Introduction

This is the second in a series of papers describing a clinical protocol for the classification and specific treatment of low back disorders (LBDs). The protocol was developed for the Specific Treatment of Problems of the Spine (STOPs) trials. As discussed in Part 1, LBDs are a prevalent and costly burden to society and the individual. There is minimal evidence supporting physiotherapy treatment as an effective strategy in dealing with this problem. Randomized controlled trials (RCTs) evaluating treatment specific to identified subgroups of LBDs have the potential to provide stronger evidence for the efficacy of physiotherapy.

The process of defining subgroups for any entity is one of classification. A variety of methods for developing and validating LBD subgroups have been recommended each one having significant limitations. In Part 1 of this series, a case was presented for researchers placing greater emphasis on classification and treatment approaches in widespread clinical use. This approach contrasts with much of the recent literature recommending or conducting research developing new classification systems and subgroups using statistical methodologies. The McKenzie approach to classifying and treating LBDs, also referred to as Mechanical Diagnosis and Therapy, has been widely adopted by physiotherapists across the world and postgraduate courses teaching the method are conducted in many countries. As such, research into the effectiveness of the McKenzie approach when applied to specific subgroups of LBDs is of potential value.

McKenzie identified a subgroup of LBDs which he called ‘derangement’. The classification and treatment of derangement was based on McKenzie’s clinical observations in conjunction with the biomechanical and pathophysiological literature on the lumbar intervertebral disc. His method involved a detailed clinical assessment, identification of specific clinical patterns and evaluation of responsiveness of subjective and physical examination ‘asterisks’ to mechanical loading strategies (MLSs) such as sustained or repeated flexion, extension and side gliding/lateral movements. McKenzie described a key feature of pain likely to be arising from the lumbar disc which he called centralization. This phenomenon was defined as the proximal movement and/or
abolition of distal symptoms in response to the application of MLSs. The concept of directional preference can be defined as the direction of MLS resulting in centralization. Movement into extension has been identified as the most commonly useful MLS in the lumbar spine.\textsuperscript{17}

The literature evaluating the efficacy of the McKenzie approach for LBDs has generally demonstrated mixed results with some evidence of small and short term effects.\textsuperscript{18,19} However, most RCTs have not evaluated the McKenzie approach when applied to specifically defined subgroups. Recently we completed a systematic review to identify and evaluate RCTs sampling more specific populations and found a lack of strong evidence supporting the McKenzie approach partially due to heterogeneity between trials.\textsuperscript{20}

Of significant interest in the RCTs on the McKenzie method to date is the nature of treatment provided and the qualification(s) of practitioners involved. A proportion of trials are pragmatic in design where McKenzie treatment is provided by practitioners with post-graduate qualifications in Mechanical Diagnosis and Therapy.\textsuperscript{21–24} A limitation of this approach is potential uncertainty around exactly how the treatment is provided and the inability for practitioners in the field without postgraduate McKenzie training to apply the treatment method. Other trials have provided a simplified McKenzie based treatment with no requirement for post-graduate training in practitioners.\textsuperscript{25–30} However, such RCTs have been criticized due to the treatment protocol not sufficiently adhering to the principles of the McKenzie method.\textsuperscript{14,31–33}

As described in Part 1 of this series, in order to adequately evaluate the efficacy of specific physiotherapy in future RCTs, we believe that new classification and specific treatment protocols are required. These clinical protocols should adhere to the key principles outlined in original descriptions of the clinical method, be reproducible\textsuperscript{34} to allow replication in subsequent trials, be generalizable to the broader physiotherapy community,\textsuperscript{34} and be developed where possible on the best available evidence.\textsuperscript{35} The McKenzie method as described in the current recommended text\textsuperscript{14} can be complex to administer with many different treatment algorithms and over 28 different treatment techniques/procedures. The McKenzie Institute recommends a minimum of 112 hours post-graduate training including written and practical examination to attain competence in the method. As part of planning for the STOPS trials, we believed that a refined clinical protocol, targeting a specific type of discogenic pain, that could be easily repeated in future clinical trials as well as in the field by physiotherapists worldwide was required. We are unaware of a detailed clinical protocol that refines, operationalizes and standardizes the clinical methods of the McKenzie approach in this manner.

The purpose of Part 2 in this series was therefore to present a classification and treatment protocol for an LBD subgroup with a directional preference that responded in a predictable and rapid manner to MLS. We named this subgroup reducible discogenic pain (RDP) using nomenclature similar to a recently published classification system\textsuperscript{10} and in a manner consistent with McKenzie’s original descriptions of his method.\textsuperscript{16} The clinical protocol was developed for use in the STOPS trials.

**Methods**

The STOPS trials protocol and methodology has been described elsewhere\textsuperscript{1} and adheres to accepted guidelines for conducting RCTs.\textsuperscript{34,36,37} The key features of the STOPS trials were:

- classification of potential participants with subacute LBDs into one of five subgroups at baseline assessment. One of these subgroups was participants with RDP;
- consenting participants being randomly allocated to either specific physiotherapy (10 sessions over 10 weeks) or evidence-based advice (2 sessions over 10 weeks);
- treatment in both physiotherapy and advice groups being specific to the relevant subgroup;
- follow-up of participants at 5 weeks, 10 weeks, 26 weeks and 12 months.

**The validity of RDP as a subgroup of LBDs**

A substantial body of literature has been published on the classification of LBDs,\textsuperscript{5} the limitations of which have been discussed in Part 1 of this series. Rather than relying on one form of research methodology as a means of validating the clinical features of RDP, we have adopted the principle of ‘convergence of validity’. George and Delitto\textsuperscript{38} described this approach as being useful in developing LBD classification systems where no one study or research design can provide complete validation. They defined convergence of validity for a classification system as:

‘…evidence supporting or refuting the system (being) gathered from different sources and from the use of different methods. In the best case scenario, these sources converge and indicate similar meanings of the underlying constructs being studied.’\textsuperscript{38} (p. 312)

We believe the convergence of validity approach is appropriate for developing clinical protocols for RCTs evaluating complex classification and treatment models such as the McKenzie method. The approach is consistent with the original definitions of evidence-based practice that emphasize the constructive interaction between the research literature and
clinical perspectives as well as more recent guidelines on developing classification systems.

The clinical features of RDP for the STOPS trials were developed based on a systematic review of relevant RCTs, publications arising from authorities on the McKenzie method, an extensive literature review, and the clinical experience of the principle author comprising 20 years of clinical practice as a Musculoskeletal Physiotherapist and credentialed McKenzie practitioner treating predominantly LBDs. Using convergence of validity principles it is not feasible within the context of the current paper to consolidate the literature on the clinical features of RDP via a systematic review or detailed critical review. However, a case for the features of RDP can be presented based where possible on high quality systematic reviews.

The validity of discogenic pain as a clinical entity is supported by extensive research on biological plausibility. The lumbar intervertebral disc is innervated, subject to pathological processes capable of producing pain and has been shown to reproduce symptoms commonly reported by people with LBDs. Biological plausibility is an important component of meaningful and clinically relevant classification systems in LBP.

There is a significant body of literature on the validity of diagnostic tests for and the clinical features of discogenic pain. Clinical guidelines have recommended lumbar discography as a useful diagnostic test for discogenic pain. However, discography is a controversial and invasive procedure that has been shown to have significant false positives in individuals without lumbar related pain and is not without risk. The value of lumbar discography as a diagnostic tool, and as a method of determining eligibility for the RDP group in the STOPS trials is therefore questionable.

Despite the limitations of discography, the ability of clinical features to diagnose discogenic pain as determined by lumbar discography has been investigated. A recent systematic review has presented preliminary evidence supporting the concurrent validity of certain features for discogenic pain, including centralization, by the ability to predict the results of lumbar discography. Another systematic review has also established that centralization predicts treatment response to people being treated with the McKenzie approach. This finding is of particular significance given that other physical factors such as examination findings have consistently been shown to be poor predictors of outcome.

Further evidence supporting the validity of certain clinical features of RDP is provided in a large multidisciplinary survey and an expert panel using the Delphi Technique. Identified features include centralization, a specific pattern of symptom onset/mecanism of injury and a predictable symptom response to specific postures and activities. The clinical features of RDP identified in this qualitative research are consistent with descriptions by McKenzie and other recognized clinical experts. Although such qualitative methods do not in isolation validate the clinical features of RDP as a subgroup of LBDs, the results converge with other quantitative research described above.

Based on the convergence of this quantitative and qualitative research as well as the descriptive clinical literature on RDP we developed a series of clinical features indicative of RDP for use in the STOPS trials. Importantly our features of RDP were consistent with McKenzie’s original clinical descriptions were clearly defined and therefore easily reproducible, and were consistent with the views of physiotherapists in the field increasing likely generalizability into clinical practice.

**Classification protocol for RDP**

As part of the STOPS trials only participants who satisfied the RDP inclusion criteria at baseline assessment were included in the RDP subgroup to receive specific treatment. A purpose designed MICROSOFT EXCEL (2008) spread sheet was developed to ensure reproducible identification of subgroup membership according to the clinical data entered at baseline by the physiotherapist assessing trial eligibility. A detailed description of the baseline assessment method can be found elsewhere. The first step in the classification process was to identify participants with features deemed to be indicative of discogenic pain. This was followed by a determination of whether the discogenic pain was positively responsive to MLSs and therefore reducible. Table 1 lists a set of clinical features identified in a recent expert panel as being indicative of discogenic pain with associated rationale. To pass the first step in the classification process, participants had to have four of the nine features from Table 1. As none of the features could be considered diagnostic in nature, and no people in previous pilot testing had all nine features, a threshold of four out of nine clinical features was chosen. This relatively low threshold aimed to exclude participants where discogenic pain was very unlikely, but not exclude participants with possible discogenic pain from the second step in classification for which stronger evidence of validity exists.

By passing both steps in the classification process, participants were classified as having RDP. The term ‘reducible’ referred to a symptom provoking posterior/posterolaterally displaced nucleus pulposus in the disc being reduced to a more central and less symptom provoking position.
within the annulus fibrosis is known to occur in both the normal and degenerate discs and has been hypothesized by McKenzie and others as being the mechanism by which MLSs are able to influence subjective and physical examination findings. The physiotherapy assessment of response to MLSs in LBDs has been shown to be reliable.

In establishing whether the participant’s discogenic pain was reducible, the following MLSs were trialled: repeated extension in standing, repeated extension in lying and positioning in prone lying (with or without pillows under the stomach) progressing to sustained extension. If a positive response was not observed, these MLSs were combined with side gliding movements/positioning to evaluate the presence/absence of a ‘lateral component’ to the directional preference. To be classified at baseline assessment as having RDP the participant had to positively respond to at least one of these MLSs. A positive response was defined as responding to at least 10 repeated movements or a period of sustained positioning by:

- an increase in possible range of motion of the MLS during application by at least 50% or
- an increase in lumbar active range of motion in any movement by at least 50% after application or
- an increase in observed segmental intervertebral motion during lumbar active range of motion testing after application or
- a reduction in an observed lateral shift postural abnormality that lasted for at least 1 minute after application.

It has been observed clinically that some people with LBDs respond positively to MLSs by proximal symptoms increasing and distal symptoms reducing in intensity. The trial physiotherapists were educated that this presentation was consistent with the phenomenon of centralization and was therefore indicative of the participant having RDP.

**Treatment protocol on directional preference management for RDP**

We named the treatment of RDP as directional preference management (DPM) and defined it as involving: regular participant application of helpful MLSs, education, postural advice, lumbar taping techniques and in some cases therapist-applied forces during MLSs. Table 2 provides an overview

<table>
<thead>
<tr>
<th>Criteria indicative of discogenic pain</th>
<th>Rationale</th>
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<tbody>
<tr>
<td>Lumbar pain + leg symptoms</td>
<td>Discogenic problems can result in somatic lumbar or leg symptoms</td>
</tr>
<tr>
<td>Prolonged sitting aggravates the symptoms</td>
<td>Sitting increases intradiscal pressure and posterior migration of the nucleus pulposus. Expert physiotherapy panel and multi-disciplinary survey evidence of validity</td>
</tr>
<tr>
<td>Forward bending aggravates the symptoms</td>
<td>As per sitting rationale</td>
</tr>
<tr>
<td>Lifting aggravates the symptoms</td>
<td>As per sitting rationale</td>
</tr>
<tr>
<td>Sit to stand aggravates the symptoms</td>
<td>Reversing the curve of the lumbar spine from flexion to extension often results in pain and stiffness potentially due to mechanical obstruction to posterior vertebral rotation from a posteriorly migrated nucleus pulposus. Expert physiotherapy panel evidence of validity</td>
</tr>
<tr>
<td>Coughing or sneezing aggravates the symptoms</td>
<td>Increased intra-abdominal and intra-discal pressure, perhaps in addition to lumbar flexion associated with coughing/sneezing, may increase posterior nucleus migration. Expert physiotherapy panel and multi-disciplinary survey evidence of validity</td>
</tr>
<tr>
<td>Symptoms much worse the next morning or day following the injury</td>
<td>Increased hydrostatic pressure within the nucleus pulposus after prolonged periods of recumbency may cause worsening of symptoms the day following injury. Expert physiotherapy panel evidence of validity</td>
</tr>
<tr>
<td>History of working in a job with heavy manual handling</td>
<td>Heavy lifting in a flexed posture can initiate subclinical pathological processes of annular tearing/fissuring that predispose the disc to becoming painful. Expert physiotherapy panel evidence of validity</td>
</tr>
<tr>
<td>Mechanism of injury associated with flexion/rotation and/or compression loading</td>
<td>These movements and forces provide maximal stress on the disc. Expert physiotherapy panel evidence of validity</td>
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Table 2  Summary of the RDP treatment protocol

<table>
<thead>
<tr>
<th>Phase 1: Preparation for DPM</th>
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<tr>
<td>• Weeks 1–2</td>
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<tr>
<td>• Participant explanations</td>
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<tr>
<td>• Management of inflammation (if applicable)</td>
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<tr>
<td>• Identification of initial MLS with which to commence treatment and homework/exercises</td>
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<table>
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<tr>
<th>Phase 2: DPM</th>
</tr>
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<tbody>
<tr>
<td>• Weeks 1–10</td>
</tr>
<tr>
<td>• Commencement and progression of appropriate MLS in homework/exercises (Fig. 3)</td>
</tr>
<tr>
<td>• Ongoing participant explanation of Phase 1 information sheets</td>
</tr>
<tr>
<td>• Additional education regarding specific issues (e.g. work) as required</td>
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<table>
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<tr>
<th>Phase 3: Specific motor control training</th>
</tr>
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<tbody>
<tr>
<td>• Weeks 3–10</td>
</tr>
<tr>
<td>• Ongoing DPM provided participant is responding</td>
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<tr>
<td>• Commencement of specific training of transversus abdominis, lumbar multifidus and the pelvic floor</td>
</tr>
<tr>
<td>• Shift in treatment program away from a pathoanatomical emphasis in participants failing to respond and where psychosocial factors are likely to be relevant</td>
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<tr>
<th>Phase 4: Transfer to independence</th>
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<tr>
<td>• Weeks 7–10</td>
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<tr>
<td>• Progression of specific motor control training towards functional retraining</td>
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<tr>
<td>• Review of progress and positive reinforcement of gains made</td>
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<tr>
<td>• Strategies for independent progression of DPM exercises</td>
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<tr>
<td>• Preparation for treatment completion and long-term exercise/self-management</td>
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</tbody>
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Table 3  Clinical notes content for Session 1

<table>
<thead>
<tr>
<th>Treatment protocol component</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1 assessment</td>
<td>To gather and interpret information relevant to treatment planning and for reassessment of the participant’s response to treatment</td>
</tr>
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</table>

Complete body chart and history
- Gather asterisks from subjective and physical examination
- Determine whether clinical evidence exists of inflammation (At least 2 of: constant symptoms, getting out of bed at night due to the pain, early morning symptoms >60 minutes)
- In the absence of inflammation, assess for relevant MLSs and reassess asterisks.

Session 1 treatment
- Explanation and information sheets regarding RDP, treatment options, treatment timeframes and recovery expectations. Open questions to the participant regarding understanding the explanation and level of engagement with the proposed treatment plan
- Management of inflammation if applicable including provision of information sheet, lumbar taping, recommend pharmacy consultation regarding non-prescription NSAIDs* and walking program short of pain onset
- In the absence of inflammation provide an appropriate dosage of the relevant MLS and reassess asterisks.
- Provide homework for regular application of the relevant MLS as an exercise. Use of specific participant information sheets
- Provide a lumbar roll, postural education, a walking program, and lumbar taping in neutral lumbar spine position. These strategies were described on the information sheet

Note: *NSAIDs=non-steroidal anti-inflammatory drugs. of the phases of treatment for the DPM of participants with RDP in the STOPS trials.

Typically DPM is provided in a personalized manner based on the clinical reasoning and decision making skills of the practitioner. However, adequate clinical reasoning skills are difficult to define, teach and measure, taking most practitioners many years to develop. In addition, and as discussed in the introduction, the McKenzie approach to DPM is complex with post-graduate training being recommended to achieve competency. Because the STOPS treatment was to be implemented by physiotherapists with a range of experience and in most cases without post-graduate qualifications, the protocol had a focus on structured processes to maximize adequate and reproducible clinical decision making across all practitioners and trial participants. The algorithmic nature of the protocol allowed each participant to receive treatment personalized to their individual presentation. Sufficient scope was also provided in the protocol for the physiotherapist to modify the treatment based on clinical presentation using clinical reasoning principles described in Part 1 of this series.

Details regarding the trial physiotherapists and their training and ongoing mentoring program have
been described in Part 1 of this series. In brief, the trial physiotherapist had a number of resources to assist in provision of the treatment protocol including a 240 page treatment manual (one-fifth of which focused on DPM), a comprehensive baseline assessment report completed by the physiotherapist who determined eligibility for the trial, a series of professionally produced participant information sheets and a blank copy of the clinical notes specifically designed for recording the progress of the RDP participant sessions. The clinical notes were structured using specific text based cues to ensure all essential components of the treatment protocol were adhered to whilst allowing the practitioner some flexibility to select treatment techniques and rates of progression for individual participants.

To our knowledge, such a precisely defined and highly specific treatment protocol, with close monitoring of treatment integrity for the DPM of RDP has not been published.

**Session 1 treatment – identifying a helpful mechanical loading strategy**

A summary of the content of the clinical notes for Session 1 is outlined in Table 3. As part of Session 1 the trial physiotherapist was required to review the information retrieved from baseline assessment, complete a body chart and gather subjective and physical examination asterisks to use for the purpose of reassessing the participant’s response to the treatment strategies. This information was required to enable the clinical reasoning methods of the protocol to operate.

Inflammation is often associated with discogenic problems and can potentially mask any positive effects of MLSs which are designed primarily for mechanical LBDs. As such, inflammation was evaluated using commonly identified clinical features and treated using the methods described below and in Table 3 before further assessment and treatment with MLSs was provided. A full description and justification of the inflammatory component of the treatment protocol is provided in Part 3 of this series.

If there were no clinical features of inflammation at Session 1, assessment and identification of the MLSs that resulted in a positive response was completed. Although MLSs were evaluated in the baseline assessment to determine eligibility and subgroup allocation for the STOPs trials, it was deemed important for the trial physiotherapist to re-establish the most effective MLS in Session 1 in case the participant’s status had changed. A series of MLSs expanded from those used at baseline assessment were described by pictures and text in the treatment manual to assist the trial physiotherapists in appropriate application. Described MLSs included extension in lying, extension in lying with participant overpressure, extension in lying with therapist overpressure, extension in lying with hips offset (incorporating lateral forces), extension in lying with hips offset and therapist overpressure (incorporating lateral forces), extension in standing, manual correction of a relevant lateral shift in standing (incorporating lateral forces) and variable positioning in prone.

There was a strong emphasis in the STOPs training, clinical mentoring program and participant information sheets on correct instruction and performance of MLSs as assessment, treatment and homework/exercise techniques. Key points of emphasis included:

- ensuring correct starting position;
- clear and specific participant instructions (each MLS had scripted instructions as a guide for physiotherapists);
- careful observation by the physiotherapist of participant performance of the MLS;
- provision of verbal and tactile feedback to the participant during and after the MLS;
- in most cases instructing the participant to perform the MLS to the point of pain onset. In the event of pain onset progressing further into the MLS range during application, the trial physiotherapist encouraged the participant to progress the movement to the new point of pain onset aiming for end of range when possible;
- close monitoring of symptom response including centralization during and after the MLS.

A decision making algorithm (Fig. 1) was developed to assist trial physiotherapists in selecting the appropriate treatment strategy in Sessions 1 through 10 on the basis of the information retrieved from assessment of MLSs. As part of the decision making algorithm, a standard nomenclature for defining better, worse or unchanged was used by the trial physiotherapists. This was developed to minimize the risk of physiotherapists making erroneous conclusions regarding participant response to the MLSs and therefore making incorrect decisions regarding treatment selection and progression.

A participant was defined as better if a positive response during or immediately after the application of the MLS was maintained. A positive response was defined as per the criteria described in the classification section above. If a participant was better a suitable MLS was determined to have been identified.

A participant was defined as worse if a negative response during or immediately after the application of the MLS was maintained. A negative response was defined as responding to at least 10 repeated movements or a period of sustained positioning by:

- a reduction in lumbar active range of motion in any movement by at least 50% after application or
- a reduction in segmental intervertebral motion during lumbar active range of motion testing after application or
a deterioration in resting pain (by at least 1 point on
an NRS or by peripheralization of symptoms defined
as the opposite of centralization) that lasted for at
least 1 minute after application (noting that during
peripheralization the intensity of proximal symptoms
may decrease while distal symptoms increase) or
an increase in an observed lateral shift postural
abnormality that lasted for at least 1 minute after
application.

If a participant was worse it was deduced that the
exacerbation was caused by:
• an incorrect MLS direction being selected and/or
• the applied force with the MLS being too high and/or
• the correct MLS direction being chosen but with the
  movement performed too rapidly to allow nuclear
  migration within the disc or
• the participant being no longer able to be classified as
  having RDP.

A participant was defined as unchanged if a negative
or positive response during or immediately after the
application of the MLS was not maintained or if
there was no immediate change in the above
described movement, motion and resting pain criteria
in response to the MLS. If a participant was
unchanged it was deduced that the lack of response
was caused by:
• an incorrect MLS direction being selected and/or
• the applied force with the MLS being insufficient to
  result in a lasting change or
• the participant being no longer able to be classified as
  having RDP.

With the trial physiotherapist having a clear under-
standing of the definitions of better, worse and
unchanged, the first step in the clinical reasoning
processes of Fig. 1 was applying and evaluating the
effect of lumbar extension as an MLS on the
participant’s asterisks. Following this application, if
the participant was unchanged, the extension MLS
was altered by a ‘progression of forces’ defined as a
graded increase in force to the lumbar spine applied
during the application of an MLS. Participant-applied
overpressure, such as ‘sagging’ into extension combi-
nation with expiration at end of range, was the first
method of progressing forces. If the participant was
still unchanged, the physiotherapist could increase the
forces in the MLS initially by applying posterior-
anteor pressure bilaterally to the transverse processes
of the lower lumbar spine during extension in lying.14

If the participant was worse or unchanged to the
progression of forces with extension, or if made worse
with participant applied extension, the ‘lateral
component’ of the directional preference was
explored. There is evidence to suggest that nuclear
material migrates posteriorly as a cause of discogenic
pain52 and in such cases a positive response to
extension usually occurs.17 However, in cases of
postero-lateral nuclear migration where extension
alone has no effect, the addition of side gliding or
rotation with or without extension can result in a
positive response.17 As with any MLS the addition of
movements exploring the presence of a lateral
component can be progressed by adding participant
applied or therapist forces.17

Figure 1  Clinical decision making algorithm for RDP.
As described in Fig. 1, once the trial physiotherapist identified the most appropriate MLS, this was repeated as a treatment technique at a specific dosage.

**Session 1 treatment – homework/exercises and other additional components**

A suitable home exercise program including dosage for regular application of the MLS was an essential component of DPM in Session 1. The trial physiotherapist modified, to suit the participant’s requirements, a specific participant information sheet which had pictures, explanatory text and ranges of suitable dosages for different MLSs. Most of the MLSs when used as a home exercise were performed as repeated movements, typically in one to two sets of 8 to 15 repetitions. The participants were encouraged to perform their MLS exercise every 1–2 hours, and a minimum of 6 times daily. Participants were advised to repeat MLS exercises rhythmically, without a sustained hold at end of range and with a short period (less than 1 second) of relaxation in between each repetition. The participant was instructed to perform the MLS to the point of pain onset. It was also emphasized to attempt to gradually increase the range of movement with each MLS repetition.

**Figure 2** Example description of a mechanical loading strategy for the trial physiotherapists.

- Participant lying relaxed on stomach
- Hands under shoulders in a “push up position”
- Instruct the participant to “slowly and gently push up through your hands, lifting your upper body and arcing your back... tell me when you first feel any pain/any increase in your pain”
- Provide tactile cues to the shoulder and lumbar spine to encourage isolated lumbar extension
- Monitor erector spinae activity and provide feedback to ensure they are relaxed. Monitor to ensure pelvis remains on the plinth
- Ensure movement does not go past pain onset. If pain onset progresses into range, encourage movement to the new pain onset point. Aim for full elbow extension provided it is not past the pain onset point
- It is acceptable for some slight elevation of the hips and pelvis off the bed
- As an assessment tool, 10 to 20 repetitions are performed, depending on response and irritability
- An increase in central low back pain may initially occur and often eases with repeated movements
- After completion, educate the participant to return to standing posture via prone maintaining an extended lumbar spine
towards end of range, but only if the point of pain onset was improving during application.

There were a number of other components in Session 1 treatment including instruction on the use of a lumbar roll to maintain a lumbar lordosis whilst sitting, postural education to maintain a lumbar lordosis during daily function, a walking program, and lumbar taping in a neutral lumbar spine position. We included a walking program based on the following benefits:

- gentle and rhythmic application of sagittal and coronal plane lumbo-pelvic movement with a predominance of lumbar extension being usually helpful for RDP;\(^{{17}}\)
- prevention of secondary effects of reduced activity;\(^{{62}}\)
- providing a positive message regarding activity and potentially minimizing development of maladaptive fear avoidance beliefs.\(^{{93}}\)

We developed a specific taping protocol used to assist with the management of inflammation and in particular to facilitate improvement in posture during functional activities.\(^{{49}}\) Participants were informed that the purpose of the tape was to serve as a reminder to help maintain correct posture which would in turn minimize lumbar flexion, assist in maintaining the reduced position of the nucleus pulposus, decrease frequency of exacerbations, improve tissue healing within the outer annulus fibrosis and assist in controlling inflammation.

A non-allergenic skin preparation was applied, followed by a layer of non-allergenic tape and finally rigid strapping tape with one vertical strip along the spine from T8 to S2, and two diagonal strips from T8 to the opposite pelvis as shown in Fig. 3. Participants were taped in a comfortable standing position with a neutral spine. In participants with an excessive lumbar lordosis, rigid tape was applied in 10–20 degrees of lumbar flexion to ensure tape was not overly tensioned. Following application, a demonstration of the tape effect was provided to the participant using the following instructions:

’Please bend forward slowly for me… can you feel the tape pulling? 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’

Advice regarding hygiene and preserving the tape was given as well as warnings regarding skin irritation. In the event of no complications wearing tape, participants were encouraged to keep the tape on until the next consultation. Skin condition was always checked between applications of tape to ensure no deterioration occurred. The participant continued with tape according to the principles outlined in Fig. 4.

As can be seen from Table 3 and the descriptions above, key components of the Session 1 protocol were procedures to educate, engage and actively encourage feedback from the participant. This is consistent with recommendations from the research and clinical reasoning literature\(^{{57,64}}\) as well as the currently recommended McKenzie text.\(^{{14}}\)

**Sessions 2–10 treatment**

The timing of Sessions 2–10 was determined by the trial physiotherapist but a general recommendation was made for treatment to be more frequent, approaching twice weekly in the early stages of the program to enable emerging hypotheses regarding the most appropriate MLS and treatment methods to be confirmed. A summary of the content of the clinical notes for Session 2–10 is outlined in Table 4.

When reviewing response to Session 1 treatment at the beginning of Session 2 a detailed evaluation of whether the participant was better, worse or unchanged between sessions was undertaken. The above described Session 1 definitions of better, worse or unchanged were used however the interview process was expanded (as described in Part 1 of this series) to evaluate between-session factors that could confound the trial physiotherapist’s estimation of treatment effect when reassessing the participant. Such factors could include social/recreational activity beyond the tolerance of the disc, a positive response post treatment not lasting until the following session’s reassessment and psychosocial factors influencing the participant’s perception of response to treatment. This evaluation was conducted on information gained from specific questioning and

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**Figure 3** Lumbar taping using hypoallergenic and rigid tape.
examination and enabled a more consistent and accurate application of the decision making algorithm described in Fig. 1 when determining Session 2 treatment. The information also allowed the trial physiotherapist to educate the participant regarding causes in symptom fluctuation as a means of improving self-management skills.

As in Session 1, information was gathered and treatment decisions made in relation to the presence of inflammation as well as subjective and physical examination asterisks. The trial physiotherapist also enquired regarding the impact of the LBDs on work participation. Any work issues identified were discussed using a problem solving approach as part of the treatment program.

After gathering necessary assessment information the clinical decision algorithm in Fig. 1 was implemented in determining Session 2 treatment as described in the Session 1 section above. A key possible outcome in Sessions 2–10 was a determination that the participant was no longer responsive to the application of MLSs irrespective of forces applied or MLS selected. In this circumstance the participant was deemed to no longer have RDP (worse or unchanged to all MLSs) and a specific motor control program was implemented. All other participants
who responded to MLSs commenced specific motor control training once consistent improvement in pain and function was noted. This treatment approach followed a standard protocol involving retraining of transversus abdominis, lumbar multifidus and the muscles of the pelvic floor, initially in non-weight bearing positions and then in conjunction with functional activities. Specific motor control training was usually commenced between weeks three to six of the 10 week treatment program and occurred in parallel with the provision of DPM. The McKenzie method emphasizes prevention of recurrence, and does allow for training muscle function.\(^\text{14}\) Given the subacute population in the STOPS trials we felt that specific motor control training was an important component of our treatment protocol to facilitate recovery\(^\text{65}\) and minimize recurrence.\(^\text{66}\) The specific motor control training protocol will be described fully in Part 3 of this series.

The reassessment, decision making processes and treatment approaches described above in Sessions 1 and 2 were subsequently continued through Sessions 3–10. Each participant progressed through the clinical decision algorithms described in Fig. 1 and Table 4 based on the trial physiotherapist’s assessment findings in each session.

If the participant reported a lack of progress five weeks into the treatment program and a readministered Orebro Musculoskeletal Pain Questionnaire score was over 105/210,\(^\text{67}\) the treatment focus shifted away from a pathoanatomical and DPM emphasis. Instead the participant received education regarding increased neural sensitivity, pacing strategies and graded activity. Cognitive restructuring and behavioural modification principles were also employed by the trial physiotherapist. There is moderate evidence supporting this approach in subacute LBDs with suspected psychosocial factors.\(^\text{68}\) A description of our treatment protocol for this patient population will be presented in Part 4 of this series.

**Discussion**

A detailed clinical protocol has been presented for people with RDP participating in the STOPS trials.

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Clinical notes content for Session 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session 2 assessment</strong></td>
<td><strong>Rationale</strong></td>
</tr>
<tr>
<td>Participant report on progress following Session 1</td>
<td>To assist in determination of between session treatment effect. Detailed questioning conducted as required to differentiate treatment effect from other confounding factors (e.g. social/recreational activity)</td>
</tr>
<tr>
<td>Detailed questioning regarding possible causes of worsening symptoms following Session 1 if applicable</td>
<td></td>
</tr>
<tr>
<td>Follow-up on presence of inflammation and compliance with homework</td>
<td>Review of inflammatory status and the need for ongoing treatment. Check of homework to continue the process of encouraging and evaluating participant engagement</td>
</tr>
<tr>
<td>Questioning regarding any work issues as a result of the low back disorder</td>
<td>The STOPS trials excluded participants with a compensation claim but managing work incapacity was still an important focus for included participants</td>
</tr>
<tr>
<td>Check Session 1 asterisks from subjective and physical examination</td>
<td>To confirm whether the participant was better, same or worse compared with Session 1</td>
</tr>
<tr>
<td><strong>Session 1 treatment</strong></td>
<td><strong>Rationale</strong></td>
</tr>
<tr>
<td>Consider hypotheses based on physiotherapist judgement of the participant being better, same or worse</td>
<td>Information from between session change leads to Session 2 treatment selection</td>
</tr>
<tr>
<td>Briefly review explanations and information sheets regarding RDP, treatment options, treatment timeframes and recovery expectations</td>
<td>Repeat explanation ensured engagement of the participant with the treatment program and enabled further practitioner feedback/questions to be asked</td>
</tr>
<tr>
<td>Consider provision of additional information sheets as required on pacing, posture, relaxation, sleep management and pain management strategies</td>
<td>Self-management strategies and specific advice were seen to be an important component of any treatment regime including DPM</td>
</tr>
<tr>
<td>Ongoing management of inflammation if applicable</td>
<td>As per Session 1 rationale</td>
</tr>
<tr>
<td>In the absence of inflammation decide on whether progressing or changing the MLS</td>
<td>As per Session 1 rationale</td>
</tr>
<tr>
<td>Provide an appropriate dosage of the relevant MLS and reassess asterisks. Provide homework based on information sheets</td>
<td></td>
</tr>
<tr>
<td>If non-responsive or consistently improving with MLSs, commence a functional stability program</td>
<td>In those failing to respond to DPM, functional stability is important to facilitate recovery and minimize recurrence&quot;(^\text{66})</td>
</tr>
</tbody>
</table>
The McKenzie based protocol maximizes the likelihood of being reproducible and generalizable compared to other RCTs and has been developed on the best available evidence in combination with the key principles of the McKenzie approach. Some may criticize the ‘non-empirical’ judgemental processes needed in preparing such a protocol. However, the use of patient oriented clinical judgement combined with the latest research literature is consistent with an evidence-based approach. The protocol is highly specific but also algorithmic, ensuring participants do not receive a ‘one size fits all’ approach which would be inconsistent with McKenzie’s method. The protocol aims to provide clear structure for clinical decision making using the principles of McKenzie. However, on close inspection of the protocol the trial physiotherapist also has many options to exercise their own clinical decision making.

In recent years, the McKenzie approach, as defined by the recommended text and post-graduate course work notes, has evolved away from pathoanatomical mechanisms in the description and justification of classification and treatment methods. This shift has been based on the premise that if the patient is improving with a specific MLS then an understanding of the source of symptoms is not necessarily important. A focus on impairment rather than pathoanatomical based classification is also consistent with an evidence-based approach. The protocol is highly specific but also algorithmic, ensuring participants do not receive a ‘one size fits all’ approach which would be inconsistent with McKenzie’s method. The protocol aims to provide clear structure for clinical decision making using the principles of McKenzie. However, on close inspection of the protocol the trial physiotherapist also has many options to exercise their own clinical decision making.

In Part 1 of this series, commonly used research designs such as concurrent validity and the use of clinical prediction rules were reviewed. Our conclusion was that such methods can at best provide only preliminary evidence of subgroup validity due to problems with inadequate diagnostic standards and feasibility issues in the complex domain of LBDs.

In Part 2 of this series we have introduced the concept of convergence of validity in justifying the criteria for the RDP subgroup. We acknowledge that this approach does not provide full validation for RDP as a subgroup of LBP or the proposed indicative features. However, in our view, there are few methodological alternatives for researchers wanting to adequately evaluate the effectiveness of complex clinical methods developed by expert practitioners such as McKenzie. We have developed a sophisticated clinical protocol based on a widely used and time honoured clinical practice which has substantial support based on convergence of validity principles. We believe it is important that this clinical protocol be evaluated in a well constructed RCT, and we have commenced this project in the STOPS trials.

The McKenzie method requires knowledge of detailed assessment and treatment protocols and post-graduate training is commonly recommended. The STOPS trials aimed to evaluate a refined version of the McKenzie method that maintained appropriate levels of treatment specificity and adhered to described clinical reasoning principles but was also generalizable to most physiotherapists with or without post-graduate training. This aim necessitated some simplification of the McKenzie approach with a strong focus on recruiting people with RDP that was highly likely to respond to DPM. Participants were only eligible for inclusion in the RDP group after baseline assessment if they responded to at least one of a variety of MLSs involving lumbar extension with or without lateral forces. There is variability in the literature regarding the definition of a positive response to MLSs and therefore the process of identifying people likely to respond to DPM. Some have recommended...
centralization can be defined by a positive response to MLSs over a period of up to seven treatment sessions.77 In order to identify highly likely responders, we restricted the definition of centralization to those who only responded within a single baseline assessment session. Given a directional preference for extension is most common in LBDs.14,17 MLSs using lumbar flexion were not tested and people with a flexion directional preference were unlikely to have been included in the trial.

We believe our clinical protocol for RDP is a positive step forward when compared to other RCTs that have evaluated the efficacy of DPM on specific subgroups. A number of these trials have used a pragmatic approach where physiotherapists with a certain level of post graduate training in the McKenzie approach are used to provide classification and treatment.12,21 However, this approach does not allow for clinical reproduction of the trial treatment by practitioners in the field or other researchers. In addition, the consistency of clinical methods using a pragmatic approach is open to question as demonstrated in a recent high quality RCT.78 In this study, which recruited people with acute LBDs, highly trained McKenzie practitioners identified 6% of participants as belonging in the McKenzie subgroup of dysfunction, despite clear guidelines in the McKenzie post-graduate training texts that this subgroup does not exist within the acute population.14,33 Given the reported reliability of the McKenzie method of classification53,54,79 this is a surprise finding that suggests significant heterogeneity in classification and treatment decision making in pragmatic RCTs on the McKenzie approach. Other RCTs evaluating the efficacy of DPM on specific subgroups have used poorly defined22,80 or overly simplistic treatment protocols29,30 that are not sufficiently consistent with McKenzie’s sophisticated clinical methods.14,16,49,50

We believe our clinical protocol adheres to the essential principles of the McKenzie approach in a manner that will allow the STOPS trials to be replicable by future studies. The clear description of the classification and treatment protocol will also enable practitioners in clinical practice to make an informed choice regarding modification of their own clinical methods. The results of the STOPS trials will therefore be more likely to be generalizable to the population of physiotherapists in clinical practice.

Summary
A clinical protocol for the classification and specific treatment of an LBD subgroup with criteria indicative of RDP has been presented. This protocol is currently being used in the STOPS trials evaluating the effectiveness of specific physiotherapy. Should the trials demonstrate significant effects, the protocol will be useful for practitioners and researchers wanting to replicate the protocol in clinical and RCT settings.

References
Ford et al. A classification and treatment protocol for LBDs: Part 2


