing it long term".*

7.3.3.6 Negative perception: difficulties with particular exercises

A few participants described some difficulties with individual exercises that were part of the FR program. This was particularly noted for precise motor control training, which some participants found difficult to master initially:

Bryony: "What do you call it, lower pelvic muscles, at the start I couldn't even work out how to clench that muscle, much to Blair's horror, so yeah abdominal muscles".

The perceived difficulties with exercises seemed to vary individually, as other participants reported that they found motor control exercises quite simple:

George: "I was fortunate that I was able to use the muscle that I was required to use, the stomach muscle that all these exercises, ah but I became more conscious of that and refined that um, a bit, that was the main thing".

Some participants who did perceive difficulties with exercises admitted to contributing to these difficulties, either by either failing to practice exercises enough, or by exceeding the recommended dosage:

David: "You just have to be careful not to overdo the exercises which I have done on a couple of occasions, you know when you get that bit of confidence that it's going well you think 'ok well I'll do a few more sets' etcetera, and a couple of times I have overdone it which has put me back a few days".

7.3.3.7 Negative perception: program limitations

The most frequent comments regarding a perceived limitation of the program related to several participants who admitted that they were sceptical in the early stages about the likelihood that they would benefit from the program. In some cases participants felt that the content of the program did not meet their initial expectations for what physiotherapy was and they were not fully engaged at the start. It was only once these participants had progressed further through the program and started to grasp the key rationale for the FR approach that they saw the merits of the program:

James: "I was ready to get my gear off and get a massage, ah and it was just talking, ah which was a bit unexpected, um but at the end ah, as you progressed through it and, you know going over, ah, I guess some theory um, it really made a lot of sense and you actually learnt what was wrong opposed to how to treat it short term".

Manu: "Right at the very start I couldn't actually figure out these arm movements and everything, but then once Greg explained to me about the inner core and what

we were trying to strengthen we're trying to work from the inside out, a lot of it actually started making sense".

The amount of theoretical information did not suit all participants, with some feeling there was too much time spent on theory during the program and others finding that some explanations were not detailed enough. Bryony pointed out that the amount of information might need to be varied for different participants based on their background:

Bryony: "I mean if you were doing it for someone who had more understanding they may need less information, but at the same time if you're doing it for someone who had absolutely no idea then they may need more information, but for me, all good".

Several suggestions for improving the program were offered by participants. These included progressing participants to a gymnasium to overcome social isolation and improve motivation, better utilising the existing skills and knowledge of participants, and considering other ways to deliver the program for busy people such telephone consultations or community based programs:

James: "Maybe having that option to do some telephone sessions or correspondence might be more beneficial, um, obviously time's always very difficult, and like I said its sort of catch 22, I was very thankful for all the time I was given, yet trying to find the time was also a problem so".

7.3.3.8 Negative perception: no negatives

Many participants stated that they perceived nothing negative about the FR program:

Daisy: "No, I think you've covered everything, I've never come home from seeing Alonzo thinking 'oh gee I wish we did this or that or', no I can't think of anything at all".

7.4 Discussion

7.4.1 Outcomes of the functional restoration program

This qualitative study revealed that participants with DHR who had undertaken a physiotherapy FR program perceived a wide range of benefits and a small number of minor negative effects.

Consistent with the convergent mixed methods design of study, it is worth considering whether the outcomes described by the participants in the qualitative study were adequately captured by the formal outcome measures utilised in the RCT (Chapter 6). The primary outcome measures used in the RCT were leg pain intensity, back pain intensity and activity limitation. While these outcomes did emerge as key themes in this qualitative study, other dimensions of improvement in pain and activity performance were also apparent from the interviews. Those other dimensions, such as faster recovery from exacerbations and engaging in more regular exercise, were not assessed in any of the outcome measures used in the RCT. Another key theme relating to outcomes that emerged from the current study was improvement in impairments and physical attributes such as increased range-of-motion, improved strength, straighter posture, weight loss and improved fitness. Since the follow-ups in the RCT did not include a physical examination, these improvements were not detected. The decision to exclude physical examination findings as outcome measures was made for practical reasons, as additional resources would have been required and asking participants to attend a physiotherapy clinic for follow-ups may have increased the rate of missing outcomes. Future studies in this area could include a follow-up physical assessment in order to detect changes in these physical elements of DHR.

A significant finding from this study was the wide range of improvements that emerged under the theme of “psychological and social benefits”. Many participants cited these improvements as the most important outcomes for them and in some cases changes in this area occurred even in the absence of significant improvement in pain or activity. The assessment of these outcomes in the RCT was limited primarily to the Orebro Musculoskeletal Pain Questionnaire, which generated a single score as a measure of psychosocial risk factors. This may not have been sensitive enough to detect the effect of the FR program on all of the psychological and social benefits noted by participants in the qualitative study.

Several of the psychosocial benefits that emerged from this qualitative study seemed to relate to beliefs and self-confidence, namely improved confidence, greater control over pain, ability to get on with life, less fear of activities and an improved perception that participants could self-manage their condition. These improvements seem to reflect constructs such as self-efficacy (confidence to perform activities despite pain), fear avoidance or kinesiophobia (the avoidance of activities due to a fear of causing pain or re-injury), personal control (the belief that an individual can control their condition) and internal health locus of control (the belief that an individual's behaviour and actions influence their health) (Brincks, Feaster, Burns, & Mitrani, 2010; Foster et al., 2008; Foster, Thomas et al., 2010). Various outcome questionnaires are available to measure these psychological constructs, including the Pain Self Efficacy Questionnaire (Nicholas, 2007), the Illness Perceptions Questionnaire (revised) (IPQ-R) (Moss-Morris et al., 2002), the Tampa scale of kinesiophobia (Roelofs et al., 2007) and the Multidimensional Health Locus of Control (MHLC) questionnaire (O'Looney & Barrett, 1983). Interestingly, a recent study that used a multivariate analysis to determine which psychosocial features best predicted the future outcome of LBDs showed that self-efficacy and personal control were two of the strongest predictors of outcome (Foster, Thomas et al., 2010). Interventions that can positively influence these psychosocial constructs may have potential to reduce the likelihood of transition from acute / subacute to chronic symptoms (Foster, Thomas et al., 2010). Changes in other psychological symptoms that were reported by participants in this study such as anxiety and depression might also be better assessed using specific outcome scales related to these constructs. The qualitative improvements in many psychological and social areas noted by participants in this qualitative study suggests that further evaluation of the relative effect of FR versus advice in relation to specific psychological and social attributes measured with validated questionnaires may be a fruitful area of future research.

Many of the outcomes reported in this qualitative study related to the known or hypothesised mechanisms of effect for FR described in Chapter 4.1.4. One of these hypothesised mechanisms was the reversal of deconditioning, and participants of this qualitative study described improved general fitness, weight-loss and increased regularity of exercise. In addition, some participants reportedly overcame their own unrealistic thoughts and expectations to reach a point where they were better able to

accept and take responsibility for managing their condition, supporting the incorporation of cognitive-behavioural strategies that aimed to alter inappropriate beliefs and behaviours. Other reported benefits that related to the known or hypothesised mechanisms of effect for FR included improved strength (particularly in the core stabilising muscles), better ability to self-manage and control pain, improved knowledge of their condition, improved psychosocial functioning, increased activity levels and reduced exacerbations. These are all potential mechanisms of effect that could be further explored using other study designs (discussed in Section 6.5.8) in order to determine whether any components of FR are particularly influential upon the outcomes that are achieved.

It was not possible in this study to determine the inter-relationships between the various improvements identified in this study. It may be that improving pain results in concurrent improvements in all other outcome areas. If that were the case, then a multimodal treatment program would not be necessary and physiotherapists could focus solely on reducing pain. Several findings of this study refute this hypothesis, at least for some participants. There were participants in this trial who reported quite significant improvements in their sense of control over their pain, yet they cited limited or no change in their overall pain intensity and activity levels. It is possible that improvements in skills relating to controlling pain and self-management may lead to positive long term changes in the primary outcomes of pain intensity and activity, even if short term changes are not forthcoming.

The importance of long term follow-up of outcome measures was also supported by one of the key themes that emerged in relation to negative outcomes. While only a few participants in the qualitative study reported little or no change in their condition, many reported ongoing problems and indicated that their condition had not yet fully resolved by the conclusion of the treatment period in the trial. This was consistent with the results of the quantitative study, which showed that no participants reported that they were unchanged or had deteriorated, while only one FR participant reported that they had fully recovered at each follow-up. While 6 month follow-up data was obtained for all participants in the quantitative RCT, longer term follow-ups are needed to assess whether improvements are maintained, and whether full recovery is achieved by a greater number of participants over a longer timeframe.

Consistent with the findings of the RCT, some negative outcomes relating to discomfort from exercises were reported by a few participants in the qualitative study. Discomfort that was attributed to exercises by participants in this study was typically minor, and often related to excessive exercise dosage (sometimes above the dosage set by the physiotherapist). In all cases the symptoms reportedly abated once the dosage of the exercise was modified.

7.4.2 Perceptions of the content and delivery of the functional restoration program

This qualitative study showed that participants with DHR who undertook a physiotherapy FR program perceived the program favourably. In general, they valued the content and delivery of the exercise program, the information and self-management skills they were taught, as well as the structure and organisation of the multiple program components. Participants described a positive interactional experience with their treating physiotherapist throughout the program. Means of improving the program to best cater for the expectations and preferences of individual participants were suggested by some participants.

An exercise based rehabilitation program was the main component of the FR protocol for all participants. Consistent with this was the key theme that emerged from the analysis indicating that participants perceived the exercises to be an integral part of the FR program. Specific motor control training, or core stability exercises, were mandatory for all participants. Another study that utilised qualitative methods to gain the perspectives of participants with LBP undergoing exercise programs reported that all participants who had been exposed to motor control exercises found them very difficult to master (Slade et al., 2009b). Although a few participants in the current study described similar difficulties with motor control training, others specifically stated that they mastered these exercises quickly with the aid of the teaching methods employed by their physiotherapist. The physiotherapists in the study had been advised to use teaching methods that have been shown to be important in other studies, including the use of written handouts and diagrams, explanation, supervision of exercises, provision of feedback, as well as regular review and progression of exercise technique (Schoo & Morris, 2003; Slade et al., 2009b). Positive comments were made by participants in this study with regard to all of these teaching methods and this may have assisted participants to master even difficult exercises such as specific motor control training.

In addition to the exercises, the FR program included a wide range of other strategies to educate the participant regarding their back condition and to equip them with skills to effectively self-manage their condition in the future. These other strategies emerged as key themes relating to program content that was valued by participants. Information and knowledge about back pain and it's management has been found to be important to people with LBDs in several other qualitative studies (Liddle, Baxter et al., 2007; Ong et al., 2011; Slade et al., 2009b; Underwood et al., 2006; Verbeek et al., 2004). Given that the FR program in this study involved people with a condition for which a distinct pathoanatomical diagnosis can be made (DHR), the physiotherapists were able to satisfy participants' desire for pathoanatomical information regarding the cause of their pain and this was valued by participants. Other studies have identified that people with LBDs typically desire this type of pathoanatomical explanation (Liddle, Baxter et al., 2007; Ong et al., 2011; Underwood et al., 2006; Verbeek et al., 2004). In addition to the provision of information, many participants considered the self-management approach of the program to be a strength. This included strategies to manage pain and techniques to assist with sleeping. Other studies have shown that people with LBDs typically value such skills that allow them to self-manage their condition (Crowe et al., 2010; May, 2001; Underwood et al., 2006) but the specific teaching of these skills is often absent from physiotherapy interventions (Cooper, Smith, & Hancock, 2009).

The combination of exercises, education, and teaching of self-management skills was integrated into a structured and organised treatment protocol. The qualitative interviews revealed that participants valued the structure and holistic nature of the FR program with its multiple components. Incorporating treatment strategies to address all aspects of a person's LBD is an essential part of adhering to the biopsychosocial model of healthcare (Weiner, 2008). Unidimensional approaches may be less suited to managing subacute DHR and several participants in this study reflected on the limitations of previous treatments that focussed solely on temporary relief of symptoms.

Another important theme to emerge from the current study related to attributes of the treating physiotherapists that were perceived positively by participants. There was a clear indication that most participants experienced a positive two-way partnership with their physiotherapist in achieving goals that were important to both parties. This relationship has been found to be important in other studies and has been variously termed "partnership in care" (Slade et al., 2009a), a "patient-centredness approach"

(Mead & Bower, 2000) or a "consultative process" (May, 2001). Aspects of this approach that emerged from the analysis included positive communication, individualised treatment, expertise and knowledge of the physiotherapist that is shared with the participant, establishment of mutual goals, listening and answering questions, along with the attitude and personality of the physiotherapist (Mead & Bower, 2000; Slade et al., 2009a). Other attributes of physiotherapists that were valued by participants included their motivational skills, their availability through regular contact and their ability to keep participants accountable and offer correction when they deviated from the most desirable path (Slade et al., 2009b). The perceptions of trial physiotherapists by participants would have been influenced by the personality and style of the individual physiotherapists, as well as by aspects of the protocol that aimed to facilitate positive interaction such as mutual goal setting. A systematic review has shown that a positive working relationship between therapists and participants can positively influence treatment satisfaction and physical functioning (Hall, Ferreira, Maher, Latimer, & Ferreira, 2010), hence the collaborative nature of the FR treatment may be one of the factors that contributed to the very high levels of treatment satisfaction that were reported by FR participants in the RCT (Chapter 6).

The negative perceptions of the program by participants offer an opportunity to refine the intervention in the future. The key theme to emerge in the area of negative perceptions related to program limitations that were identified by some participants. Several participants had an expectation that they would receive passive physiotherapy treatment such as massage and these expectations were not met. The FR program intended to omit passive treatment modalities in favour of promoting management skills that could be continued after the conclusion of the 10 week treatment period. Given the risk of persistent or recurrent symptoms in DHR (Sections 2.4 & 3.1), the achievement of participant independence for long term management was essential (Blyth et al., 2005; Hansen et al., 2010; Harding & Williams, 1995; May, 2010). Other studies have shown that failing to meet participants' expectations can lead to dissatisfaction with treatment (Liddle, Baxter et al., 2007; Verbeek et al., 2004). It was interesting that in the current study, several participants who expected manual treatment initially were able to overcome this to embrace the FR program as it progressed. Some even reflected that their initial expectations were not realistic or appropriate, noting that the program helped them to overcome these unrealistic perceptions and expectations. Another study has also found that participants can take

some time to embrace a self-management approach if they have an initial expectation of receiving manual treatment or a quick-fix (May, 2007). This suggests that seeking to meet the initial expectations of all participants might not necessarily be the best approach, rather assessing and managing these expectations through education, discussion and cognitive restructuring may be more suitable if participant expectations are unrealistic (Grazebrook & Garland, 2005; Nicholas, 2008).

Some participants suggested alternative ways of delivering the program to better suit their needs, such as telephone consultations. While this would save time for participants, it would also remove some of the benefits of the program that were highly valued by participants, such as supervision of exercises and feedback regarding exercise technique. One participant realised this contradiction in his preferences and labelled it a “catch 22” (James’ quotation from section 7.3.3.7), stating that his weekly sessions with the physiotherapist were both appreciated and resented due to the time commitment required. Previous research has indicated that most people perceive closely supervised and individualised exercise programs to be essential (Cooper, Smith, & Hancock, 2008; Slade et al., 2009b). Progressing to a gym program was another suggested setting for exercise delivery. While this would be feasible in a study with additional funding for gymnasium memberships and additional follow-up consultations, another study has shown that many participants with LBDs are reluctant to attend gymnasiums (Slade et al., 2009b).

Other comments from participants that could be used to improve the FR program included their desire for additional tailoring of the program to their individual preferences. Examples of this included differing preferences regarding the number of exercises, the type of exercises and the amount of theoretical information provided to participants. The authors of a previous qualitative study have developed a checklist that can be used to determine the exercise preferences of participants (Slade et al., 2009b). While this thesis did intentionally draw upon many of the items on that checklist when developing the FR protocol for people with DHR, this needed to be balanced with maintaining an operationally defined and replicable program which required a certain core structure and common elements. It may however be possible to further question participants at the start of the program with regards to their previous experiences and management preferences, as this may provide more opportunities to tailor the program to suit as many participants as possible.

7.4.3 Study strengths and limitations

There were several strengths of this study. A range of methods were utilised to maximise rigour and trustworthiness (Barbour, 2001; Liamputtong-Rice & Ezzy, 1999; Mays & Pope, 2000). These included verbatim transcription of voice recorded interviews with subsequent member checking, analysis by two independent data coders and the use of rich thick description to allow transparency in the interpretation of themes. Triangulation of data was achieved through the concurrent quantitative and qualitative methods that provided a means of verifying the results between the two studies that comprised this convergent mixed methods design. A strong case can also be made that data saturation was achieved in the qualitative study, since analysis of the last three interviews revealed that no new codes or themes emerged from the data (Auerbach & Silverstein, 2003; Cutcliffe, 2000; Liamputtong-Rice & Ezzy, 1999).

The use of telephone interviews for three participants could be seen as a potential limitation of the study. However, given that a consecutive sample of participants was sought without any exclusions, combined with the wide geographical area in which participants were treated, conducting telephone interviews on these three participants was necessary. The validity of telephone interviews has been shown to be good (Novick, 2008), and one study directly comparing face-to-face and telephone interviews found no substantial differences in content (Sturges & Hanrahan, 2004).

Members of the advice group were not interviewed, as the perceptions and outcomes of participants who completed the FR program were of primary interest as part of the evaluation of the utility of this treatment. Future research could investigate the perceptions and outcomes of people with DHR who receive advice.

7.5 Chapter summary and conclusion

A qualitative study was undertaken involving 15 participants with DHR who completed the FR intervention in the RCT. The study found that participants valued their physiotherapist, as well as the exercises, skills and knowledge learnt during the program. A wide variety of positive outcomes were perceived by participants and these were categorised into reduced symptoms, improved activity performance, physical improvements and improvement in various psychological and social dimensions. As part of a convergent mixed methods design, it was found that the outcomes reported by participants in this qualitative study reinforced the results of the RCT in Chapter 6,

while also relating to known or hypothesised mechanisms of effect for the FR program. A wider range of outcomes were reported by participants than those that were measured via formal questionnaires in the RCT. In particular, the specific measurement of psychological constructs such as depression, anxiety, self-efficacy and personal control may be insightful in future trials utilising this multimodal FR program. Perceived negative outcomes were rare, relating to discomfort associated with exercises and failure to benefit or fully recover. In order to better suit a wider range of participants, the FR program would need to allow greater flexibility in content and delivery style while incorporating the preferences and existing skills of participants to design a tailored and personalised intervention.

CHAPTER 8: CONCLUSIONS

Low back disorders are a prevalent source of pain and activity limitation that pose a significant burden to individuals and their communities in western countries. It has been proposed that the identification of subgroups within the domain of LBDs may increase the potential for specific treatments to demonstrate meaningful effects in RCTs. The broad aim of this thesis was to evaluate the conservative management of a pathoanatomical LBD subgroup, DHR. In pursuit of this aim, background literature was reviewed relevant to DHR, followed by four original research studies. The current chapter summarises the findings of this thesis, discusses its contribution to the existing literature and makes recommendations for future research.

8.1 Summary of findings and contribution to the literature

Background research in this thesis established that DHR has an estimated population prevalence of 2-5%, although the limitations of existing epidemiological studies limit the accuracy of this estimate. By reviewing the anatomy and pathophysiology of the intervertebral disc, the typical pathogenesis of DHR was found to commence with physical trauma leading to internal degradation and fissuring of the annulus, culminating in herniation of nuclear and/or annular disc material towards a spinal nerve root. Mechanical and inflammatory irritation of the nerve root results in referred leg pain and impaired neural conduction known as radiculopathy. Studies were discussed that suggested good potential for a disc herniation to reduce in size over time, as well as for nerve function to improve once mechanical and inflammatory irritation abates. However, the disc itself was shown to possess limited healing potential leading to a significant risk of persistent or recurrent symptoms among people with DHR.

The well established pathophysiological processes involved in the development of, and recovery from, DHR make this condition one of the most widely recognised and accepted pathoanatomical subgroups of LBDs. Studies were reviewed that demonstrated DHR to be a well validated subgroup according to recommended methodologies for evaluating classification systems. This process identified the most valid and reliable features indicative of DHR to be the presence of referred pain (particularly extending below the knee for lower lumbar disc herniations, or into the anterior thigh for upper and mid lumbar disc herniations), physical examination findings suggestive of neural impingement (straight-leg-raise for the lower lumbar

levels or prone-knee-flexion for the upper lumbar region) or impaired nerve conduction (segmental motor, reflex or sensory reduction), along with MRI or CT confirmation of a herniated disc.

Once DHR has been accurately diagnosed, a range of treatments are available. It was found that the natural history of DHR has not been well established but it appeared that most people experience some improvements despite failing to fully recover. Epidural injection of corticosteroid, and discectomy surgery, are both popular invasive treatments that target the specific pathophysiological processes involved in this condition. While systematic reviews have shown both of these treatments to be effective at hastening improvement in symptoms in the short term, long term effectiveness has not been demonstrated. In addition, a small risk of significant adverse events is associated with these interventions and the cost of administering them is significant especially in the case of discectomy surgery. For these reasons, conservative and non-injection management plays an important role in the treatment of DHR.

Prior to this thesis being undertaken, the effectiveness of conservative and non-injection treatments for people with a valid diagnosis of DHR had not been established via a systematic review. In Chapter 3 of this thesis, a systematic review was undertaken to determine the effectiveness and safety of conservative treatments for people with clinical and radiological evidence of DHR. Meta-analysis conducted on two homogenous trials provided strong evidence that advice was less effective than microdiscectomy at short term follow-up but equally effective at long term follow-up, for people with subacute DHR. Moderate evidence was obtained from individual trials showing that stabilisation exercises were superior to no treatment, that manipulation was better than sham manipulation, that no difference existed between traction, laser and ultrasound, and that the addition of mechanical traction to medication and electrotherapy modalities added some additional benefits.

It was clear from the systematic review that the effectiveness of multimodal treatment programs had not been previously evaluated in a RCT for people with DHR. In Chapter 4, functional restoration was introduced as a potential multimodal conservative treatment for this population. Functional restoration has demonstrated effectiveness in people with non specific LBP but the existing evidence to support the use of FR for people with DHR is limited to a case series that did not utilise standardised outcome

measures. To gain an additional indication of the potential outcomes and safety of FR for people with DHR, a case series was undertaken involving 95 participants with a clinical and radiological diagnosis of DHR who had undergone physiotherapy FR. Participants achieved statistically and clinically significant improvements in activity limitation measured on the Oswestry Disability Index, as well as overall improvements rated on a global rating of change scale. A low risk of minor adverse events was also found.

Following on from the preliminary evidence obtained in the case series, a pilot RCT was designed to compare physiotherapy FR versus advice in people with subacute DHR. A detailed FR treatment protocol for people with DHR was developed and justified in Chapter 5. This multimodal program utilised a series of mandatory and optional treatment components that could be consistently applied while maintaining the flexibility to tailor the treatment to individual participants.

The methodology and results of the pilot RCT were presented in Chapter 6 of this thesis. A total of 36 participants with subacute DHR were randomised to receive either physiotherapy FR (10 sessions over 10 weeks) or physiotherapy advice (2 sessions over 10 weeks). Ten physiotherapists administered the treatments at eleven private clinics across metropolitan Melbourne, Australia. Outcomes were measured at baseline, 5 weeks, 10 weeks and 6 months following randomisation, which measured back pain (NRS), leg pain (NRS), activity limitation (a modified version of the Oswestry Disability Index), Sciatica Frequency and Bothersomeness scales, global rating of change, psychosocial status (Orebro Musculoskeletal Pain Questionnaire), quality of life (EuroQol-5D), interference with work, number of work days missed and three treatment satisfaction scales. Most outcomes showed a consistent pattern of absent to small between group differences at the 5 week follow-up, with moderate to large (and sometimes statistically significant) effects favouring FR at the 10 week and 6 month follow-ups. Several outcomes at 10 weeks and 6 months were also shown to be clinically meaningful for a greater proportion of FR group participants. Adverse events in both groups were rare in frequency and minor in severity. This pilot RCT involving people with a clinical and radiological diagnosis of DHR appeared to be the first to investigate the effectiveness and safety of FR in this population. Despite the low sample size that was a result of the strict inclusion criteria, the findings of the trial suggested that FR has significant potential to become recognised as a safe and effective

treatment option for the conservative management of people with subacute DHR if a larger trial is performed.

A qualitative study was presented in Chapter 7 that was conducted concurrently with the RCT to in a convergent mixed methods design. While the RCT provided data from valid and reliable outcome measures, the qualitative study allowed fifteen participants with DHR who were allocated to the FR group to describe their outcomes and perceptions of the program in their own words. Semi-structured interviews were conducted with participants, then the manuscripts were coded and key themes identified by two researchers. Participants valued attributes of their physiotherapist, the exercises, learning management skills and the knowledge obtained during the program. A wide variety of positive outcomes were perceived by participants and these were categorised into reduced symptoms, increased activity levels, physical benefits and improvement in various psychological and social dimensions. Perceived negative outcomes were rare but related to discomfort associated with exercises and failure to benefit or fully recover. Suggestions for improving the program related mainly to a desire for increased flexibility in program content and delivery to suit individual participants.

As a whole, this thesis makes a contribution to the existing literature regarding the conservative management of DHR. Research that targets specific subgroups within the LBD population has been recognised as a high research priority and the central focus of this thesis on people with clinical symptoms and a radiological diagnosis of DHR fits with this agenda. The systematic review, case series, RCT and qualitative study involving people with DHR not only provided a logical progression of research methodologies but each study also filled a gap in the literature relating to the conservative management of this LBD subgroup. Having reviewed the key findings and context of this thesis in relation to the existing literature, avenues for future research identified from the findings of this thesis are discussed in the next section.

8.2 Avenues for future research

While this thesis answered multiple questions and filled several gaps in the existing literature regarding the conservative management of DHR, avenues for future research were also identified.

The systematic review revealed that high quality RCTs investigating the conservative management of DHR are scarce. Few existing conservative treatments for this population have been shown to be effective in RCTs. Given the potential for safe and effective conservative treatments to reduce the rate of expensive hospital admissions and surgical intervention for people with DHR, there is clearly a need for additional high quality RCTs in this field.

To ensure that RCTs focus on treatments with the highest likelihood of positively changing clinical practice, significant background and preparatory work should be performed prior to progressing to the RCT stage. Preliminary evidence from case series' or small pilot RCTs should be established before fully powered trials are considered for this population. The development of treatments for pathoanatomical subgroups such as DHR can be assisted by considering the known or hypothesised mechanisms by which the treatment might have a therapeutic effect, but this requires a sound knowledge of the anatomy, pathophysiology and healing processes associated with the disorder.

Given that the RCT in this thesis was a pilot study, one of its main aims was to determine the feasibility of conducting a fully powered trial evaluating the effectiveness of FR in the future. Given the encouraging outcomes achieved in the pilot RCT, combined with the low risk of adverse events, a larger trial appears warranted. Based on data from the pilot RCT, a total sample size of either 173 or 211 is recommended to provide 80% power to detect statistically significant between group differences on the highest number of primary outcomes. Given the low rate of eligibility of volunteers for the pilot RCT, recruitment of this many participants is likely to be very challenging. To ensure that a fully powered trial could be completed within the budget and timeframes typically imposed by major funding bodies, other recruitment methods would need to be considered. These might include close collaboration with the neurosurgery department of large public hospitals where people with DHR are often referred for evaluation or placed on waiting lists for discectomy. Expanding the trial to include other major cities may also be an option. Another way of increasing recruitment would be to expand the eligibility criteria. For example, including participants with chronic symptoms would greatly increase the proportion of volunteers who are eligible, as this was the most common reason for exclusion in the pilot RCT. While the FR intervention is likely to remain appropriate for participants

with chronic symptoms, the suitability of the advice intervention for a chronic population is questionable. Further piloting on a chronic population might be required prior to finalising such a decision.

A longer follow-up period would also be informative for a fully powered trial. In the pilot RCT, only one participant in each group had fully recovered by the 6 month follow-up. Chapters 2 & 3 of this thesis suggested that achieving a full recovery from DHR may be elusive for most people but healing can continue beyond the 6 month follow-up of this trial. A 12 month and 24 month follow-up would provide useful insight into the proportion of people with DHR who achieve a full recovery, as well as the proportion of those whose symptoms recur following recovery.

The findings of the qualitative study provide an opportunity to reconsider the outcome measures to be used in a future trial. Functional restoration participants involved in the semi-structured interviews identified outcomes that had not been thoroughly assessed by the standardised outcome measures that were selected for the pilot RCT. These outcomes included physical characteristics such as strength and flexibility, sleep quality, self-efficacy, health locus of control, kinesiophobia, anxiety and depression. To avoid additional burden on trial participants, questionnaires assessing some or all of these new outcomes could perhaps replace outcomes that showed only small between group differences in the pilot RCT such as the EuroQol-5D and work outcomes.

The qualitative study also provided insight into how the FR program could be improved to suit all participants. Some participants voiced their preference for greater flexibility in the content and delivery of their treatment program to ensure that it met their expectations and recognised their existing skills and knowledge. Additional time could perhaps be spent at the first treatment session discussing participant expectations and past experiences to allow greater opportunity for tailoring the program. Striking a balance between providing a structured protocol that can be administered and replicated consistently, while also allowing considerable freedom to individualise the program to every participant, remains a challenge. While most participants were satisfied with the existing FR program, attempting to improve it to suit as many participants as possible is always worth considering.

In summary, this thesis has filled several gaps in the literature regarding the conservative management of DHR. Functional restoration appears to have good potential to become recognised as a safe and effective conservative treatment for people with this condition but a larger RCT would be required to draw definitive conclusions capable of influencing clinical practice. There remains a strong need for further research into the conservative management of DHR and future high quality studies are likely to have a significant impact on the existing evidence base.

APPENDICES

Appendix A: Peer reviewed journal articles resulting from this thesis

Due to journal copyright conditions, the actual journal articles could not be included in the electronic version of this thesis. The citations of the articles, along with their uniform resource locators, are presented below:

Hahne, A. J., Ford, J. J., & McMeeken, J. M. (2010). Conservative management of lumbar disc herniation with associated radiculopathy: A systematic review. *Spine, 35*(11), E488-E504. http://journals.lww.com/spinejournal/Abstract/2010/05150/Conservative_Management_of_Lumbar_Disc_Herniation.23.aspx

Hahne, A. J., Ford, J. J., Hinman, R. S., Taylor, N. F., Surkitt, L. D., Walters, A. G., McMeeken, J. M. (2010). Outcomes and adverse events from physiotherapy functional restoration for lumbar disc herniation with associated radiculopathy. *Disabil Rehabil, 33*(17-18), 1537-1547. http://informahealthcare.com/doi/abs/10.3109/09638288.2010.533814

Hahne, A. J., Ford, J. J., Surkitt, L. D., Richards, M. C., Chan, A. Y., Thompson, S. L., Hinman, R. S., Taylor, N. F. (2011). Specific treatment of problems of the spine (STOPS): design of a randomised controlled trial comparing specific physiotherapy versus advice for people with subacute low back disorders. *BMC Musculoskelet Disord, 12*(1), 104. http://www.biomedcentral.com/1471-2474/12/104

Appendix B: General search strategy for relevant articles

Ovid Medline SP core condition search

1) Sciatica/
2) Radiculopathy/
3) Intervertebral disk displacement/
4) (lumbar or back or lumbo$).ti,ab
5) (2 or 3) and 4
6) 1 or 5
7) Limit to English
8) Limit to 1996+

CINAHL (EBSCO)

1) Sciatica/
2) Radiculopathy/
3) Intervertebral disk displacement/
4) (lumbar or back or lumbo$).ti,ab
5) (2 or 3) and 4
6) 1 or 5
7) Limit to English
8) Limit to 1996+

The search targeted major and minor subject headings most relevant to DHR, and was restricted to English articles published between 1996 and December 2010. The start date for the search was arbitrarily established but it was thought that relevant studies published prior to this date would be readily identified in the reference lists of more recent papers. The citations from each database were downloaded into a bibliographical program (Endnote X)[6], combined, and duplicates removed. A total of 4426 citations were obtained. The keyword search feature of Endnote was then used to identify citations of most relevance to each section of the thesis. For example, a search for the term "pathophysiology" in the title, abstract, or subject heading sections of the citation was used to identify papers of potential relevance to the pathophysiology of DHR. Full text copies of relevant articles were then obtained. Additional papers were identified by checking the reference lists of key articles, and from the personal libraries of members of the Low Back Research Team at La Trobe University. A weekly ISI Web of Science email alert was also established between January 2008 and the date of thesis submission to identify new articles in the field that had been added to that database.

[6] Thomson Reuters, 3 Times Square, New York, NY 10036

Appendix C: Database search terms for the systematic review

MEDLINE (Ovid SP)

Phase 1: Condition terms

1) Sciatica/
2) Sciatic$.ti,ab
3) Radiculopathy/
4) Intervertebral disk displacement/
5) Spinal nerve roots/
6) Pain, referred/
7) ((nerv$ or root$ or neuro$ or neural) ADJ5 (compress$ or involv$ or displac$ or imping$ or irritat$ or entrap$ or compromi$)).ti,ab
8) (neurological ADJ5 signs).ti,ab
9) ((refer$ or radiat$) ADJ5 (pain or symptoms)).ti,ab
10) (parasthesia or numbness).ti,ab
11) radicul$.ti,ab
12) ((disc or disk or discs or disks or pulposus) ADJ5 (sequest$ or protru$ or extru$ or prolaps$ or slipped or displac$ or ruptur$ or herniat$ or derange$)).ti,ab
13) (lumbar or back or lumbo$ or L1 or L2 or L3 or L4 or L5 or S1).mp
14) (3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12) AND 13
15) 1 OR 2 OR 14

Phase 2: Trial type terms

16) Randomized Controlled Trial (pub type)
17) Controlled clinical trial (pub type)
18) Clinical trial (pub type)
19) Randomized controlled trials/
20) Exp Clinical trials/
21) Double-blind method/
22) single-blind method/
23) Random Allocation/
24) Placebos/
25) Research Design/
26) ((singl$ or doubl$ or tripl$ or trebl$) adj25 (blind$ or mask$)).ti,ab
27) placebo$.ti,ab
28) random$.ti,ab
29) (clin$ adj25 trial$).ti,ab
30) versus.ti,ab (recommended by Zhang et al. 2006)
31) (latin adj square).ti,ab (added by van Tulder et al. 2003)
32) Cross-over Studies/ (added by van Tulder et al. 2003)
33) 16-33 / OR

Phase 3: Combine disorder and trial type, Limit to human

34) 33 AND 15
35) Limit 34 to yr= “1971-2008”
36) Limit 35 to humans

EMBASE (Ovid 1988 to 2008):

Phase 1: Condition terms

Appendix C continued

1) ischialgia/
2) sciatic$.ti,ab
3) lumbar disk hernia/
4) radiculopathy/ or radicular pain/ or radiculitis/
5) intervertebral disk hernia/
6) spinal nerve/ or spinal root/ or nerve root injury/
7) ((nerv$ or root$ or neuro$ or neural) ADJ5 (compress$ or involv$ or displac$ or imping$ or irritat$ or entrap$ or compromi$)).ti,ab
8) (neurological ADJ5 signs).ti,ab
9) ((refer$ or radiat$) ADJ5 (pain or symptoms)).ti,ab
10) (parasthesia or numbness).ti,ab
11) radicul$.ti,ab
12) ((disc or disk or discs or disks or pulposus) ADJ5 (sequest$ or protru$ or extru$ or prolaps$ or slipped or displac$ or ruptur$ or herniat$ or derange$)).ti,ab
13) (lumbar or back or lumbo$ or L1 or L2 or L3 or L4 or L5 or S1).mp
14) (4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12) AND 13
15) 1 OR 2 OR 3 OR 14

Phase 2: Trial type terms

16) clinical trial/
17) controlled study/
18) randomized controlled trial/
19) double blind procedure/
20) multicenter study/
21) single blind procedure/
22) crossover procedure/
23) placebo/
24) randomization/
25) ((singl$ or doubl$ or tripl$ or trebl$) adj25 (blind$ or mask$)).ti,ab
26) placebo$.ti,ab
27) random$.ti,ab
28) (clin$ adj25 trial$).ti,ab
29) (Versus).ti,ab
30) (latin adj square).ti,ab
31) 16-33 / OR

Phase 3: Combine disorder and trial type, Limit to human

32) 31 AND 15
33) Limit 32 to yr= “1988-2008”
34) Limit 33 to humans

<u>EMBASE (Elseiver, Monash 1974 to 1988)</u>:

Phase 1: Condition terms

1) Ischialgia:de (de=index term from EMTREE)
2) Sciatic neuralgia:de
3) Sciatic*:ti,ab

Appendix C continued

4) 'Lumbar disk hernia':de
5) Radiculopathy:de or 'radicular pain':de or radiculitis:de
6) 'Intervertebral disk hernia':de
7) 'Spinal nerve':de or 'spinal root':de or 'nerve root injury' or 'spinal root compression':de
8) ((nerv* or root* or neuro* or neural) and (compress* or involv* or displac* or imping* or irritat* or entrap* or compromi*)):ti,ab
9) 'neurological *5 signs':ti,ab (within 5 words, must be in order though)
10) 'signs *5 neurological'.ti,ab
11) ((refer* or radiate or radiating) and (pain or symptoms).ti,ab
12) (parasthesia or numbness):ti,ab
13) radicul*:ti,ab
14) ((disc or disk or discs or disks or pulposus) and (sequest* or protru* or extru* or prolaps* or slipped or displac* or rupture* or herniat* or derange*)):ti,ab
15) (lumbar or back or lumbo* or L1 or L2 or L3 or L4 or L5 or S1):ti,ab,de
16) (5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 11 OR 12 OR 13 OR 14) AND 15
17) 1 OR 2 OR 3 OR 4 OR 16

Phase 2: Trial type terms

18) Clinical trial:de
19) Controlled study:de
20) Randomized controlled trial:de
21) Double blind procedure:de
22) Multicenter study:de
23) Single blind procedure:de
24) Crossover procedure:de
25) Placebo:de
26) Randomization:de
27) ((singl* or doubl* or tripl* or trebl*) adj25 (blind* or mask*)):ti,ab
28) Placebo*:ti,ab
29) Random*:ti,ab
30) (clin* and trial*):ti,ab
31) (Versus):ti,ab
32) 'latin square':ti,ab
33) 18-32 / OR

Phase 3: Combine disorder and trial type, Limit to human

34) 34 AND 14
35) Limit 35 to yr= "1971-2008"
36) Limit 36 to humans

<u>CINAHL (Ovid SP)</u>

Based on medline search and article by (Wong et al., 2006b)

RCT's (modified from medline strategy and from article by Wong et al., 2006b to suit CINAHL headings)

Appendix C continued

- Clinical trial (pub type)
- Exp Clinical Trials/
- Random Assignment/
- Placebos/
- Study Design/
- ((singl$ or doubl$ or tripl$ or trebl$) adj25 (blind$ or mask$)).ti,ab
- (clin$ adj25 trial$).ti,ab
- (latin adj square).ti,ab
- placebo$.ti,ab
- random$.ti,ab
- versus.ti,ab
- Crossover design/
- OR /
- Animal/ not human/
- 30 not 31

CONDITION

As per medline but replace MeSh heading “Pain, referred/” with “referred pain/”

AMI (Australasian medical index…Informit)

Phase 1: Condition terms

1) MH=(sciatica)
2) TI,AB=(sciatic*)
3) MH=(radiculopathy)
4) MH=(intervertebral disk displacement)
5) MH=(spinal nerve roots)
6) MH=(referred pain)
7) TI,AB=((nerv* or root* or neuro* or neural) %5 (compress* or involve* or displac* or imping* or irritat* or entrap* or compromi*))
8) TI,AB=(neurological %5 signs)
9) TI,AB=((refer* or radiat*) %5 (pain or symptoms))
10) TI,AB=(parasthesia or numbness)
11) TI,AB=(radicul*)
12) TI,AB=((disc or disk or discs or disks or pulposus) %5 (sequest* or protru* or extru* or prolaps* or slipped or displac* or rupture* or herniat* or derange*))
13) TI,AB,MH=(lumbar or back or lumbo* or L1 or L2 or L3 or L4 or L5 or S1)
14) (3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12) AND 13
15) 1 OR 2 OR 14

Phase 2: Trial type terms

16) MH=(randomized controlled trials)
17) MH=(clinical trials)
18) MH=(double blind method)
19) MH=(single blind method)
20) MH=(random allocation)
21) MH=(placebos)

Appendix C continued

22) MH=(research Design)
23) TI,AB=((singl* or doubl* or tripl* or trebl*) %5 (blind* or mask*))
24) TI,AB=(placebo*)
25) TI,AB=(random*)
26) TI,AB=(clin* %25 trial*).ti,ab
27) TI,AB=(versus)
28) TI,AB=(latin % square)
29) MH=(cross over studies)
30) 16-30 / OR

Phase 3: Combine disorder and trial type, Limit to human

31) 30 AND 15
32) MH=animal
33) MH=human
34) 32 NOT 33
35) 31 NOT 34
36) Limit 35 to yr= "1971-2008"

Current Contents (1993-2008, OVIDSP)

Phase 1: Condition terms

1) Sciatica.kp,kw (kp=keyword plus, kw=author keywords)
2) Sciatic$.ti,ab
3) Radiculopathy.kp,kw
4) "Intervertebral disk displacement".kp,kw
5) "Spinal nerve roots".kp,kw
6) "referred pain".kp,kw
7) ((nerv$ or root$ or neuro$ or neural) ADJ5 (compress$ or involv$ or displac$ or imping$ or irritat$ or entrap$ or compromi$)).ti,ab
8) (neurological ADJ5 signs).ti,ab
9) ((refer$ or radiat$) ADJ5 (pain or symptoms)).ti,ab
10) (parasthesia or numbness).ti,ab
11) radicul$.ti,ab
12) ((disc or disk or discs or disks or pulposus) ADJ5 (sequest$ or protru$ or extru$ or prolaps$ or slipped or displac$ or ruptur$ or herniat$ or derange$)).ti,ab
13) (lumbar or back or lumbo$ or L1 or L2 or L3 or L4 or L5 or S1).mp
14) (3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12) AND 13
15) 1 OR 2 OR 14

Phase 2: Trial type terms

16) "randomized controlled trial".kp,kw
17) "clinical trial".kp,kw
18) "double-blind".kp,kw
19) "single-blind".kp,kw
20) "random".kp,kw
21) "placebo".kp,kw

Appendix C continued

22) "research design".kp,kw
23) ((singl$ or doubl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).ti,ab
24) placebo$.ti,ab
25) random$.ti,ab
26) (clin$ adj25 trial$).ti,ab
27) versus.ti,ab
28) (latin adj square).ti,ab
29) "cross-over".kp,kw
30) 16-29 / OR

Phase 3: Combine disorder and trial type, Limit to human

31) 30 AND 15
32) animal.kp,kw
33) human.kp,kw
34) 32 NOT 33
35) 31 NOT 34
36) Limit 35 to yr= "1971-2008"

Cochrane CENTRAL register of controlled trials

1) Sciatica/
2) Sciatic*:ti,ab
3) Radiculopathy/
4) Intervertebral disk displacement/
5) Spinal nerve roots/
6) Pain, referred/
7) ((nerv* or root* or neuro* or neural) near/5 (compress* or involve* or displac* or imping* or irritat* or entrap* or compromi*)):ti,ab
8) (neurological near/5 signs):ti,ab
9) ((refer* or radiat*) near/5 (pain or symptoms)):ti,ab
10) (parasthesia or numbness):ti,ab
11) Radicul*:ti,ab
12) ((disc or disk or discs or disks or pulposus) near/5 (sequest* or protru* or extru* or prolaps* or slipped or displac* or rupture* or herniat* or derange*)):ti,ab
13) (lumbar or back or lumbo* or L1 or L2 or L3 or L4 or L5 or S1) (all text)
14) (#3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12) AND #13
15) #1 OR #2 OR #14
16) Limit to date range

AMED (Ovid 1985-2008)

Phase 1: Condition terms

1) Sciatica/
2) Sciatic$.ti,ab
3) Radiculopathy.mp
4) Intervertebral disk displacement/
5) Spinal nerve roots/

Appendix C continued

6) ((nerv$ or root$ or neuro$ or neural) ADJ5 (compress$ or involv$ or displac$ or imping$ or irritat$ or entrap$ or compromi$)).ti,ab
7) (neurological ADJ5 signs).ti,ab
8) ((refer$ or radiat$) ADJ5 (pain or symptoms)).ti,ab
9) (parasthesia or numbness).ti,ab
10) radicul$.ti,ab
11) ((disc or disk or discs or disks or pulposus) ADJ5 (sequest$ or protru$ or extru$ or prolaps$ or slipped or displac$ or ruptur$ or herniat$ or derange$)).ti,ab
12) (lumbar or back or lumbo$ or L1 or L2 or L3 or L4 or L5 or S1).mp
13) (3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12) AND 13
14) 1 OR 2 OR 13

Phase 2: Trial type terms

15) Randomized Controlled Trial (pub type) (no pub types in 2008)
16) Controlled clinical trial (pub type)
17) Clinical trial (pub type)
18) Randomized controlled trials/
19) Exp Clinical trials/
20) Double-blind method/
21) Random Allocation/
22) Placebos/
23) Research Design/
24) ((singl$ or doubl$ or tripl$ or trebl$) adj25 (blind$ or mask$)).ti,ab
25) placebo$.ti,ab
26) random$.ti,ab
27) (clin$ adj25 trial$).ti,ab
28) versus.ti,ab
29) (latin adj square).ti,ab
30) 16-29 / OR
31) 14 AND 30
32) Animal/ not human/
33) 31 not 32

PEDro

Difficult to combine searches therefore each condition term was searched separately in a title & abstract search:

1) radicul*
2) sciatic*
3) disc herniat*
4) disk herniat*
5) disc prolaps*
6) disk prolaps*
7) disc displac*
8) disk displac*
9) disk extru*

Appendix C continued

10) disc extru*
11) pulposus
12) refer* pain lumbar
13) radiat* pain lumbar
14) neurological signs
15) numbness lumbar
16) parasthesia lumbar
17) parasthesia back

Appendix D: Ethical approval for the case series

THE UNIVERSITY OF MELBOURNE

16 November 2007

Dr Jon Ford
Physiotherapy
The University of Melbourne

Dear Dr Ford

Project title: **Physiotherapy functional restoration for lumbar disc herniation with associated radiculopathy: A retrospective file review**
Researchers: **Dr Jon Ford, Andrew John Hahne, Adam Graham Walters, Luke Desmond Surkitt, Professor Joan Mcmeeken, Dr Rana Hinman**
Ethics ID: **0718601**

This is to confirm that the Health Sciences Human Ethics Sub-Committee noted the approval of the above minimal risk project by the Physiotherapy Human Ethics Advisory Group for the period **14 Nov-2007** to **31-Dec-2008.**

It is your responsibility to ensure that all people associated with the Project are made aware of what has actually been approved.

Research projects are normally approved to 31 December of the year of approval. Projects may be renewed yearly for up to a total of five years upon receipt of a satisfactory annual report. If a project is to continue beyond five years a new application will normally need to be submitted.

Please note that the following conditions apply to your approval. Failure to abide by these conditions may result in suspension or discontinuation of approval and/or disciplinary action.

(a) **Limit of Approval:** Approval is limited strictly to the research as submitted in your Project application.

(b) **Amendments to Project:** Any subsequent variations or modifications you might wish to make to the Project must be notified formally to the Human Ethics Advisory Group for further consideration and approval before the revised Project can commence. If the Human Ethics Advisory Group considers that the proposed amendments are significant, you may be required to submit a new application for approval of the revised Project.

(c) **Incidents or adverse affects:** Researchers must report immediately to the Advisory Group and the relevant Sub-Committee anything which might affect the ethical acceptance of the protocol including adverse effects on participants or unforeseen events that might affect continued ethical acceptability of the Project. Failure to do so may result in suspension or cancellation of approval.

(d) **Monitoring:** All projects are subject to monitoring at any time by the Human Research Ethics Committee.

(e) **Annual Report:** Please be aware that the Human Research Ethics Committee requires that researchers submit an annual report on each of their projects at the end of the year, or at the conclusion of a project if it continues for less than this time. Failure to submit an annual report will mean that ethics approval will lapse.

(f) **Auditing:** All projects may be subject to audit by members of the Sub-Committee.

Please quote the ethics registration number and the name of the Project in any future correspondence.

On behalf of the Ethics Committee I wish you well in your research.

Yours sincerely

Kate Murphy
Executive Officer, Human Research Ethics
Tel: 8344 2073 or e-mail:k.murphy@unimelb.edu.au.

cc: HEAG Chair – Physiotherapy

Melbourne Research Office
The University of Melbourne Victoria 3010 Australia
T: +61 3 8344 2000 **F:** +61 3 9347 6739 **W:** http://www.research.unimelb.edu.au/

unimelb.edu.au

Appendix E: Taping protocol used in the functional restoration program

Participants should be informed that the purpose of the tape is to serve as a reminder to help them maintain correct posture, and provide some additional support and pain relief while their core stabilising muscles are becoming stronger. This may reduce pressure on the injured disc, reduce exacerbations, improve tissue healing and reduce inflammation.

The following protocol should be followed:

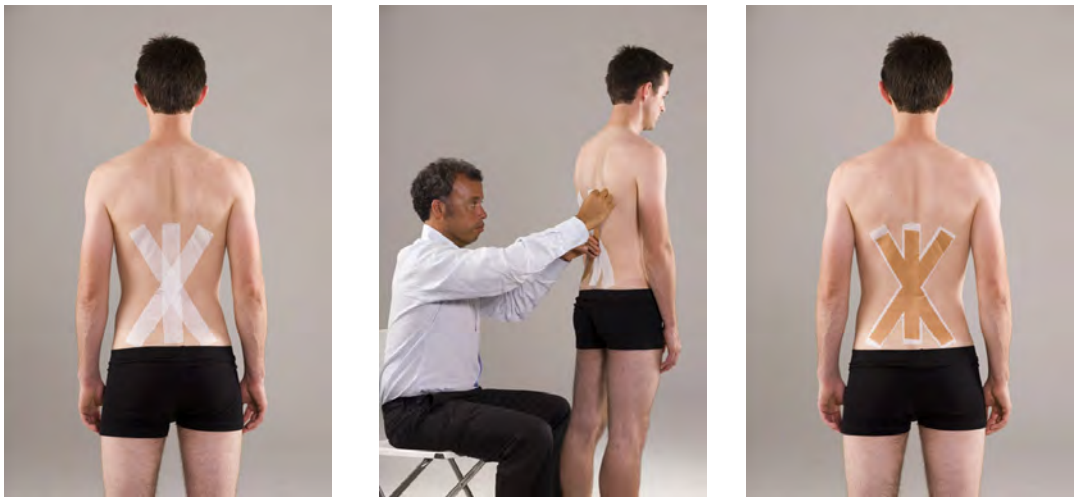
- Tape with the participant standing in a comfortably upright position. In participants with an excessive lordosis, rigid tape should be applied in 10-20 degrees of lumbar flexion to ensure tape is not overly tensioned (resulting in tape dislodging when the participant puts on their shoes)
- Check the skin area to be taped. Do NOT apply or re-apply tape over broken or damaged skin.
- Apply skin preparation (eg. Comfeel) to the area to be taped.
- Apply non-allergic tape (eg. Fixomul, Hypafix) first, in all cases.
- Apply rigid strapping tape over the non-allergic tape. Ensure there is no rigid tape in direct contact with the skin.
- Tape should be applied in three strips, one vertically along the spine from T8 to S2, and two diagonally (approx 35 degree angle) from T8 to the opposite PSIS.
- Give the following instructions regarding the tape and its function:

  "Bend forward slowly for me… feel the tape pulling there? That is the limit of how far you should bend. When at home and at work if you feel the tape pulling it means you are bending your back too much and you should try and do the activity by bending your knees"

- Give the following warnings / information about the tape:

  "This is a waterproof tape, so it should dry off after you have a shower. It is also a low-allergy tape, so it should not cause any itching. However, if it does itch, or if it becomes annoying, then you must take it off. Otherwise, try to leave it on for the next 3-4 days. Take it off the day before you see me next time, and I can reapply some more tape then. It can take a couple hours to get used to the tape, and it may feel a little strange because it will limit your forward movement and keep you straight when you sit. But it usually stretches a bit after a couple of hours, so it won't stay quite this tight for long".

Appendix E continued

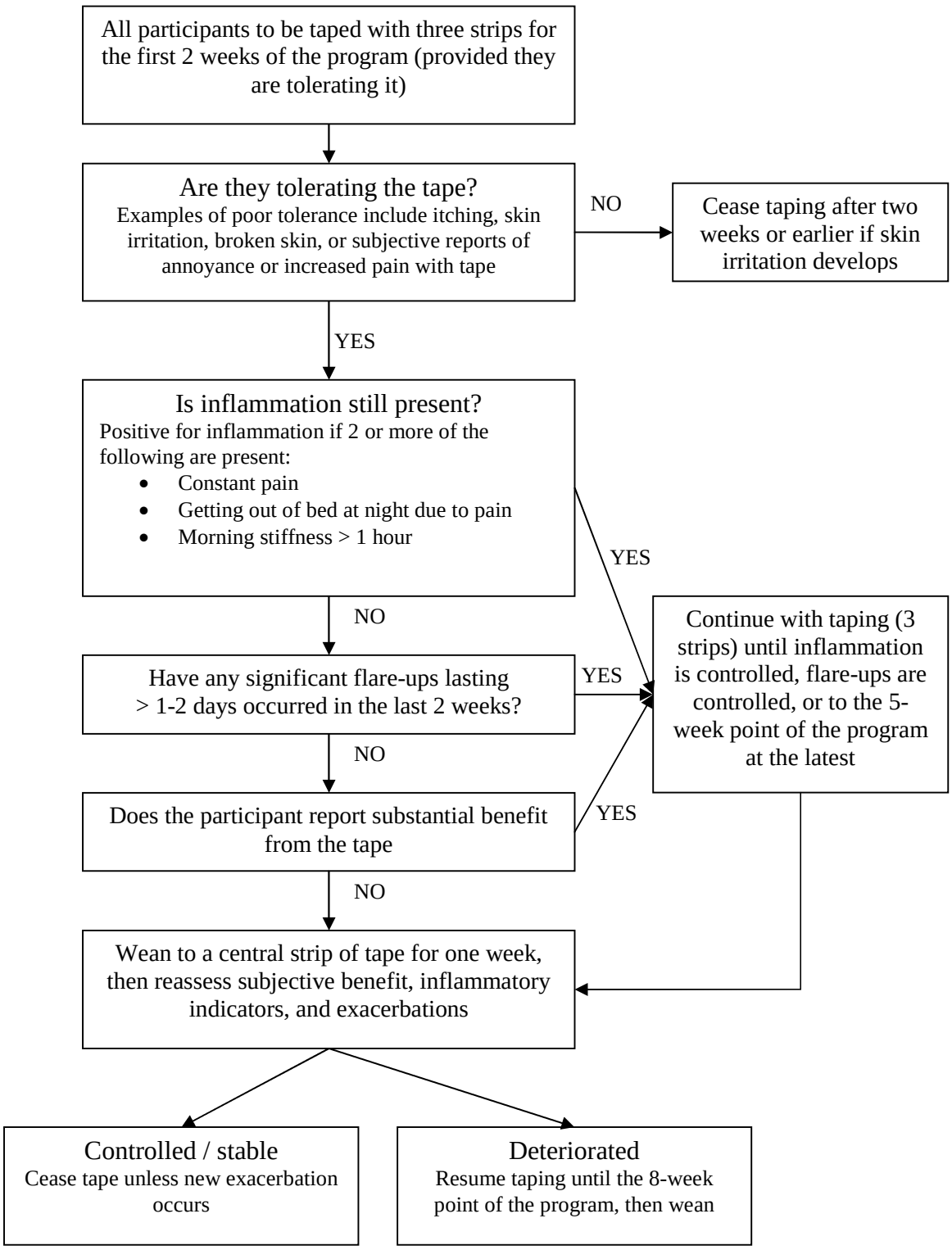


Lumbar spine taping protocol

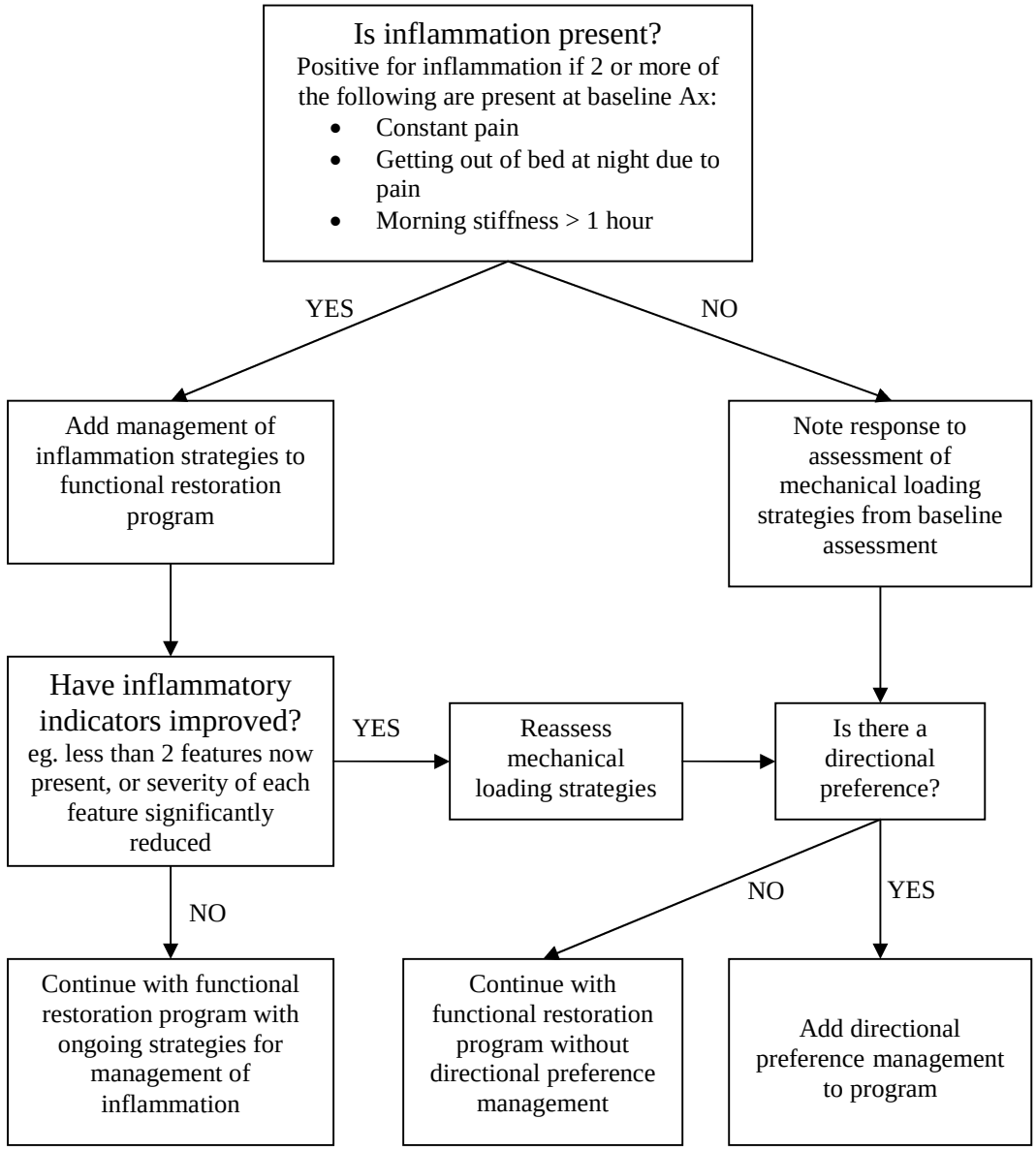
Tape weaning should be achieved firstly by reducing from three strips to one central strip (do once only). If no recurrence in symptoms occurs attributable to the tape weaning, the tape can be ceased. The tape should be re-applied during any future exacerbations where objective deterioration has occurred, even in participants who have been weaned off the tape.

Appendix E continued

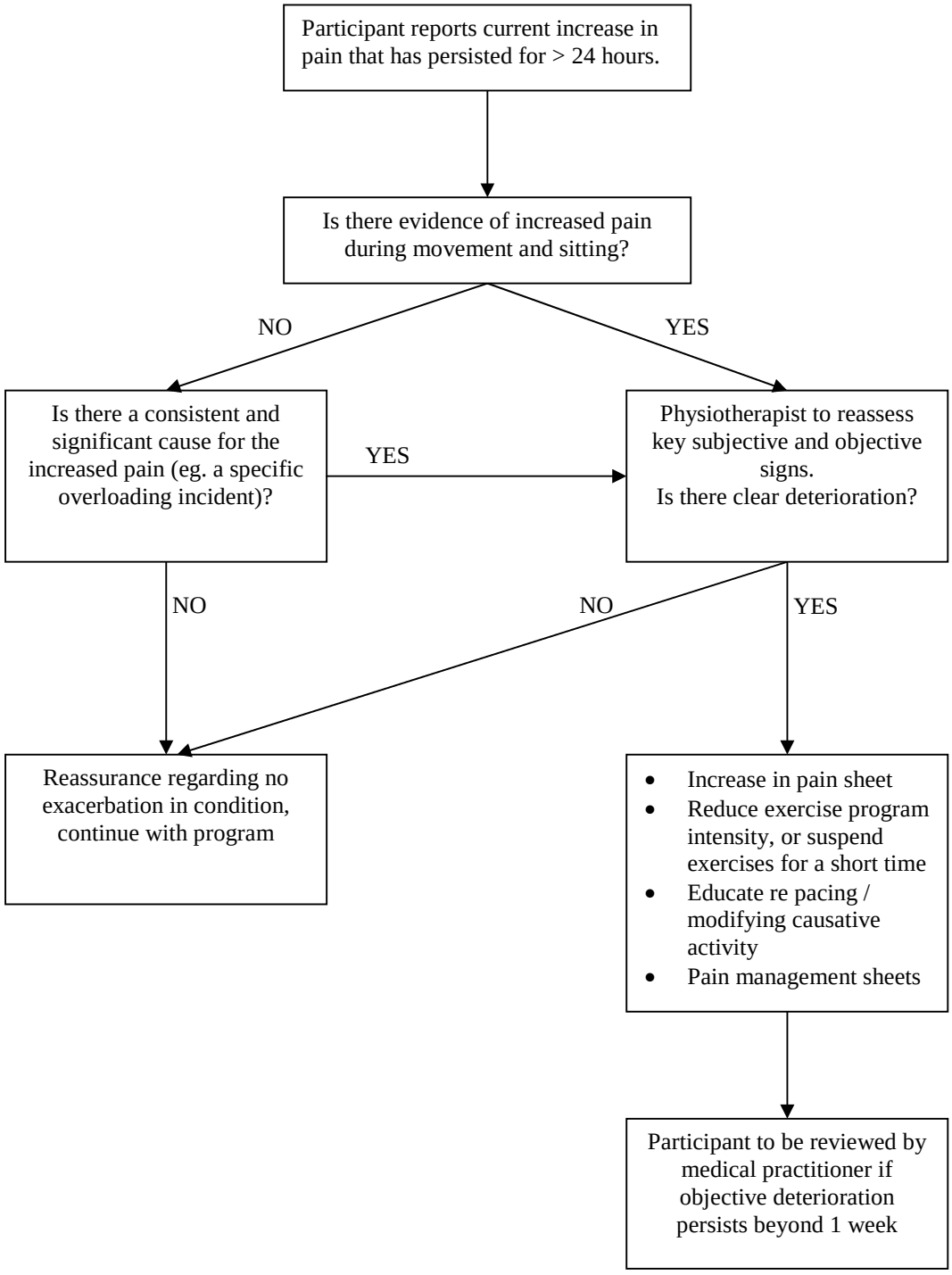
The decision making algorithm that guided the weaning and ceasing of taping is presented below:



Appendix F: Decision making algorithm for implementation of directional preference management into the functional restoration program



Appendix G: Decision making algorithm for dealing with an increase in pain during the functional restoration program



Appendix H: Clinical notes from Session 1 used by physiotherapists in the trial

Participant ID:

SESSION ONE

Date of session: Details of DNA / cancellations prior to this attendance?

Brief overview of the trial ☐

History and listening (to maximise a personalised explanation)

Complete a detailed body chart (clear all areas, ask relationship question) ☐

History of symptoms (from first episode) particularly thinking about relationships, mechanism of injury (refer back to this during later explanations):

History of other treatment/consultations in the past plus results/recommendations (refer back to this during later explanations:

Work status (record type of work, hours, duties, any issues, or state if not job attached):

Baseline asterisks (list only those related to the LBD): Refer back to these during flare-ups etc.

Medication type, dose (if known) and number per day:

Night waking frequency:

Getting out of bed frequency:

tolerance before P2:

tolerance before P2:

Current resting BACK pain out of 10:

Current resting LEG pain out of 10:

Other subjective asterisk name and score:

Other subjective asterisk name and score:

Extension in standing P1:

Other examination name and P1 range:

Appendix H continued

Presence of inflammation

Inflammation present (Yes/No):

(At least 2 of: constant symptoms, GOOB at night due to the pain, AM symptoms > 60 minutes)

Response to repeated movements (directional preference)

Check if there was a positive response to repeated movements at the baseline assessment:

- o Yes ☐ State mechanical loading strategy (eg. EIL)
- o No ☐

Session 1 treatment components (mandatory components underlined)

DHR diagnosis explanation (participant handout): ☐

Treatment options (participant handout): ☐

Program timeframes and expectations (participant handout) ☐

Ensure the participant is engaged, ask "how does that sound to you?" ☐

Taping (follow protocol on pages 66-67 of manual) ☐

Management of inflammation (if inflammation positive):

- o Refer to page 69 of manual and follow flow chart on page 83 of manual ☐
- o Inflammation (Info Sheet) ☐
- o NSAIDs - a minimum of Voltaren Rapid 25mg (100-150mg per day in 2-3 doses): (Progress to prescription based on clinical judgement) ☐
- o Walking to P1 2-4 times per day for 5-30 minutes and increase intensity beyond 2 x 30 minutes: ☐

Implementation of DPM (if no inflammation, and positive response to repeated movements at baseline)

- o Directional preference management for herniated discs (participant handout) ☐
- o Walking program (4 times per day, 10-15 minutes): ☐

Posture (participant handout, cover today only if time) ☐

Ask for and answer any participant questions: ☐

Note any other comments or deviations from standard protocol and reasons:

Appendix H continued

Post treatment

Record any adverse events (describe as mild, significant or serious) that occurred during or between the session(s):

Planning for next session

Homework prescribed with written clear instructions using Info Sheets:	☐
All Patient Info Sheets and written instructions placed in the Participant Folder:	☐
Remind participant to bring Participant Folder to next session:	☐
Take the participant to reception and book in 3-5 days post Day 1:	☐

Other comments:

Note: components that are underlined are compulsory.

A "minor adverse event" refers to any symptom or event reported by the participant that may potentially be related to the intervention including short-term pain associated with exercises.

A "significant" adverse event is any symptom or event potentially related to the intervention that interrupts the participant's ability to continue with the RCT intervention, or requires the participant to be referred to a medical practitioner. This does <u>not</u> include routine referrals back to medical practitioners for medication reviews. This <u>will</u> include:

- Deterioration in leg symptoms (pain, numbness, lower limb muscle strength) for more than 1 week
- Deterioration or new onset of shoulder symptoms that continue for more than 1 week
- Onset of saddle paraesthesia or urinary retention (immediate referral required)

A "serious" adverse event is any symptom or event potentially related to the intervention that results in admission to hospital, or permanent disability, or is life threatening.

Appendix I: Ethical approval for the randomised controlled trial

La Trobe University
Faculty of Health Sciences
MEMORANDUM

TO: Jon Ford
School of Physiotherapy

SUBJECT: *Reference:* **FHEC08/196**

Student or Other Investigator: Andrew Hahne

Title: **STOPSS (Specific treatment of problems of the spine study): A pilot randomised controlled trial comparing physiotherapy functional restoration and advice for people with lumbar disc herniation and associated radiculopathy**

DATE: 19 December, 2008

The Faculty Human Ethics Committee (FHEC) has considered and approved the project. You may now proceed.

Please note that the Informed Consent forms need to be retained for a minimum of 7 years. Please ensure that each participant retains a copy of the Informed Consent form. Researchers are also required to retain a copy of all Informed Consent forms separately from the data. The data must be retained for a period of 15 years.

Please note that any modification to the project must be submitted in writing to FHEC for approval. You are required to provide an annual report (where applicable) and/or a final report on completion of the project. A copy of the progress/final report can be downloaded from the following website:
www.latrobe.edu.au/rgso/forms-resources/forms/ethic-prog-final.rtf.

Please return the completed form to The Secretary, FHEC, Faculty of Health Sciences Office, La Trobe University, Victoria 3086.

If you have a student/s involved in this project, a copy of this memorandum is enclosed for you to forward to the student(s) concerned.

Natalie Humphries
Secretary
Faculty Human Ethics Committee
Faculty of Health Sciences

Appendix J: Examples of newspaper advertisements calling for volunteers to participate in the randomised controlled trial

Leader newspaper advertisement.

Shoppers guide advertisement.

Herald-sun classifieds advertisement.

Appendix K: A poster calling for volunteers to participate in the randomised controlled trial

Appendix L: Flyers left in doctor's clinics, pharmacies, and radiology clinics to supplement the posters

Appendix M: Phone screening form used for preliminary determination of eligibility for the trial

Date:_____ Screening sheet number: _____

Phone screening conducted by: _____

"Thank-you for enquiring about our research trial. I am one of the physiotherapists who treat people in the trial, which is going to compare two different physiotherapy treatment programs for people with low back problems or sciatica. People who are suitable for the trial and agree to participate will receive a free course of physiotherapy treatment for their back problem. Would you like me to ask you a few questions to see if you might be suitable?"

Participant (first and last name) : _____

DOB: _____(If less than 18 years old, or more than 65 = NOT eligible)

Gender: **M** ☐ **F** ☐

Suburb of residence: _____

Best contact phone number:_____ Alternative contact number: _____

How did you find out about the study? _____

Screening questions. Any ticks in shaded boxes = automatic exclusions.

	Yes	**No**	
Can you read English well enough to fill out some questionnaires? (NB. If significant difficulty understanding or speaking English during this phone call, exclude this patient)	☐	☐	
Have you got back pain, leg symptoms (pain, pins & needles, numbness) or both?		☐ Back ☐ Leg ☐ Both	
How long have you had your current episode of **back** pain for?	_____		
When was the last time that you went for a period of 4 weeks where you had no **back** pain?	_____		
Decide: is this person in a new current episode of back pain that has lasted between 6 weeks and 6 months, with no previous back pain greater than 6 months continuous with the current episode?	☐ duration _____	☐	If less than 6 weeks needs to wait
How long have you had your current episode of **leg** symptoms for?	_____		
When was the last time that you went for a period of 4 weeks where you had no **leg** symptoms?	_____		
Decide: is this person in a new current episode of leg symptoms that has lasted between 6 weeks and 6 months, with no previous leg symptoms greater than 6 months continuous with the current episode?	☐ duration _____	☐	If less than 6 weeks needs to wait

Appendix M continued

IF NO TO BOTH BACK AND LEG DURATION:	**Exclude**	☐	
IF YES TO <u>EITHER</u> BACK OR LEG DURATION: *	**Proceed**	☐	
	Yes	**No**	
Do you have a WorkCover, TAC, or a compensation claim for your back or leg problem?	☐	☐	
Have you had back surgery before?	☐	☐	
Have you had any injections in your back in the last 6 weeks?	☐	☐	If YES, needs to wait until 6/52 post
Are you currently planning to undergo back surgery or to receive any injections into your back in the next 3 months?	☐	☐	
On average over the last week, how severe would you rate your back or leg pain on a scale of 0 to 10, if 0 is no pain and 10 is the worst pain possible?	_____/10		IF less than 2/10 exclude
Does your back or leg pain stop you from walking more than 1km?	☐	☐	IF NO to all of these then exclude volunteer
Does your back or leg pain stop you from sitting more than 1 hour?	☐	☐	
Does your back or leg pain stop you from standing more than 1 hour?	☐	☐	
Does your back or leg pain disturb your sleep?	☐	☐	
Are you pregnant, or have you had a baby in the last 6 months?	☐	☐	
Have you had any physiotherapy treatment for your current episode of back / leg pain?	☐	☐	
IF yes, who was the physio and how many sessions?	_____		IF > 5 sessions with a Study Physio exclude
Aside from seeing your GP, are you having any treatment for your back at the moment such as physiotherapy, massage, chiropractic or pilates?	☐	☐	
<u>IF Yes</u>, "if you went in our trial, would you be willing to stop this treatment for the 10 weeks that the trial would go for?"	☐	☐	
Do you have cancer?	☐	☐	
"If you were accepted into the trial, you would need to attend one of our physiotherapy clinics in _____ (closest clinic) for a 30-minute physiotherapy session up to 10 times in a 10-week period. Do you think you would have the time to commit to this?"	☐	☐	

Appendix M continued

* Although back pain was not required for the present trial, participants without DHR were assessed for eligibility for trials investigating other low back pain subgroups at La Trobe University.

Is this patient eligible for the research project? yes ☐ no ☐ unclear/possible☐

Action required:

☐ **Arrange appointment for physical assessment:**

"You are most likely suitable for the trial, but to be sure of this I need you to come into one of our clinics where a trial physiotherapist can assess your back. The assessment will take 30-45 minutes, would be free, and if you were suitable treatment would start within a week of the assessment. Would you like me to arrange a time and place for you to do this assessment?

Appointment details: Physio _____ Clinic _____ Date _____ Time _____

"I will post you an information pack that contains information about the trial, and some questionnaires for you to fill our prior to the assessment. It is important that you fill out the questionnaires and bring them to your assessment. Can you please also bring along any x-rays or scans as well as any reports that you have for your back problem".

Address to post pack _____

Appendix N: Procedures undertaken at the interview and physical examination to confirm or refute the eligibility of potential trial participants

Each participant's eligibility was confirmed or refuted by a face-to-face interview and physical examination conducted by a treating physiotherapist. The content of this assessment is outlined below:

Interview

- The participant's pain drawing was checked by the physiotherapist and area's were cleared to ensure that no symptoms or locations had been missed. As discussed in Section 2.5.2.4, the pain drawing has been shown to be a reliable means of determining the presence and location of leg symptoms (Ford et al., 2009; Margolis et al., 1988) which is important information for diagnosing DHR (Section 2.5.2).
- A full history of the participant's back / leg symptoms was obtained through detailed questioning. This was to confirm that the participant was experiencing a new episode of leg symptoms, as well as to establish the duration of the episode.
- The radiologist's report from any CT or MRI scan reports were checked, with the details entered into the assessment spreadsheet.

Physical examination

- Lower limb neurological examination was undertaken with the participant in a seated position. This involved testing of knee jerk and ankle jerk reflexes, myotomal strength testing and dermatomal sensation in response to light touch with a tissue (Vroomen, de Krom, & Knottnerus, 2000). As discussed in Section 2.5.2.4, moderate to high levels of reliability have been demonstrated for these tests in people with suspected lower limb nerve root compression (Vroomen, de Krom, & Knottnerus, 2000).
- Straight-leg-raise testing was performed and was considered positive if the participant's usual lower limb symptoms were reproduced at any angle during passive raising of the leg by the physiotherapist (Vroomen, de Krom, & Knottnerus, 2000). As discussed in Section 2.5.2.4 the reliability of the SLR test has been shown to be good when tested on people with suspected lower limb

nerve root compression, especially when reproduction of usual leg symptoms is the definition of a positive test (Vroomen, de Krom, & Knottnerus, 2000).

- Prone knee flexion test, which was considered positive if the participant's usual anterior thigh symptoms were reproduced at any angle during passive knee flexion performed by the physiotherapist (Borenstein, Wiesel, & Boden, 2004; Herron & Pheasant, 1980). The reliability of this test has been shown to be good in people with suspected nerve root compression (see Section 2.5.2.4) (Vroomen, de Krom, & Knottnerus, 2000).

In addition to confirming eligibility, the assessment was used to gain information pertaining to the baseline characteristics of the participants. Subjective information relating to the history of the participant's back and leg symptoms, the mechanism of onset, as well as the nature and behaviour of symptoms, was obtained from the Subjective Complaints Questionnaire that was completed by all participants (Ford et al., 2009).

As part of the physical examination, the assessment of mechanical loading strategies was also performed to determine whether a DP was present. Mechanical loading strategies included sustained prone positioning and repeated extension movements in a prone position (with or without lateral shift of the pelvis). Directional preference was defined as the direction of movements or postures that produce either centralisation of symptoms, sustained decrease in symptoms (by at least 1 point on a 0-10 numerical rating scale), or improvement in range-of-motion following the assessment of mechanical loading strategies (Ford, Surkitt et al., 2011; Werneke, 2009; Werneke et al., 2010; Wetzel & Donelson, 2003). Assessing for a DP has been shown to be reliable (Fritz, Delitto, Vignovic, & Busse, 2000; Wetzel & Donelson, 2003). Although the presence of a DP was not required to be eligible for the trial, establishing this at baseline was an important baseline characteristic of the participants. In addition, the presence of a DP identified participants who would receive DPM as a treatment strategy if allocated to the FR group (see Chapter 5).

Appendix O: Participant information sheet for the randomised controlled trial

Spinal Management
Clinics of Victoria

PARTICIPANT INFORMATION SHEET

Project title: STOPS (Specific treatment of problems of the spine) Trial: A pilot randomised controlled trial comparing functional restoration and advice for people with lumbar disc herniation and associated radiculopathy.

Researchers:

Andrew Hahne, email: ajhahne@students.latrobe.edu.au

- Physiotherapist.
- Doctoral student, Low Back Pain Research Team, Musculoskeletal Research Centre, La Trobe University.
- Consulting physiotherapist, Spinal Management Clinics, LifeCare.

Dr. Jon Ford, email: j.ford@latrobe.edu.au

- Musculoskeletal Physiotherapist
- Research Fellow, Low Back Research Team, Musculoskeletal Research Centre, La Trobe University
- General Manager, Spinal Management Clinics, LifeCare

Professor Nicholas Taylor, email: n.taylor@latrobe.edu.au

- Physiotherapist
- Professor of Physiotherapy, School of Physiotherapy, La Trobe University and Eastern Health La Trobe University,

Dr. Rana Hinman, email: ranash@unimelb.edu.au

- Physiotherapist
- Senior lecturer, The University of Melbourne.

Emeritus Professor Joan McMeeken, email: j.mcmeeken@unimelb.edu.au

- Physiotherapist
- Professor Emeritus of The University of Melbourne.

Aims of project:

This project is part of Andrew Hahne's doctoral research being conducted through La Trobe University, which is being supervised by Dr. Ford, Professor Taylor, Dr. Hinman, and Professor McMeeken. The project aims to compare two different physiotherapy treatments for people with leg pain resulting from disc herniations (or "slipped discs"). The results of the project should help us to start to find out which physiotherapy treatment approaches are the most effective for people with your condition. Volunteers are being identified for this project through doctors, surgeons, physiotherapists, public flyers, and newspaper advertising.

Funding / sponsorship:

The treatment in the trial is being carried out at 14 different physiotherapy clinics within the network of Spinal Management Clinics, which is a sub-division of LifeCare Health/Health Networks Australia. LifeCare Health/Health Networks Australia are providing the treatment in this trial at no cost to participants.

Description of research procedures:

All eligible people who agree to participate in this project will be required to:

- Attend an assessment at the participating physiotherapy clinic closest to you. The physiotherapist will ask you questions about your back problem, and then perform a brief physical assessment to see if you fit the eligibility criteria for the study. During the physical assessment, the physiotherapist will ask to look at your lower back area, and they will assess how strong your stomach muscles are. They will measure how far you can bend your back forwards, backwards and side-ways. They will also lift your legs whilst you are lying on your back, press on your back to find any areas of pain, and check the reflexes, sensation, and muscle strength in your legs. You will also be asked to perform ten backward bending movements of your lower back whilst you are lying on your stomach. The assessment will take about 30 minutes.
- Complete a registration form, which will ask you to provide your name, date of birth, and contact details. You will also be asked to provide contact details for two alternative contact people (eg. friends or relatives). This will allow the researchers to still contact you in case you move house or change your phone number.
- Complete a set of written questionnaires at the first physiotherapy assessment. You will then be posted the same questionnaires after 5 weeks, 10 weeks, 6 months, 12 months and 24 months to complete, and a reply paid enveloped will be included for you to return them. The questionnaires ask about your pain, what medications you are taking for your back condition, and the way your condition affects your life and daily activities. The full set of questionnaires should take about 30 minutes to complete.
- You will be able to continue seeing your doctor or medical specialist, and you will be able to take any medications that are recommended by your doctor or pharmacist.
- During the first ten weeks of the trial, you will be asked to avoid having other treatments including surgery or injections. However, if your condition deteriorates or your doctor or specialist recommends that you need other treatments, then we will not stop you from having these.
- Attend a one-on-one interview with one of the researchers, at the end of the treatment program. You will be asked questions about how you found the treatment program, and any changes that you have noticed since commencing the treatment. The interview will take about 30-45 minutes, and will be voice recorded on a tape. The interview will then be transcribed into a manuscript. You will be sent a copy of the interview manuscript to check that it is accurate.

If you agreed to participate, you will be randomly assigned to receive one of two physiotherapy treatments. You will have a 50% chance of receiving either treatment, but we are not able to predict which treatment you will receive. The two physiotherapy treatments will involve:

1) Physiotherapy advice group
    - If you are assigned to this treatment you will attend two 30-minute sessions with the physiotherapist who assessed you. One session will be done shortly after you commence the trial, and the other will be about five-weeks later. At these sessions, the physiotherapist will give you information and advice about your condition, and recommend ways to manage your

condition at home. The physiotherapist will answer any questions or concerns that you may have about your condition. They will also give you some practical tips such as showing you how to lift correctly, and they will suggest some home exercises such as walking.

2) Physiotherapy functional restoration group
   - If you are assigned to this treatment you will attend ten 30-minute sessions with the physiotherapist who assessed you. The sessions will be spread over a 10-week period. During these sessions, the physiotherapist will give you information about your condition, and will show you ways to manage it. They will start you on an exercise program that you will perform in the clinic under supervision on each visit, and an additional 3-5 times per week at home. The exercises will involve gentle stomach strengthening exercises, walking, light arm weights, squats or lunges, stepping exercises, and back strengthening exercises. The exercise dosage will be chosen to suit you. You will be asked to keep a record of the days that you performed the exercises at home.
   - The physiotherapist will apply three strips of strapping tape to your back for 2-3 days at a time during the first 3-4 weeks of the treatment program. A non-allergy tape will be used to avoid any skin irritation.

Possible benefits:

By participating in this trial, you will receive free physiotherapy treatment for your condition. Based on previous research, we expect that many participants in both of the physiotherapy treatment groups will benefit from participating in this project. Possible benefits may include improved pain and improved ability to perform activities. However, we cannot guarantee that you will benefit from participating in the trial.

Your participation in this research should help us to start to work out which of the two physiotherapy treatments are more effective for treating people with conditions like yours. This may benefit other people with this condition in the future by ensuring that physiotherapists can offer them the best treatment.

Possible risks:

It is not expected that participation in this trial will pose any significant health risks to you. Some people who do the functional restoration treatment may experience some mild discomfort in their stomach, shoulders, knees, arms or legs from undertaking some of the exercises, but this would normally be expected to resolve within 1-2 days. In addition, some people who have the functional restoration treatment may experience a minor increase in their usual back or leg symptoms during or after the exercises, but these would normally be expected to resolve within 1-2 hours of completing the exercises. The risk of discomfort or increased symptoms will be minimized by the fact that exercises will be supervised by an experienced physiotherapist. Your physiotherapist will also be able to modify the dosage of exercises to reduce any discomfort that may be experienced.

To minimize risks, people will NOT be eligible to participate if they are pregnant, have disturbed bladder or bowel function due to their back condition, have deteriorating weakness if their leg or foot muscles due to their back condition, are unable to walk safely, or have spinal stenosis or spondylolisthesis. If any signs of significant deterioration in your condition were to occur during the trial, we would refer you to your medical practitioner for further investigations or management and you may cease the trial if they recommend this.

Use of data and confidentiality:

Your personal details and identity will be known only by the treating physiotherapist, the principal researcher (Mr. Andrew Hahne), and an administrative assistant. Your personal records will be stored in secure locations such as locked filing cabinets, and amongst the other medical records at your treating physiotherapy clinic. An identification code rather than your name will be written on questionnaires that you fill in. You will therefore remain anonymous throughout the study.

If you participate in the one-on-one interview with Mr. Hahne at the completion of the functional restoration treatment, the tape recorded interview and resultant manuscript will not contain your name. You will have an opportunity to check the manuscript for accuracy before it is used in any reports.

The results of this study will be shared through journal articles, conference presentations, and a thesis completed by Mr. Hahne. You will not be identifiable in any of these reports. It is possible that the data may be used for other research projects by members of the La Trobe University Low Back Research Team in the future to answer different research questions. This would only occur with the permission of the current researchers, and none of your personal or identifiable information would be given to other researchers.

All computer records relating to this study will be kept on password-protected computers of Mr. Hahne, Dr. Ford, and Professor Taylor. All hard-copy records will be kept at your treating physiotherapy clinic, and in a locked filing cabinet at La Trobe University, Bundoora, for a period of 15 years after publication. The raw data and computer files will then be destroyed.

Project results:

If you would like to know your individual results or the results of the trial overall, a summary of these will be available from Mr. Hahne upon request.

Follow-up procedures:

If you choose to participate in the trial, we will send questionnaires to your nominated address after 5 weeks, 10 weeks, 6 months, 12 months and 24 months to measure your progress. While your name will not appear on the questionnaire, they will be coded so we can tell if you have returned them or not. If you do not complete and return the questionnaires within one-week of receiving them, your treating physiotherapist or one of the researchers will contact you or one of the alternative contact people that you designated on your personal details form.

Participation is voluntary:

Participation in this research project is voluntary, and hence you are not obliged to take part. You are also free to withdraw from the project at a later stage if you change your mind.

If you choose not to participate, or withdraw from the project at a later stage, there will be no penalties for this decision. However, you will only receive the free physiotherapy treatment offered in this research trial if you agree to participate. If you do not participate, or if you withdraw from the trial at a later stage, your treating physiotherapist will still be willing to treat you for their normal consultation fee.

Declaration of dual interests

Please note that Dr Jon Ford is the supervisor of La Trobe University higher degree research students involved in conducting this project and is also a partner of the

LifeCare/Spinal Management Clinics where the treatment for the project will occur. Some of the higher degree students are also engaged in providing physiotherapy services from LifeCare/Spinal Management Clinics.

In the event of any opportunities for financial benefit arising as a result of the trial, the researchers would negotiate with the Doctoral Candidate their potential role in realising and benefiting from the opportunity. The roles of each researcher would be defined according to the level and significance of their input into the trial. If consensus was not reached an additional party, with no direct relationship to the research, would be appointed by the Physiotherapy Head of School to resolve the conflict.

Further questions or information:

If you have any questions or want further information regarding this trial, you can contact the principal researcher, Dr Jon Ford on 0422 244 183 or j.ford@latrobe.edu.au, Mr. Andrew Hahne on 0408 148 720 or ajhahne@students.latrobe.edu.au, or Prof. Nicholas Taylor on 03 9479 5815 or n.taylor@latrobe.edu.au

Complaints:

If you have any complaints that the investigator has not been able to answer to your satisfaction, you may contact Natalie Humphries, Secretary, Faculty Human Ethics Committee, Faculty of Health Sciences, La Trobe University, Victoria, 3086 (Ph. 03 9479 3573, e-mail: n.humphries@latrobe.edu.au).

Withdrawing from the project:

You have the right to withdraw from active participation in this project at any time. If you are unable to continue with the treatment for any reason, we would still value your responses on the follow-up questionnaires that we send to you. However, if you wish to take no further part in the project (including the follow-up questionnaires), you may withdraw from the project completely.
Furthermore, you may demand that existing data arising from your participation are not used in the research project provided that this right is exercised within four weeks of the completion of your participation in the project. **If this is the case, you are asked to complete the "Withdrawal of Consent Form" or to notify one of the researchers by e-mail or telephone that you wish to withdraw your consent for your data to be used in this research project.**

Appendix P: Consent form for the randomised controlled trial

Spinal Management
Clinics of Victoria

Consent form

Version 1, 25/11/08

Project title: STOPS (Specific Treatment of Problems of the Spine) Trial: A pilot randomised controlled trial comparing physiotherapy functional restoration and advice for people with lumbar disc herniation and associated radiculopathy.

Please read the "participant information form" prior to signing this consent form. If you wish to enrol in the above project, please read the following statement, and sign and date the form below if you agree with the statement and wish participate in the study:

> "I (the participant) have read (or, where appropriate, have had read to me) and understood the **participant information sheet**, and any questions I have asked have been answered to my satisfaction. I agree to participate in the project, realising that I may physically withdraw from the study at any time and may request that no data arising from my participation are used, up to four weeks following the completion of my participation in the research. I agree that research data provided by me or with my permission during the project may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used."

Name of Participant (printed):_____

Signature: _____Date _____

Name of Investigator (printed):_____

Signature: _____Date _____

Name of Student Supervisor (printed):_____Date: _____

Appendix Q: Baseline self-administered questionnaires

Spinal Management
Clinics of Victoria

Please write your name here: _____

Please write you date of birth here: _____/_____/_____

In order for us to determine whether you are eligible to participate in the trial, we need to find out some detailed information about your low back and leg (sciatica) problem. Please complete the following questionnaires **before** you attend for your physiotherapy assessment. If you do participate in the trial, some of these questionnaires will be sent to you to complete again after 5 weeks, 10 weeks and 6 months, and these will be used to asses any changes that may be occurring in your condition.

It is important that you answer **all** questions. If you are unsure what a particular question is asking, answer all of the questions that you can, and then ask the physiotherapist at your assessment to help you with any questions you have not understood.

Your answers to the questions on the following pages will remain confidential. When we receive your completed questionnaire booklet, we will remove your name and date of birth and replace these with an identification number. This identification number will allow us to analyse data without using your name. Please leave this cover page attached, and keep all the pages intact, otherwise we will not know who this booklet belongs to.

Identification number:_____

1. Please write the date that you filled out this questionnaire booklet: _____ / _____ / _____

2. Please rate your **back** pain by circling the number below that best describes your pain on average over the last week

0 1 2 3 4 5 6 7 8 9 10
No pain *Worst pain possible*

3. Please rate your **leg** pain by circling the number below that best describes your pain on average over the last week

0 1 2 3 4 5 6 7 8 9 10
No pain *Worst pain possible*

4. OSWESTRY DISABILITY QUESTIONNAIRE (modified)

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking **one box in each section** for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement ***which most clearly describes your problem.***

Section 1: Pain Intensity
☐ I have no pain at the moment
☐ The pain is very mild at the moment
☐ The pain is moderate at the moment
☐ The pain is fairly severe at the moment
☐ The pain is very severe at the moment
☐ The pain is the worst imaginable at the moment

Section 2: Personal Care (Washing, Dressing, etc.)
☐ I can look after myself normally without causing extra pain
☐ I can look after myself normally but it causes extra pain
☐ It is painful to look after myself and I am slow and careful
☐ I need some help but can manage most of my personal care
☐ I need help every day in most aspects of self care
☐ I do not get dressed, wash with difficulty and stay in bed

Section 3: Lifting
☐ I can lift heavy weights without extra pain
☐ I can lift heavy weights but it gives me extra pain
☐ Pain prevents me lifting heavy weights off the floor but I can manage if they are conveniently placed e.g. on a table
☐ Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
☐ I can only lift very light weights
☐ I cannot lift or carry anything

Section 4: Walking
☐ Pain does not prevent me walking any distance
☐ Pain prevents me from walking more than 2 kilometres
☐ Pain prevents me from walking more than 1 kilometre
☐ Pain prevents me from walking more than 500 metres
☐ I can only walk using a stick or crutches
☐ I am in bed most of the time

Section 5: Sitting
☐ I can sit in any chair as long as I like
☐ I can only sit in my favourite chair as long as I like
☐ Pain prevents me sitting more than one hour
☐ Pain prevents me from sitting more than 30 minutes
☐ Pain prevents me from sitting more than 10 minutes
☐ Pain prevents me from sitting at all

Section 6: Standing
☐ I can stand as long as I want without extra pain
☐ I can stand as long as I want but it gives me extra pain
☐ Pain prevents me from standing for more than 1 hour
☐ Pain prevents me from standing for more than 30 minutes
☐ Pain prevents me from standing for more than 10 minutes
☐ Pain prevents me from standing at all

Section 7: Sleeping
☐ My sleep is never disturbed by pain
☐ My sleep is occasionally disturbed by pain
☐ Because of pain I have less than 6 hours sleep
☐ Because of pain I have less than 4 hours sleep
☐ Because of pain I have less than 2 hours sleep
☐ Pain prevents me from sleeping at all

Section 8: Social Life
☐ My social life is normal and gives me no extra pain
☐ My social life is normal but increases the degree of pain
☐ Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport
☐ Pain has restricted my social life and I do not go out as often
☐ Pain has restricted my social life to my home
☐ I have no social life because of pain

Section 9: Traveling
☐ I can travel anywhere without pain
☐ I can travel anywhere but it gives me extra pain
☐ Pain is bad but I manage journeys over two hours
☐ Pain restricts me to journeys of less than one hour
☐ Pain restricts me to short necessary journeys under 30 minutes
☐ Pain prevents me from traveling except to receive treatment

Section 10: Work/Housework
☐ My normal housework/work activities do not cause pain.
☐ My normal housework/work activities increase my pain, but I can still perform all that is required of me.
☐ I can perform most of my housework/work activities, but pain prevents me from performing more physically stressful activities (eg lifting, vacuuming).
☐ Pain prevents me from doing anything but light housework/work duties.
☐ Pain prevents me from doing even light housework/work duties.
☐ Pain prevents me from performing any housework/work duties.

5. How often in the PAST WEEK have you had each of the following symptoms? (please circle one number for each symptom)

	Not at all	Very rarely	A few times	About half the time	Usually	Almost always	Always
1. Low back pain	0	1	2	3	4	5	6
2. Leg pain (sciatica)	0	1	2	3	4	5	6
3. Numbness or tingling in leg, foot, or groin	0	1	2	3	4	5	6
4. Weakness in leg or foot (e.g. difficulty lifting foot)	0	1	2	3	4	5	6
5. Back or leg pain while sitting	0	1	2	3	4	5	6

6. On a scale of 0 to 6, please rate the following symptoms according to how bothersome they were in the PAST WEEK: (please circle one number for each symptom)

	Not bothersome			Somewhat bothersome			Extremely bothersome
1. Low back pain	0	1	2	3	4	5	6
2. Leg pain (sciatica)	0	1	2	3	4	5	6
3. Numbness or tingling in leg, foot, or groin	0	1	2	3	4	5	6
4. Weakness in leg or foot (e.g. difficulty lifting foot)	0	1	2	3	4	5	6
5. Back or leg pain while sitting	0	1	2	3	4	5	6

7. We would like to know what other treatments you have tried for your current back problem before you commenced this trial. Please indicate by ticking the boxes below if you have had any of the following treatments for your back / leg problem (tick all relevant boxes)

☐ Seen my general practitioner (doctor).
If you have seen your doctor, how many visits have you had? _____

☐ Seen a surgeon.
If you have seen a surgeon, how many visits have you had? _____

☐ Seen another specialist doctor (eg. rheumatologist, sports physician)
If you have, how many visits and what type of specialist did you see?

_____

☐ Seen a chiropractor.
If you have seen a chiropractor, how many visits have you have? _____

☐ Seen an osteopath.
If you have seen an osteopath, how many visits have you have? _____

☐ Seen a massage therapist.
If you have seen a massage therapist, how many visits have you have? _____

☐ Seen a physiotherapist.
If you have seen a physiotherapist, how many visits have you have? _____

☐ Had acupuncture.
If you have had acupuncture, how many visits have you have? _____

☐ Had an injection into your back (eg. an epidural or nerve block). If so, please indicate the date and type of injection?

_____

☐ Had back surgery.
If you have had back surgery, indicate the date and type of surgery:

_____

☐ Any other treatments? If you have, please state:

_____

8. Prior to commencing in this trial, how satisfied have you been with your overall healthcare / treatment for your current episode of low back pain or leg symptoms (sciatica)? (tick one box)

☐ Very dissatisfied ☐ Somewhat dissatisfied ☐ Neither satisfied nor dissatisfied ☐ Somewhat satisfied ☐ Very satisfied

9. Prior to commencing in this trial, how satisfied have you been with **the results** of your overall healthcare / treatment for your current episode of low back pain or leg symptoms (sciatica)? (tick one box)

☐ Very dissatisfied ☐ Somewhat dissatisfied ☐ Neither satisfied nor dissatisfied ☐ Somewhat satisfied ☐ Very satisfied

10. If you had to spend the rest of your life with the back or leg symptoms you have right now, how would you feel about it? (tick one box)

☐ Very dissatisfied ☐ Somewhat dissatisfied ☐ Neither satisfied nor dissatisfied ☐ Somewhat satisfied ☐ Very satisfied

11. Since your current episode of low back or leg trouble (sciatica) began, approximately how many days did this problem prevent you from going to work or school?

_____ days

12. During the past 4 weeks (30 days), how many days did low back pain or leg pain (sciatica) prevent you from going to work or school?

_____ days

13. During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)? (please tick one box)

☐ Not at all ☐ A little bit ☐ Moderately ☐ Quite a bit ☐ Extremely

14. Are you currently: (please tick one box)

☐ Working full-time ☐ Working part-time ☐ Not working

15. If you are working, are you:

☐ employed at your usual job

☐ on light duties or some restricted work assignment

☐ employed at a different job compared to the job you had when you were injured

16. If you are not working, what is the reason for this?

- ☐ paid leave/sick leave because of low back problems
- ☐ paid leave/sick leave because of other reason(s)
- ☐ unpaid leave
- ☐ unemployed because of low back problems
- ☐ unemployed because of other reason(s)
- ☐ student
- ☐ keeping house/ homemaker
- ☐ retired
- ☐ on a disability pension

17. Prior to developing your current episode of low back or leg (sciatica) trouble, were you:

☐ Working full-time ☐ Working part-time ☐ Not working

18. If you were working, were you:

- ☐ employed at your usual job
- ☐ on light duties or some restricted work assignment

19. If you were not working, what was the reason for this?

- ☐ paid leave/sick leave because of low back problems
- ☐ paid leave/sick leave because of other reason(s)
- ☐ unpaid leave
- ☐ unemployed because of low back problems
- ☐ unemployed because of other reason(s)
- ☐ student
- ☐ keeping house/ homemaker
- ☐ retired
- ☐ on a disability pension

20. Please write down any medications you took for your back or leg condition **in the last 24-hours**. (Include medication prescribed by your doctor as well as other medication).

Name of medication	**Number of tablets taken in the last 24-hours**	**Medication strength as shown on the pack (mg)**
Example: Panadol	*2*	*500mg*
1		
2		
3		
4		
5		
6		
7		
8		

21. By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking around	❑	PLEASE TICK
I have some problems in walking around	❑	ONE BOX
I am confined to bed	❑	

Personal Care

I have no problems with personal care	❑	PLEASE TICK
I have some problems washing or dressing myself	❑	ONE BOX
I am unable to wash or dress myself	❑	

Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities	❑	PLEASE TICK
I have some problems with performing my usual activities	❑	ONE BOX
I am unable to perform my usual activities	❑	

Pain/Discomfort

I have no pain or discomfort	❑	PLEASE TICK
I have moderate pain or discomfort	❑	ONE BOX
I have extreme pain or discomfort	❑	

Anxiety/Depression

I am not anxious or depressed	❑	PLEASE TICK
I am moderately anxious or depressed	❑	ONE BOX
I am extremely anxious or depressed	❑	

22. To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today

23. # Orebro Musculoskeletal Pain Screening Questionnaire

4. **Where do you have pain? Place a tick for all appropriate sites.**

❑ neck ❑ shoulders ❑ upper back ❑ lower back ❑ leg Other (please state)_____

5. **How many days of work have you missed because of pain during the past 18 months? Tick one**

❑ 0 days [1] ❑ 1-2 days[2] ❑ 3-7 days [3] ❑ 8-14 days [4] ❑ 15-30 days [5]

❑ 1 month [6] ❑ 2 months [7] ❑ 3-6 months [8] ❑ 6-12 months [9] ❑ over 1 year [10]

6. **How long have you had your current pain problem? Tick one**

❑ 0-1weeks [1] ❑ 1-2 weeks [2] ❑ 3-4 weeks [3] ❑ 4-5 weeks [4] ❑ 6-8 weeks [5]

❑ 9-11 weeks [6] ❑ 3-6 months [7] ❑ 6-9 months [8] ❑ 9-12 months [9] ❑ over 1 year [10]

7. **Is your work heavy or monotonous? Circle the best alternative.**

0 1 2 3 4 5 6 7 8 9 10
Not at all *Extremely*

8. **How would you rate the pain that you have had during the past week? Circle one.**

0 1 2 3 4 5 6 7 8 9 10
No pain *Pain as bad as it could be*

9. **In the past 3 months, on average, how bad was your pain? Circle one.**

0 1 2 3 4 5 6 7 8 9 10
No pain *Pain as bad as it could be*

10. **How often would you say that you have experienced pain episodes, on average, during the past 3 months? Circle one.**

0 1 2 3 4 5 6 7 8 9 10
Never *Always*

11. **Based on all the things you do to cope, or deal with your pain, on an average day, how much are you able to decrease it? Circle one (10-)**

0 1 2 3 4 5 6 7 8 9 10
Can't decrease it at all *Can decrease it completely*

12. **How tense or anxious have you felt in the past week? Circle one.**

0 1 2 3 4 5 6 7 8 9 10
Absolutely calm and relaxed *As tense and anxious as I've ever felt*

13. **How much have you been bothered by feeling depressed in the past week? Circle one.**

0 1 2 3 4 5 6 7 8 9 10
Not at all *Extremely*

14. **In your view, how large is the risk that your current pain may become persistent? Circle one.**

0 1 2 3 4 5 6 7 8 9 10
No risk *Very large risk*

15. **In your estimation, what are the chances that you will be working in 6 months? Circle one (10-)**

0 1 2 3 4 5 6 7 8 9 10
No chance *Very large chance*

16. **If you take into consideration your work routines, management, salary, promotion possibilities and work mates, how satisfied are you with your job? Circle one (10-)**

0 1 2 3 4 5 6 7 8 9 10
Not satisfied at all *Completely satisfied*

Here are some of the things which other people have told us about their pain. For each statement please circle one number from 0 to 10 to say how much physical activities, such as bending, lifting, walking or driving would affect your pain.

17. **Physical activity makes my pain worse.**

0 1 2 3 4 5 6 7 8 9 10
Completely disagree *Completely agree*

18. **An increase in pain is an indication that I should stop what I'm doing until the pain decreases.**

0 1 2 3 4 5 6 7 8 9 10
Completely disagree *Completely agree*

19. **I should not do my normal work with my present pain.**

0 1 2 3 4 5 6 7 8 9 10
Completely disagree *Completely agree*

Here is a list of 5 activities. Please circle the one number which best describes your current ability to participate in each of these activities (10-)

20. **I can do light work for an hour.**

0 1 2 3 4 5 6 7 8 9 10
Can't do it because pain problem *Can do it without pain being a problem*

21. **I can walk for an hour.**

0 1 2 3 4 5 6 7 8 9 10
Can't do it because pain problem *Can do it without pain being a problem*

22. **I can do ordinary household chores.**

0 1 2 3 4 5 6 7 8 9 10
Can't do it because pain problem *Can do it without pain being a problem*

23. **I can go shopping.**

0 1 2 3 4 5 6 7 8 9 10
Can't do it because pain problem *Can do it without pain being a problem*

24. **I can sleep at night.**

0 1 2 3 4 5 6 7 8 9 10
Can't do it because pain problem *Can do it without pain being a problem*

PATIENT DETAILS

Date of birth	_____ / _____ / _____

Gender	☐ male ☐ female

Current postcode	_____
Current occupation	_____
Weight (in kilograms)	_____
Height (in centimeters)	_____

Highest level of education?	☐ completed primary school ☐ completed secondary school ☐ completed tertiary course

In what country were your parents born?	☐ both in Australia ☐ one in Australia ☐ both overseas

Are you a smoker?	☐ yes ☐ no

If you are a smoker, on average, how many cigarettes do you smoke a day?	☐ less than 10 ☐ 10 - 20 ☐ more than 20

ARE YOUR SYMPTOMS STABLE?

Have you taken any tablets for your back today?	☐ No ☐ 1 to 3 tablets ☐ 4 to 6 tablets ☐ more than 6 tablets

If you have taken tablets today, what kind were they?	☐ not applicable ☐ pain killers ☐ anti-inflammatory ☐ muscle relaxant ☐ anti-depressant ☐ don't know ☐ other (please describe) _____ _____

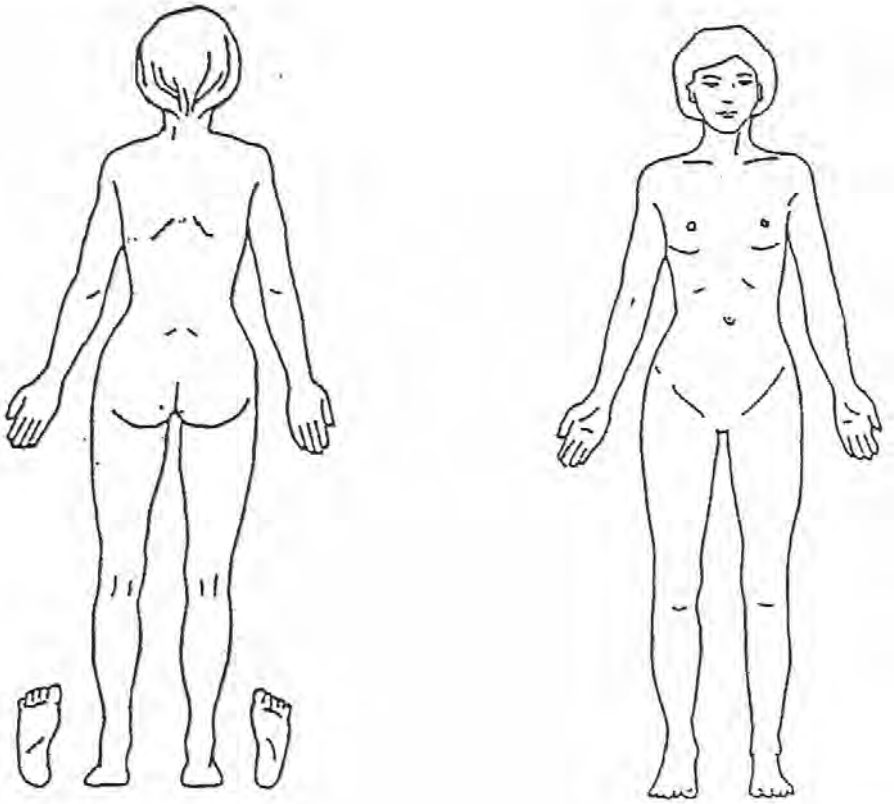
A "flare up" is a period of 1 - 14 days where your symptoms are much worse than normal. Are you currently experiencing a "flare up"?	☐ yes ☐ no

Have you done anything today or yesterday that has aggravated your pain?	☐ yes ☐ no If yes please describe _____ _____ _____

WHERE ARE YOUR SYMPTOMS?

- Mark the areas where you feel the described symptoms that come from your back
- Be as exact as possible in marking where the symptoms begin and end on the body
- Use the appropriate symbols
- Include all affected areas

Dull Aching		Burning		Numb	
Stabbing		Pins and Needles		Cramp	



SYMPTOM DETAILS

In the past 3 days have you had pins and needles or numbness below your waist that is related to your back problem?	☐ yes ☐ no (If the answer is yes please ensure you have marked the location on the previous page)
In the past 3 days where has your most severe pain been? Please tick only one box.	☐ back ☐ buttock(s) ☐ groin (s) ☐ upper leg(s) ☐ lower leg(s) ☐ foot / feet
In the past 3 days have you experienced "foot drop" or difficulty rising up onto your toes?	☐ yes ☐ no
Over the past 3 days do your symptoms in the back feel mostly deep inside or more on the surface?	☐ deep ☐ on the surface ☐ not applicable
Over the past 3 days do your symptoms in the leg feel mostly deep inside or more on the surface?	☐ deep ☐ on the surface ☐ not applicable
If you have leg and back symptoms, are they related? For example when your back gets worse, does your leg also get worse?	☐ yes ☐ no ☐ not applicable

WHAT POSITIONS AND ACTIVITIES ARE LIMITED BY YOUR SYMPTOMS?

For us to understand your back problem it is important that we know how your symptoms feel with different positions and activities.

For each position or activity tick the box next to the answer that best matches your problem over the last 24 hours. Please answer all questions.

For example, if you had to stop walking after 15 minutes because of your low back symptoms you would tick the box "15 minutes".

Pain prevents me from walking longer than:	☐ at least 30 minutes ☐ 30 minutes ☐ 15 minutes ☐ 5 minutes ☐ cannot do at all
Pain prevents me from standing in one place without moving or shifting weight longer than:	☐ at least 30 minutes ☐ 30 minutes ☐ 15 minutes ☐ 5 minutes ☐ cannot do at all
Pain prevents me from sitting with my backside against the backrest of a firm chair longer than:	☐ at least 30 minutes ☐ 30 minutes ☐ 15 minutes ☐ 5 minutes ☐ cannot do at all
Pain prevents me from sitting in a soft couch in a slouched position longer than:	☐ at least 30 minutes ☐ 30 minutes ☐ 15 minutes ☐ 5 minutes ☐ cannot do at all

Pain prevents me from lying on my back longer than:	☐ at least 30 minutes ☐ 30 minutes ☐ 15 minutes ☐ 5 minutes ☐ cannot do at all ☐ not applicable

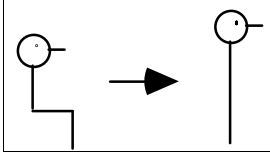
Pain prevents me from lying on my stomach longer than:	☐ at least 30 minutes ☐ 30 minutes ☐ 15 minutes ☐ 5 minutes ☐ cannot do at all ☐ not applicable

WHICH POSITIONS AND ACTIVITIES DO YOU FIND DIFFICULT?

Following are some further positions and activities that you may find difficult. For each position or activity circle the number or tick the box next to the answer that best matches your problem over the last 24 hours. Please answer all questions.

How difficult is getting into a car as a result of your symptoms?	0 = not difficult at all 1 = minimally difficult 2 = somewhat difficult 3 = fairly difficult 4 = very difficult 5 = unable to do

If getting into a car is difficult because of your symptoms which part of the activity is most difficult?	☐ bending the back to sit down ☐ twisting the back ☐ lifting the legs into the car ☐ ducking the head ☐ not applicable

How difficult is standing up from sitting as a result of your symptoms? 	0 = not difficult at all 1 = minimally difficult 2 = somewhat difficult 3 = fairly difficult 4 = very difficult 5 = unable to do

If standing up from sitting is difficult because of your symptoms, which part of the activity is most difficult?	☐ leaning forward to get up ☐ straightening up your back from a bent position ☐ not applicable

WHICH ACTIVITIES DO YOU FIND DIFFICULT? (CONTINUED)

How difficult is coughing or sneezing as a result of your symptoms?	0 = not difficult at all 1 = minimally difficult 2 = somewhat difficult 3 = fairly difficult 4 = very difficult 5 = unable to do

When lying down on your side, is it sorer to lie on one side than the other?	☐ yes ☐ no

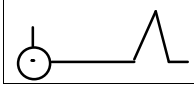
If so, which side is the <u>most</u> comfortable to lie on?	☐ the sore side ☐ the good side ☐ not applicable

How difficult is forward bending?	0 = not difficult at all 1 = minimally difficult 2 = somewhat difficult 3 = fairly difficult 4 = very difficult 5 = unable to do

How difficult is lifting objects from the floor to waist level?	0 = not difficult at all 1 = minimally difficult 2 = somewhat difficult 3 = fairly difficult 4 = very difficult 5 = unable to do

WHAT RELIEVES YOUR SYMPTOMS?

Consider the following activities / positions. Do they relieve your symptoms? Please tick the appropriate box. Choose one answer only that best matches your problem over the last 24 hours.

Standing in one place without moving or shifting weight	☐ yes ☐ no
Sitting with you backside against the backrest of a firm chair	☐ yes ☐ no
Sitting in a soft couch slouched	☐ yes ☐ no
Walking short distances (For example one block)	☐ yes ☐ no
Lying on your back	☐ yes ☐ no
Lying on your back with your legs bent 	☐ yes ☐ no
Lying on your sore side	☐ yes ☐ no ☐ not applicable
Lying on your good side	☐ yes ☐ no ☐ not applicable

WHAT RELIEVES YOUR SYMPTOMS? (CONTINUED)

Lying on your stomach	☐ yes ☐ no

Other activities that ease your symptoms?

Please describe:_____

_____

HISTORY OF YOUR SYMPTOMS

The following section of the questionnaire relates to the history of your symptoms. Please answer all the following questions by ticking the box. Choose one answer only that best matches your problem .

Is this the first episode of low back or leg symptoms in your life?	☐ yes ☐ no
How many weeks has this episode of **leg** symptoms lasted?	_____ weeks
How many weeks has this episode of **back** symptoms lasted?	_____ weeks
If this is not the first episode of symptoms how many episodes have you had in your life?	☐ up to 4 ☐ more than 4 ☐ not applicable
If this is not the first episode of symptoms, when was your first episode?	☐ less than 1 month ago ☐ 2 - 6 months ago ☐ 6 - 12 months ago ☐ 1 - 2 years ago ☐ more than 3 years ago ☐ not applicable
Since your first episode how often have you had symptoms?	☐ less than half the time ☐ more than half the time ☐ constantly

HISTORY OF YOUR SYMPTOMS (CONTINUED)

Describe the <u>first time</u> your symptoms came on	☐ symptoms came on suddenly due to a specific cause ☐ symptoms came on suddenly for no apparent reason ☐ symptoms came on gradually due to a specific cause ☐ symptoms came on gradually for no apparent reason ☐ can't remember ☐ other (describe) _____ _____

If your symptoms came on due to a specific cause, please describe this	_____ _____

When your symptoms came on, were you	☐ bending forward ☐ twisting ☐ lifting ☐ combination of the above ☐ none of the above ☐ can't remember

At what time of day did the symptoms come on?	☐ morning ☐ afternoon ☐ evening ☐ night time ☐ can't remember

HISTORY OF YOUR SYMPTOMS (CONTINUED)

When your symptoms first came on, how was it the following day?	☐ better than on the first day ☐ much worse over the next day ☐ much worse the next morning ☐ the same the next day ☐ can't remember

Have you ever worked for greater than 6 months in a job involving heavy lifting? (For example storework lifting > 15kg)	☐ yes ☐ no

HISTORY OVER THE PAST THREE DAYS

The following section of the questionnaire relates to your symptoms over the past three days. Please answer all the following questions by circling the number or ticking the box. Choose one answer only that best matches your problem

In the past 3 days what time of the day have your symptoms usually been the worst?	☐ always the same amount of pain ☐ morning ☐ afternoon ☐ when you are trying to get to sleep at night ☐ at night while sleeping ☐ no specific pattern ☐ both morning and evening

In the past 3 days how often have the symptoms made it hard to get to sleep?	☐ not at all ☐ some nights ☐ most nights ☐ every night

In the past 3 days how often have the symptoms woken you while sleeping?	☐ not at all ☐ some nights ☐ most nights ☐ every night

In the past 3 days if the symptoms have woken you, what has been the reason?	☐ not applicable ☐ rolling over ☐ wake due to pain without moving ☐ Other _____

HISTORY OVER THE PAST THREE DAYS (CONTINUED)

In the <u>past 3 days</u> if the symptoms have woken you, how long has it taken to get back to sleep?	☐ not applicable ☐ less than 30 minutes ☐ greater than 30 minutes ☐ nothing helps, can't fall back to sleep
In the <u>past 3 days</u> if the symptoms have woken you, what have you done so you can go back to sleep? Please tick one box only (the thing you <u>usually</u> do to get back to sleep)	☐ not applicable ☐ nothing helps, can't fall back to sleep ☐ change positions in bed ☐ sit up ☐ get out of bed ☐ take medication ☐ Other _____
Is your bed firm, or is it soft and saggy in the middle?	☐ firm ☐ soft

Are your symptoms constantly with you 24 hours a day even when you rest or gently walk?	☐ yes ☐ no

In the <u>past 3 days</u> have you had a <u>painful or stiff back</u> in the morning?	☐ yes ☐ no

If so how long does it take for the pain/stiffness to ease if you don't take medication?	☐ less than one hour ☐ greater than 1 hour ☐ constant pain/stiffness all day ☐ I always take medication

Appendix R: Self-administered follow-up outcome questionnaires

Identification number:_____

Please note: You do not need to write your name on this questionnaire, because we now identify you in this trial via the identification number written above. Please keep all of the pages stapled together, and send the entire booklet back once you have finished it.

1. Please write the date that you filled out this questionnaire booklet: _____ / _____ / _____

2. "Please indicate how your back and leg condition has changed since you started in the trial, by ticking ONE of the boxes below?"

- ☐ 1. Completely recovered
- ☐ 2. Much improved
- ☐ 3. Slightly Improved
- ☐ 4. No change
- ☐ 5. Slightly worsened
- ☐ 6. Much worsened
- ☐ 7. Vastly worsened

3. Please rate your **back** pain by circling the number below that best describes your pain on average over the last week

0 1 2 3 4 5 6 7 8 9 10
No pain *Worst pain possible*

4. Please rate your **leg** pain by circling the number below that best describes your pain on average over the last week

0 1 2 3 4 5 6 7 8 9 10
No pain *Worst pain possible*

5. OSWESTRY DISABILITY QUESTIONNAIRE (modified)

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking **one box in each section** for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement ***which most clearly describes your problem.***

Section 1: Pain Intensity
☐ I have no pain at the moment
☐ The pain is very mild at the moment
☐ The pain is moderate at the moment
☐ The pain is fairly severe at the moment
☐ The pain is very severe at the moment
☐ The pain is the worst imaginable at the moment

Section 2: Personal Care (Washing, Dressing, etc.)
☐ I can look after myself normally without causing extra pain
☐ I can look after myself normally but it causes extra pain
☐ It is painful to look after myself and I am slow and careful
☐ I need some help but can manage most of my personal care
☐ I need help every day in most aspects of self care
☐ I do not get dressed, wash with difficulty and stay in bed

Section 3: Lifting
☐ I can lift heavy weights without extra pain
☐ I can lift heavy weights but it gives me extra pain
☐ Pain prevents me lifting heavy weights off the floor but I can manage if they are conveniently placed e.g on a table
☐ Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
☐ I can only lift very light weights
☐ I cannot lift or carry anything

Section 4: Walking
☐ Pain does not prevent me walking any distance
☐ Pain prevents me from walking more than 2 kilometres
☐ Pain prevents me from walking more than 1 kilometre
☐ Pain prevents me from walking more than 500 metres
☐ I can only walk using a stick or crutches
☐ I am in bed most of the time

Section 5: Sitting
☐ I can sit in any chair as long as I like
☐ I can only sit in my favourite chair as long as I like
☐ Pain prevents me sitting more than one hour
☐ Pain prevents me from sitting more than 30 minutes
☐ Pain prevents me from sitting more than 10 minutes
☐ Pain prevents me from sitting at all

Section 6: Standing
☐ I can stand as long as I want without extra pain
☐ I can stand as long as I want but it gives me extra pain
☐ Pain prevents me from standing for more than 1 hour
☐ Pain prevents me from standing for more than 30 minutes
☐ Pain prevents me from standing for more than 10 minutes
☐ Pain prevents me from standing at all

Section 7: Sleeping
☐ My sleep is never disturbed by pain
☐ My sleep is occasionally disturbed by pain
☐ Because of pain I have less than 6 hours sleep
☐ Because of pain I have less than 4 hours sleep
☐ Because of pain I have less than 2 hours sleep
☐ Pain prevents me from sleeping at all

Section 8: Social Life
☐ My social life is normal and gives me no extra pain
☐ My social life is normal but increases the degree of pain
☐ Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport
☐ Pain has restricted my social life and I do not go out as often
☐ Pain has restricted my social life to my home
☐ I have no social life because of pain

Section 9: Traveling
☐ I can travel anywhere without pain
☐ I can travel anywhere but it gives me extra pain
☐ Pain is bad but I manage journeys over two hours
☐ Pain restricts me to journeys of less than one hour
☐ Pain restricts me to short necessary journeys under 30 minutes
☐ Pain prevents me from traveling except to receive treatment

Section 10: Work/Housework
☐ My normal housework/work activities do not cause pain.
☐ My normal housework/work activities increase my pain, but I can still perform all that is required of me.
☐ I can perform most of my housework/work activities, but pain prevents me from performing more physically stressful activities (eg lifting, vacuuming).
☐ Pain prevents me from doing anything but light housework/work duties.
☐ Pain prevents me from doing even light housework/work duties.
☐ Pain prevents me from performing any housework/work duties.

6. How often in the PAST WEEK have you had each of the following symptoms? (please circle one number for each symptom)

	Not at all	Very rarely	A few times	About half the time	Usually	Almost always	Always
1. Low back pain	0	1	2	3	4	5	6
2. Leg pain (sciatica)	0	1	2	3	4	5	6
3. Numbness or tingling in leg, foot, or groin	0	1	2	3	4	5	6
4. Weakness in leg or foot (e.g. difficulty lifting foot)	0	1	2	3	4	5	6
5. Back or leg pain while sitting	0	1	2	3	4	5	6

7. On a scale of 0 to 6, please rate the following symptoms according to how bothersome they were in the PAST WEEK: (please circle one number for each symptom)

	Not bothersome			Somewhat bothersome			Extremely bothersome
1. Low back pain	0	1	2	3	4	5	6
2. Leg pain (sciatica)	0	1	2	3	4	5	6
3. Numbness or tingling in leg, foot, or groin	0	1	2	3	4	5	6
4. Weakness in leg or foot (e.g. difficulty lifting foot)	0	1	2	3	4	5	6
5. Back or leg pain while sitting	0	1	2	3	4	5	6

8. Aside from the treatment you received from your physiotherapist in this trial, please indicate by ticking the boxes below if you have had any of the following treatments for your back / leg problem **since you started the trial**: (tick all relevant boxes)

☐ Seen my general practitioner (doctor).
If you have seen your doctor, how many visits have you had? _____

☐ Seen a surgeon.
If you have seen a surgeon, how many visits have you had? _____

☐ Seen another specialist doctor (eg. rheumatologist, sports physician)
If you have, how many visits and what type of specialist did you see?

_____

☐ Seen a chiropractor.
If you have seen a chiropractor, how many visits have you have? _____

☐ Seen an osteopath.
If you have seen an osteopath, how many visits have you have? _____

☐ Seen a massage therapist.
If you have seen a massage therapist, how many visits have you have? _____

☐ Seen another physiotherapist.
If you have seen another physiotherapist, how many visits have you have? _____

☐ Had acupuncture.
If you have had acupuncture, how many visits have you have? _____

☐ Had an injection into your back (eg. an epidural or nerve block). If so, please indicate the date and type of injection?

_____

☐ Had back surgery.
If you have had back surgery, indicate the date and type of surgery:

_____

☐ Any other treatments? If you have, please state:

_____

9. Since you started to have treatment for your back or leg (sciatica) problem in this research trial, how satisfied have you been with your physiotherapy care? (tick one box)

☐ Very dissatisfied ☐ Somewhat dissatisfied ☐ Neither satisfied nor dissatisfied ☐ Somewhat satisfied ☐ Very satisfied

10. Since you started to have treatment in this research trial, how satisfied are you with **the results** of this physiotherapy treatment for your low back pain or leg problem (sciatica)? (tick one box)

☐ Very dissatisfied ☐ Somewhat dissatisfied ☐ Neither satisfied nor dissatisfied ☐ Somewhat satisfied ☐ Very satisfied

11. If you had to spend the rest of your life with the back or leg symptoms you have right now, how would you feel about it? (tick one box)

☐ Very dissatisfied ☐ Somewhat dissatisfied ☐ Neither satisfied nor dissatisfied ☐ Somewhat satisfied ☐ Very satisfied

12. During the past 4 weeks (30 days), approximately how many days did your low back or leg problem (sciatica) prevent you from going to work or school?

_____ days

13. Since you started the trial, approximately how many days in total did low back pain or leg pain (sciatica) prevent you from going to work or school?

_____ days

14. During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)? (please tick one box)

☐ Not at all ☐ A little bit ☐ Moderately ☐ Quite a bit ☐ Extremely

15. Are you currently: (please tick one box)

☐ Working full-time ☐ Working part-time ☐ Not working

16. If you are working, are you:

☐ employed at your usual job

☐ on light duties or some restricted work assignment

☐ employed at a different job compared to the job you had when you were injured

17. If you are not working, what is the reason for this?

☐ paid leave/sick leave because of low back problems

☐ paid leave/sick leave because of other reason(s)

☐ unpaid leave

☐ unemployed because of low back problems

☐ unemployed because of other reason(s)

☐ student

☐ keeping house/ homemaker

☐ retired

☐ on a disability pension

18. Please write down any medications you took for your back or leg condition **in the last 24-hours**. (Include medication prescribed by your doctor as well as other medication).

Name of medication	**Number of tablets taken in the last 24-hours**	**Medication strength as shown on the pack (mg)**
Example: Panadol	*2*	*500mg*
1		
2		
3		
4		
5		
6		
7		
8		

19. Have you noticed any adverse, harmful or unpleasant effects that you think may have been due to the treatment program that you undertook in this trial? If so, please explain.

20. By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking around	❑	PLEASE TICK
I have some problems in walking around	❑	ONE BOX
I am confined to bed	❑	

Personal Care

I have no problems with personal care	❑	PLEASE TICK
I have some problems washing or dressing myself	❑	ONE BOX
I am unable to wash or dress myself	❑	

Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities	❑	PLEASE TICK
I have some problems with performing my usual activities	❑	ONE BOX
I am unable to perform my usual activities	❑	

Pain/Discomfort

I have no pain or discomfort	❑	PLEASE TICK
I have moderate pain or discomfort	❑	ONE BOX
I have extreme pain or discomfort	❑	

Anxiety/Depression

I am not anxious or depressed	❑	PLEASE TICK
I am moderately anxious or depressed	❑	ONE BOX
I am extremely anxious or depressed	❑	

21. To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today

22. # Orebro Musculoskeletal Pain Screening Questionnaire

4. **Where do you have pain? Place a tick for all appropriate sites.**

   ❑ neck ❑ shoulders ❑ upper back ❑ lower back ❑ leg Other (please state)_____

5. **How many days of work have you missed because of pain during the past 18 months? Tick one**

   ❑ 0 days [1] ❑ 1-2 days[2] ❑ 3-7 days [3] ❑ 8-14 days [4] ❑ 15-30 days [5]

   ❑ 1 month [6] ❑ 2 months [7] ❑ 3-6 months [8] ❑ 6-12 months [9] ❑ over 1 year [10]

6. **How long have you had your current pain problem? Tick one**

   ❑ 0-1weeks [1] ❑ 1-2 weeks [2] ❑ 3-4 weeks [3] ❑ 4-5 weeks [4] ❑ 6-8 weeks [5]

   ❑ 9-11 weeks [6] ❑ 3-6 months [7] ❑ 6-9 months [8] ❑ 9-12 months [9] ❑ over 1 year [10]

7. **Is your work heavy or monotonous? Circle the best alternative.**

   0 1 2 3 4 5 6 7 8 9 10
   Not at all *Extremely*

8. **How would you rate the pain that you have had during the past week? Circle one.**

   0 1 2 3 4 5 6 7 8 9 10
   No pain *Pain as bad as it could be*

9. **In the past 3 months, on average, how bad was your pain? Circle one.**

   0 1 2 3 4 5 6 7 8 9 10
   No pain *Pain as bad as it could be*

10. **How often would you say that you have experienced pain episodes, on average, during the past 3 months? Circle one.**

    0 1 2 3 4 5 6 7 8 9 10
    Never *Always*

11. **Based on all the things you do to cope, or deal with your pain, on an average day, how much are you able to decrease it? Circle one (10-)**

    0 1 2 3 4 5 6 7 8 9 10
    Can't decrease it at all *Can decrease it completely*

12. **How tense or anxious have you felt in the past week? Circle one.**

    0 1 2 3 4 5 6 7 8 9 10
    Absolutely calm and relaxed *As tense and anxious as I've ever felt*

13. **How much have you been bothered by feeling depressed in the past week? Circle one.**

    0 1 2 3 4 5 6 7 8 9 10
    Not at all *Extremely*

14. **In your view, how large is the risk that your current pain may become persistent? Circle one.**

    0 1 2 3 4 5 6 7 8 9 10
    No risk *Very large risk*

15. **In your estimation, what are the chances that you will be working in 6 months? Circle one (10-)**

    0 1 2 3 4 5 6 7 8 9 10
    No chance *Very large chance*

16. **If you take into consideration your work routines, management, salary, promotion possibilities and work mates, how satisfied are you with your job? Circle one (10-)**

    0 1 2 3 4 5 6 7 8 9 10
    Not satisfied at all *Completely satisfied*

Here are some of the things which other people have told us about their pain. For each statement please circle one number from 0 to 10 to say how much physical activities, such as bending, lifting, walking or driving would affect your pain.

17. **Physical activity makes my pain worse.**

0 1 2 3 4 5 6 7 8 9 10
Completely disagree *Completely agree*

18. **An increase in pain is an indication that I should stop what I'm doing until the pain decreases.**

0 1 2 3 4 5 6 7 8 9 10
Completely disagree *Completely agree*

19. **I should not do my normal work with my present pain.**

0 1 2 3 4 5 6 7 8 9 10
Completely disagree *Completely agree*

Here is a list of 5 activities. Please circle the one number which best describes your current ability to participate in each of these activities (10-)

20. **I can do light work for an hour.**

0 1 2 3 4 5 6 7 8 9 10
Can't do it because pain problem *Can do it without pain being a problem*

21. **I can walk for an hour.**

0 1 2 3 4 5 6 7 8 9 10
Can't do it because pain problem *Can do it without pain being a problem*

22. **I can do ordinary household chores.**

0 1 2 3 4 5 6 7 8 9 10
Can't do it because pain problem *Can do it without pain being a problem*

23. **I can go shopping.**

0 1 2 3 4 5 6 7 8 9 10
Can't do it because pain problem *Can do it without pain being a problem*

24. **I can sleep at night.**

0 1 2 3 4 5 6 7 8 9 10
Can't do it because pain problem *Can do it without pain being a problem*

Appendix S: Exercise chart completed by participants in the functional restoration group as a record of exercises completed at home and in the physiotherapy clinic

EXERCISE PROGRAM SHEET

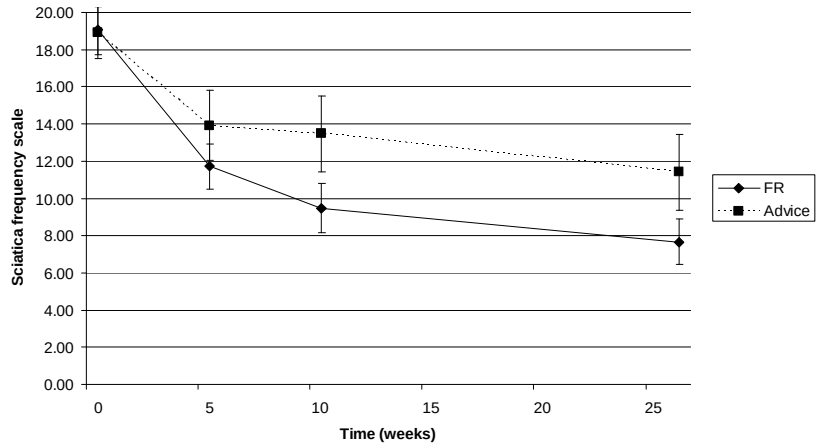
Name: _____ **Page number:** _____

* Please do each exercise with control and remember to activate your stabilising muscles at all times.

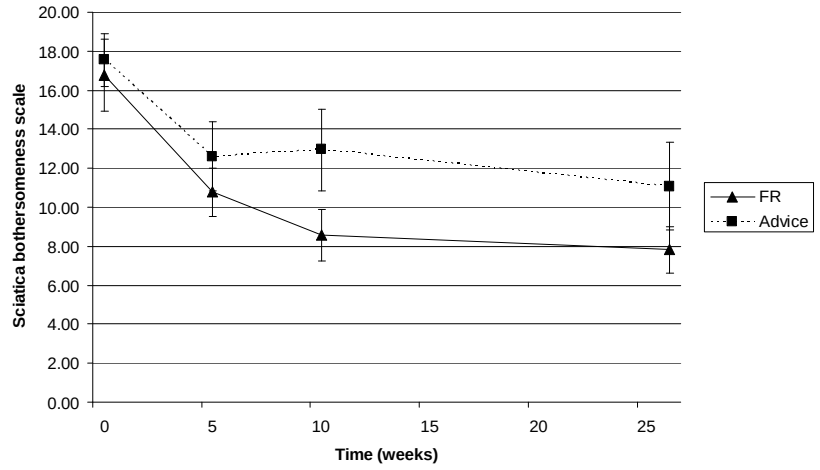
	DATE			Treadmill	Step ups	Bicep Curls	Forward Raises	Side Raises			
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
20											
21											
22											

Appendix T: Graphs showing group mean scores at each measurement point for the secondary outcomes of: a) sciatica frequency scale; b) sciatica bothersomeness scale; and c) psychosocial status on the Orebro (error bars represent standard errors)

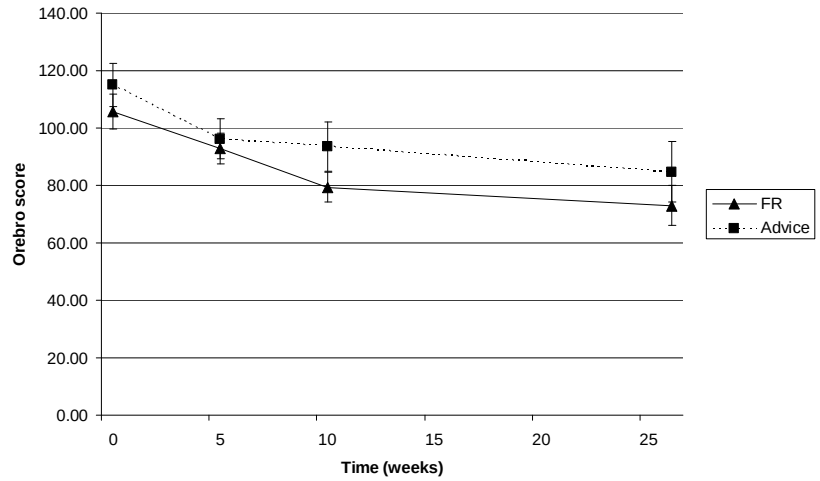
a)



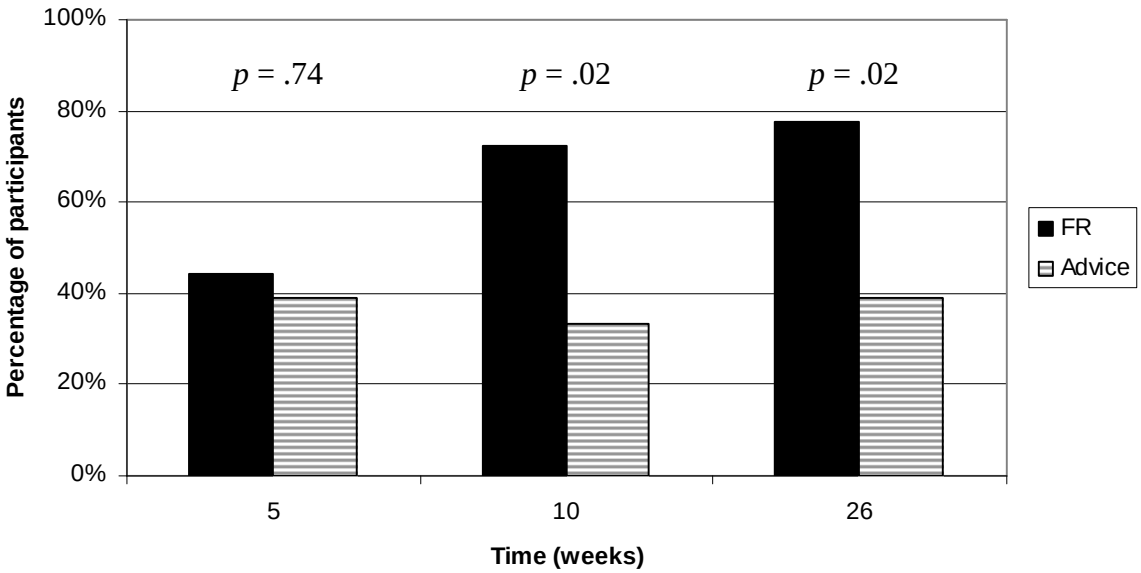
b)



c)

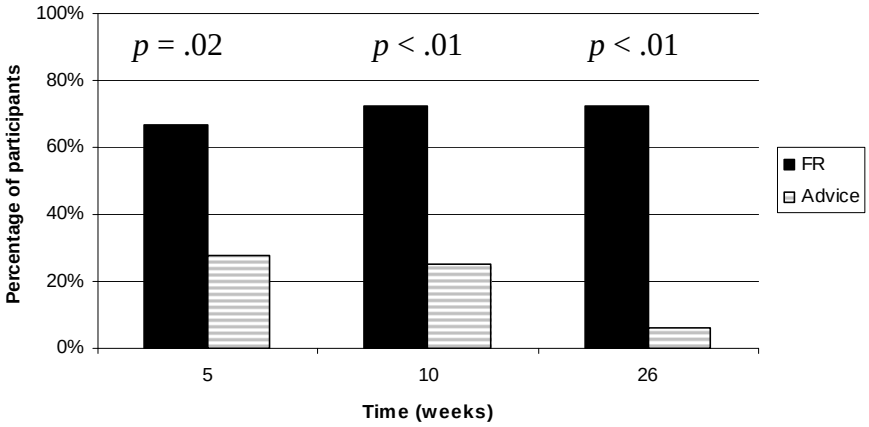


Appendix U: Graph showing proportion of participants in each group who reported being at least "much improved" on the global rating of change scale at each follow-up

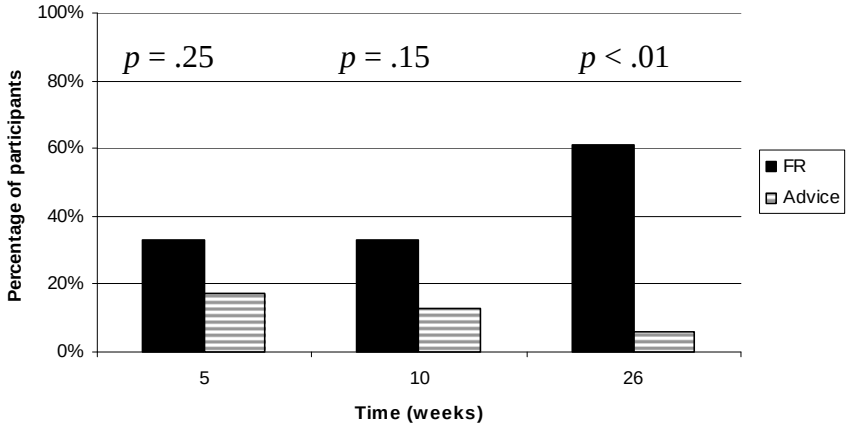


Appendix V: Graphs showing proportion of participants in each group who reported being "very satisfied" with: a) their physiotherapy care; b) the results of their physiotherapy care; and c) the prospect of enduring their current symptoms for the rest of their life

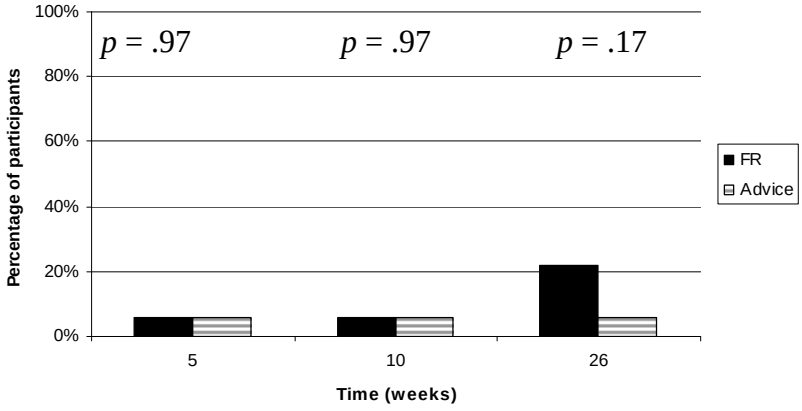
a)



b)



c)



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